Submitter : Ronald Taniguchi **Date & Time:** 10/04/2004 05:10:02

Organization : Hawaii Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

Thank you for the opportunity to comment on the Medicare Part D proposed rules to implement the prescription drug benefit. I am writing on behalf of our member pharmacists and pharmacy technicians, who practice in independent and chain retail, managed care, hospital, senior care, mail service and specialty settings throughout the state of Hawaii.

Due to the complexity and breadth of the issues, comments are offered focusing on the following subject areas within the proposed rules: Medication Therapy Management Programs; quality improvement; e-prescribing; contracting issues; and general administration of Part D benefits.

Medication Therapy Management Programs

Although it is prudent to allow some flexibility to allow maturation of MTMP, it is not prudent to allow a PDP complete flexibility to design MTMP. PDPs incur the cost of MTMP but do not reap the cost savings that will be gained by Medicare Parts A and B. Therefore, PDPs have an adverse incentive to incur the costs of MTMP. A descriptive requirement for MTMP is necessary so all PDPs will incur approximately the same MTMP costs and will contribute proportionally to the savings in Medicare Parts A and B. Without a stringent requirement, the bare minimum is likely to be provided and will most likely be a simple repackaging of population-based activities already performed by PDPs.

In order for this new Medicare program to succeed, CMS must assume a strong oversight and standards-setting role in Medication Therapy Management Services. This is not without precedent. In OBRA-90 the federal government declared minimum standards of pharmacy practice for patient counseling.

CMS has a responsibility to ensure that MA-PDs and PDPs actually engage in a reasonable analytical process to determine MTMS payment rates and that those rates are sufficient to allow pharmacists to provide face-to-face MTMS. Absent such oversight, plans will have strong incentives to pay only for minimally effective telephonic MTMS ? coincidentally provided by MA-PDs and PDPs themselves.

In addition to the specific comments below, CMS should adopt the MTMS definition principles outlined in a consensus statement developed by 11 national pharmacy organizations, including organizations representing managed care pharmacy (Appendix A); this document also has been submitted by the American Pharmacists Association, which convened the consensus-building workgroup, and many others.

More specifically, CMS should:

? Require PDPs and MA-PDs to provide MTMS for patients with two or more chronic conditions and taking two or more prescription or prescribed over-the-counter drugs.
? Clarify the rules to ensure that pharmacists may provide fee-for-service MTMS to non-targeted beneficiaries, since MTMS is not a covered service under Part D for non-targeted beneficiaries.
? CMS rules must allow for all pharmacists to be included in MTMS, not limit MTMS to those who possess a certain advanced degree (e.g. Pharm.D.), title (?clinical pharmacist? or ?pharmacist practitioner? or pharmacists practicing at an in-network pharmacy (some pharmacists work independently and are not attached to a particular pharmacy). The criteria MTMS payment should be the quality of services rendered. MTMS services currently provided in the private sector not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary hospitalizations and expensive emergency room visits. Examples of MTMS include, but should not be limited to, anticoagulation therapy management, diabetes monitoring and education, asthma teaching, cholesterol monitoring, anemia therapy management, dosing of medication therapies in the elderly, compliance management education for HIV patients with complex medication regimens and assuring patients with chronic diseases such as heart failure are taking the right medications.
? All pharmacists practicing within a region (regardless of practic

CMS-4068-P-1001-Attach-1.doc

Hawaii Pharmacists Association
PO Box 1198
Honolulu HI 96807

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, Maryland 21244-8014

Re: CMS-4068-P

Dr. Mark McClellan, Administrator:

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- All pharmacists practicing within a region (regardless of practice setting) should be afforded the opportunity to provide and be paid for MTM services such that plan sponsors should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service. Furthermore, all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.
- Plans should be required to inform pharmacists who among their patients are eligible for MTMS. Similarly, plans should be required to inform beneficiaries that they are eligible for MTMS.
- Pharmacists, as learned health care professionals, should be allowed to initiate MTMS and plans should be required to provide payment for such services. Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services and be eligible to provide MTM services to these patients. Identification of targeted beneficiaries should not be left solely to the plan. Plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription.
- MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required to pay pharmacists for MTM services at the

same rate and under the same terms in which they pay other providers for MTM services. They should not be allowed to discriminate and leave pharmacists engaged in direct patient care out.

- MTM services should be able to be provided in conjunction with and outside of product dispensing, and not necessarily incident to a visit to a physician or other non-pharmacist provider.
- An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.
- Plan sponsors should be required to establish at CMS-specified set of MTM services. The specified set of services should be a minimum set while additional services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, chronic and acute pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management, training for self-administration of drugs (e.g. insulin) and adverse drug event assessment and prevention should be included.
- CMS should consider developing a program to accredit plans that agree to meet the above stated conditions that add value to and lower the cost of care.
- CMS must outline specific quality assurance requirements that PDP must report to ensure appropriate implementation and ongoing operations of MTMP. Due to the adverse incentive for PDP to provide MTMP, it is imperative the CMS establish stringent reporting and accountability standards for MTMP. It would be appropriate for Quality Improvement Organizations to serve in this capacity. PDP should report how many beneficiaries received each type of MTM service and from which provider type. A specified percentage of beneficiaries within each PDP should receive MTM services, and these services should be diverse based on patient-specific needs. PDP must supply documentation that supports how individual beneficiary needs are identified and met, how the appropriate MTM provider type was selected, and outcomes achieved through these services. Methods to ensure beneficiary choice of MTMP provider should also be documented.
- Information on effective MTMP services that could be publicized and used by beneficiaries (page 210): PDPs have an adverse incentive to promote effective MTMP. For instance, an effective HIV/AIDS MTMP would stimulate more enrollment of beneficiaries with HIV/AIDS, diabetes and other high-cost diseases. Thus, more drug costs would be incurred by the PDP. Further, any savings in Medicare Parts A and B would be not be realized by the PDP. Therefore, it is critical that requirements for all PDPs outline quality and other performance benchmarks. PDPs should be held financially responsible for not meeting these benchmarks related to MTMP.

Quality Improvement Organizations

CMS suggests that it will adopt OBRA-90's patient counseling standard as the minimum standard of practice. In the context of Part D, OBRA-90 is an insufficient standard which would allow PDPs and MAs to evade the intent of MTMS requirements.

On page 235 of the proposed rule, CMS states that QIOs will be required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. In the proposed 8th

Scope of Work Task 1d3: Part D benefit, QIOs are asked to comment on their role to implement quality improvement projects.

Task 1d3: Part D benefit- As an additional part of the QIO efforts in the physician office setting, QIOs will work with Medicare Prescription Drug Plans (PDPs), Medicare Advantage prescription drug plans (MA-PD), and fallback plans (referred to as drug plans) and with providers to improve care for beneficiaries enrolled in these plans.

QIOs will identify and offer technical assistance to all drug plans that serve beneficiaries within their state to implement quality improvement programs under part D. QIOs will implement quality improvement projects

- *To establish measures that determine the baseline level of performance of the drug plans and providers with whom it is working*
- *To develop and implement interventions*
- *To assess the intervention's effect on the measures*
- *And to report on the drug plans and providers.*

A model for the quality improvement projects outlined in the MMA proposed regulations is the Iowa Medicaid Drug Utilization Review (DUR) Program. The retrospective DUR program is performed through a contractual relationship between Iowa's QIO, Iowa Foundation for Medical Care (IFMC) and the Department of Human Services (DHS). The clinical intervention, educational and assessment components of the retro DUR program are provided by pharmacists at the Iowa Pharmacy Association (IPA) through a subcontract with the IFMC.

The Mountain-Pacific Quality Health Foundation, the QIO for Montana, Wyoming, and Hawaii also has a similar model that provides drug utilization review services, prior authorization, and pharmacy case management services for the Montana Medicaid program.

QIO's are in a unique position to provide quality initiatives for Medicare beneficiaries as 8th Scope of Work (SOW) activities roll out over the coming months. There can be a significant amount of synergy between SOW activities and the Medicare Prescription Drug Benefit. Much of this synergy depends upon the integration of medical and pharmacy claims information, which was previously unavailable in the Medicare program but has been used extensively in the Medicaid programs.

The following points should be considered for the final regulation implementing a Medicare prescription drug benefit or within QIO Scope of Work activities:

- Quality improvement projects will include the four bullets listed in Task 1d3 above.
- QIOs must have timely access to pharmacy and medical claims for quality improvement projects and quality oversight of the PDPs.
- Of the elements listed in the proposed rule as desirable for quality assurance systems, actionable, educational interventions and the assessment of those interventions are essential.
- Educational interventions are best done by QIOs or a third party (independent of the PDP) contracted by the QIO.
- Educational interventions will focus on significant and actionable therapeutic or cost containment issues to improve the quality of care provided.
- Quality improvement projects will be performed by the QIO or a third party (independent

of the PDP) contracted by the QIO.
- Further definition of the Medicare Prescription Benefit will be necessary for QIO's to fully implement quality improvement programs.
- Oversight of formulary decisions and subsequent review of PDP formulary decisions could be key components necessary for QIO's to assess quality, especially in the dual-eligible long term care patients.

E-Prescribing

CMS' suggestion to provide prescribers with enhanced reimbursement for their services if they adopt e-prescribing systems is commended. It may even be necessary for CMS to provide grants to build the necessary technology infrastructure in rural areas, where Internet access remains primarily dial-up service that is too slow and unreliable to accommodate e-prescribing.

An essential step toward broad adoption of e-prescribing would be for CMS to require all MA-PDs and PDPs to accept electronic prescription and dispensing records, including scanned records, as valid for purposes of payment audits. Until payers fully accept electronic records, e-prescribing will be hindered.

Contracting Issues

Suggestions in this area are:
- MA-PDs and PDPs should be required to gain CMS approval of model contract language, and plans should be required to use only those contracts in agreements with pharmacies. Such a requirement could be crafted to leave reimbursement rates up to the discretion of plans.
- CMS must provide oversight of reimbursement rates, but without determining rates, to ensure that payment for pharmacy services is adequate to provide fair reimbursement to pharmacies for both basic dispensing services and other services, especially Medication Management Therapy Services. PDP sponsors or MA organizations should be required to substantiate a payment setting process which considers reasonable standards and recognition of pharmacy provider costs.
- Prior authorization processes must provide for reasonable therapeutic exceptions, taking into account the welfare of the patient (such as patient stability under complex multiple medication regimens) as well as cost of a particular products. MA-PDs and PDPs should be required to include in their contracts provisions to pay pharmacies to dispense emergency supplies for up to 72 hours of medication pending resolution of prior authorizations
- MA-PDs and PDPs should be required to accept successful electronic adjudication of a claim as evidence of patient eligibility.

General Administration Issues
- CMS should consider requiring MA-PDs and PDPs to reimburse pharmacists for immunization services at the same rates paid to other immunization providers under Part B. Pharmacists have become a major source of immunization services in recent years, and CMS should take advantage of the claims processing efficiencies of Part D to increase immunization rates among the elderly.
- MA-PDs and PDPs should be required to maintain 24/7 help desk access for pharmacists

and patients. Claims processing and medication therapy issues obviously can occur at any hour of the day or night, on any day of the week.

- MA-PDs and PDPs should be required to establish pharmacy and therapeutics (P&T) committees to oversee development of formularies, formulary exceptions processes, prior authorization processes, and retrospective drug use review. P&T Committees should be comprised of equal numbers of pharmacists and physicians, and should include both pharmacy and physician specialists.
- MA-PDs and PDPs should be required to adopt the NCPDP-approved patient claim card format, as CMS suggests.
- When patients must or choose to use an out-of-network pharmacy, expenses should be counted toward total out-of-pocket expenses. In addition, the rules should specify that pharmacies may charge their "usual and customary" fees to out-of-network patients, and those patients would then need to seek reimbursement from their MA-PD or PDP. Since an out-of-network pharmacy by definition will not have access to the preferred pharmacy rate for any product, this approach would appropriately balance patient choice with payment issues.
- The proposed requirement that pharmacies inform patients of the cost of a comparable, lower-cost generic drug if a generic drug is not being dispensed is commended. This is simply good public policy; it would encourage patients to choose generics and thereby play a stewardship role in the program. Left unaware of cost differentials, patients may use more expensive therapies at taxpayer expense.
- The transition of "dual eligible" patients from state-based Medicaid to the new Part D is a concern. CMS must take great care to ensure that "dual eligible" patients do not suffer interruptions in their drug therapies. MA-PDs and PDPs must be required to provide benefits information to patients, their caregivers and their involved physicians and pharmacies at least 45 days in advance of the changeover in order to provide adequate time to make the necessary adjustments in drug therapies without putting patients' lives at risk.

Thank you for the opportunity to provide input related to this important program. We strongly support CMS in its efforts to provide appropriate medication therapy to Medicare beneficiaries.

Respectfully submitted,

Ronald T. Taniguchi, Pharm.D., M.B.A.
Interim Executive Director

Appendix A

Medication Therapy Management Services Consensus Statement
Definition and Program Criteria

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

a. Performing or obtaining necessary assessments of the patient's health status;
b. Formulating a medication treatment plan;
c. Selecting, initiating, modifying, or administering medication therapy;
d. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
e. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
f. Documenting the care delivered and communicating essential information to the patient's other primary care providers;
g. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;
h. Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens;
i. Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

A program that provides coverage for Medication Therapy Management services shall include:

a. Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient. These services are distinct from formulary development and use, generalized patient education and information activities, and other population-focused quality assurance measures for medication use.
b. Face-to-face interaction between the patient* and the pharmacist as the preferred method of delivery. When patient-specific barriers to face-to-face communication exist, patients shall have equal access to appropriate alternative delivery methods. Medication Therapy Management programs shall include structures supporting the establishment and maintenance of the patient*-pharmacist relationship.
c. Opportunities for pharmacists and other qualified health care providers to identify patients who should receive medication therapy management services.
d. Payment for Medication Therapy Management Services consistent with contemporary provider payment rates that are based on the time, clinical intensity, and resources required to provide services (e.g., Medicare Part A and/or Part B for CPT & RBRVS).
e. Processes to improve continuity of care, outcomes, and outcome measures.

October 1, 2004

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

Re: CMS-4068-P Medicare Prescription Drug Benefit NPRM (42-CFR Parts 403, 411, 417 and 423) – Comments

Dear Centers for Medicare and Medicaid Services:

MediMedia appreciates the opportunity to comment on the Medicare Prescription Drug Benefit NPRM.

MediMedia Information Technologies is a division of MediMedia USA, a $250 million publishing company. One of the world's leading providers of healthcare communication, educational materials and services, MediMedia is an *independent* international company with a reputation for the quality and innovation of its products, and the strength of its truly global representation.

We own and distribute the InfoScan Formulary Database, which contains more than 3,400 health plan, PBM, PPO and self-insured employer formularies. In addition to most of the plans associated with Rx Hub and CAQH, we represent many of the smaller plans and PBMs who have thus far chosen not to affiliate with those organizations.

We have been providing a formulary database to electronic health records (EHR), computerized physician order entry (CPOE) and ePrescribing software companies since 1994. Our clients include WebMD's Medical Manager, GE Medical's MedicaLogic, Cerner, NextGen, Misys and others – a veritable a "who's who" of mature health care information technology providers.

The following are areas where we feel we can make recommendations and add comment:

General Comments:
Subpart B. Eligibility and Enrollment

8. Part D Information That CMS Provides to Beneficiaries (FR 46643)

… We propose building on our experience in implementing the drug discount care 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.

A DIVISION OF MEDIMEDIA USA, INC.
780 Township Line Road, Yardley, PA 19067
800-643-7226 267-685-2770 267-685-2969 FAX

Recommendation:
Physicians utilizing ePrescribing, CPOE and EHR software applications have had an exceedingly difficult time identifying a patient's formulary. Separate from benefits information, which determines payment and coverage information, formularies specifically list drugs and their position on the formulary. Physicians are interested in selecting the most cost-effective alternative from the formulary for their patient, as well as to reduce telephone calls from the pharmacy or plans telling them of a drug's formulary status. The formulary will list the medicine with the most cost-effective without getting into the much more complex benefit issues which can only be settled in the pharmacy when a claim is made. Making an informed decision, has been shown to reduce formulary-related telephone calls by as much as 84%.

To facilitate linking the formulary to the patient, we recommend that the Issuer field on the NCPDP's "Pharmacy ID Card Standard" include an ability to include a formulary identification. The field is available to describe the issuer and we suggest than an issuer be required to have an identifier for each formulary being offered. Using this field to identify not only a plan, PBM or other card issuer, but the specific formulary the patient is using would allow physicians to quickly identify the list of drugs being used for the formulary including preferred, non-preferred, prior authorized and prescribing limitations from third party databases such as ours. This information would not provide exact coverage information, but, as the PBMs testified in July's NCVHS's Security and Standards Subcommittee, benefit information is almost impossible to accurately calculate until the claim is submitted at the pharmacy.

Subpart C. Voluntary Prescription Drug Benefit and Beneficiary Protections
4. Access to covered Part D Drugs
b. Formulary requirements (FR 46661)

Recommendations:
Prior authorization is, of course, the process of obtaining certification or authorization from a health plan or PBM for specified medications or specified quantities of medications. It often involves appropriateness review against pre-established criteria. Those criteria can vary by plan and, within a plan, by drug.

The process of obtaining approval is onerous, by design. It's purpose is to encourage appropriate use of medications most likely to have certain risk factors, and the approval criteria is generally developed and endorsed by the plan's P&T committee, based on information from the FDA and manufacturers, medical literature, actively practicing consultant physicians and appropriate external organizations.

Failure to obtain prior authorization often results in a financial penalty to the patient or member, so physicians are highly reluctant to prescribe those drugs thus labeled. In fact, almost any physicians' office that has even a moderate number of managed care patients will tell you that prior authorization tops its list on a "pain scale."

For this reason, the ePrescribing system that can reduce the "pain" of prior authorization will be making a substantial positive impact on a practice.

We also believe that as ePrescribing becomes more commonplace, the rate of on-formulary prescribing will increase, making prior authorization a more attractive cost-containment tactic. **Automating the process will allow clinically appropriate prescribing.**

In today's paper world, the prescriber does not know if the drug is on prior authorization or not. While he or she quickly learns that it's likely that growth hormones or anti-fungal agents have been designated as requiring prior auth, what trips him or her up are therapeutic categories that are less consistent across plans. One example is with the Cox-2s such as Celebrex and Bextra, which have been launched in the last 2-3 years or Proton Pump

Inhibitors where availability of lower cost options have created prior authorization restrictions on many medications.

Should the office want to continue with a prior authorization request, the staff would obtain a form from the plan or a Web site. The form has a series of questions designed to help a clinician determine if the prescription is medically necessary. While it is more complex than "yes/no" the fact is, computers were designed to automate paper processes like this. Not all plans make prior authorization processes clear or the criteria available.

At a minimum, when the prescriber is using a software solution that leverages the InfoScan Formulary Database, these drugs will be flagged as requiring prior authorization.

We recommend that information about prior authorization of specific drugs be made public on websites and criteria, especially automatic criteria be included.

But that's only a first step.

An algorithm can run either in the software system or interactively that allows the physician to enter diagnosis codes, answer questions and document his/her clinical judgment. Some plans for some drugs might issue an approval code at this moment. In other cases, a form would be created and transmitted to the plan's clinicians for approval. When approval is obtained, the code can be transmitted with the prescription to the pharmacy, where it can be included with the claim transmitted to the prescription payor.

We recommend a standard be created for automated prior authorization, to reduce – but not eliminate – barriers to patients receiving clinically relevant medications.

c. Use of Standardized Technology (FR 46662)

> As provided under section 1860D–4(b)(2)(B)(ii) of the Act, we will consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards. Given that NCPDP is recognized as the industry standard for current prescription drug programs, and we relied on its standards in developing requirements for discount card sponsors' cards under the Medicare Prescription Drug Discount Card and Transitional Assistance Program, we are proposing basing our card standards on NCPDP's ''Pharmacy ID Card Standard.''

Recommendations:
We agree that NCPDP's "Pharmacy ID Card Standard" is the best ANSI-accredited standard available to identify not only the information needed to process a claim but the specific formulary. It would be a missed opportunity if your card did not include the specific formulary identifier, as it would clarify much of the confusion currently in physician offices. We recommend making it part of the part of the "issuer" field on the card.

6. Dissemination of Plan Information (§ 423.128) (F.R. page 46663)

> We solicit comments on how best to coordinate the requirements of § 423.128 and § 422.111 of our proposed rule for MA–PD plans.

c. Provision of Specific Information (F.R. p 46664)

> In addition, we are proposing requiring that plans maintain Web sites as one means of disseminating information to current and prospective Part D enrollees…

Recommendations:
We agree that formulary web sites would be a valuable means of making the benefit clear and understandable to patients. Frequently, the need for formulary information by physicians surpasses the need by patients. Physicians have been trained and have experience with formulary information. For patients formulary terms are confusing. While these web sites could also be a resource for the physician and his or her staff, physicians and staff will be more frequently looking in sources of compiled formularies. As mentioned elsewhere, the challenge for physicians is having the patient clearly identify the formulary they are using. The most effective way to access this information would be leveraging the formulary identifier that we mentioned above. This identifier could be stored in the EHR, CPOE, ePrescribing or practice management system.

On the Web site, we recommend that the formulary be primarily a list of drugs and their formulary status – that it not include benefit coverage information. As the PBMs testified at NCVHS, such information is difficult to calculate until later in the process.

We also recommend that drugs requiring prior authorization be thus flagged, and that there be a clear process for how to request certification to prescribe a drug that requires prior authorization. (We go into more detail about PA later in our comments.)

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

4. Electronic Prescription Program (§ 423.159) (F. R. page 46671)

1. Many in the industry urge us to move expeditiously to establish electronic prescribing standards. However, the statute intentionally provided for a deliberative process by directing the NCVHS to study, select and recommend electronic prescribing standards. Any comments received in response to this proposed rule will be considered along with the NCVHS' recommendations in the development of the proposed rule on the electronic prescribing standards. We are particularly interested in comments that help us identify consensus or reach consensus on eprescribing standards ahead of the statutory time frame, and to help us identify and evaluate industry experience based on pilot programs engaged in e-prescribing activities in 2004 and 2005.

Recommendations:

<u>NCPDP Script</u>
We agree with NCVHS that NCPDP's Script standard has become the de-facto standard for new prescriptions, prescription renewals, cancellations and changes between prescribers and dispensers, and could be adopted ahead of the statutory timeframe.

The only other ANSI-accredited standard that addresses any of these prescription-related functions is HL7, and that standard is not being used extensively in the ambulatory setting. To that end, we also support its recommendation that HHS support a cross-walk between NCPDP and HL7. It may be best for that cross-walk to have a demonstration project.

<u>Formulary</u>
There is no ANSI-accredited standard format for formulary. What's more, a dominant format does not exist. To our knowledge, there are at least five formulary formats in the marketplace. Besides ours, Rx Hub, CAQH, ProxyMed and ePocrates all have formulary formats that are being used by ePrescribing applications. In addition, some of our larger, more mature clients have their own formats to which we have to comply. Therefore, we support and endorse NCVHS's recommendations that these organizations and other interested stakeholders come together in an ASNI-accredited organization to create one standard. After such a standard has been created, a demonstration project may not be necessary.

Prior Authorization

Prior authorization is the process of obtaining certification or authorization from a health plan or PBM for specified medications or specified quantities of medications. It often involves appropriateness review against pre-established criteria. Those criteria can vary by plan and, within a plan, by drug. It is possible that the burden of this process discourages physicians from prescribing medically appropriate medications.

As ePrescribing becomes more commonplace, we believe that the rate of on-formulary prescribing will increase, making prior authorization a more attractive cost-containment tactic. We recommend that HHS take actions to facilitate automating this process, which will better facilitate clinically appropriate prescribing.

There is an ANSI-accredited standard for automated prior authorization request through X12 (278); however, we understand that it is not in widespread use. It is possible that this is because this standard does not meet the business needs of constituents.

We recommend that the X12 transaction for prior authorization be studied to determine if it is the best such standard, for it may not be. X12 envisions a two-way transaction between a physician and plan; however, it is possible that the physician could have a clinical dialogue with its EMR, CPOE or ePrescribing system to determine if the drug is medically necessary, and transmit these results either to the plan for approval, or to the pharmacy to transmit to the plan for the same. HL7 may be a better standard for a clinical dialogue. If the request-response is between the pharmacy and plan, NCPDP's Script may be appropriate. This requires more study.

In addition, we recommend that drugs that require any type of Prior Authorization should be transparent and have an explicit list of requirements used as part of the process. By transparent, we mean that the exceptions need to be predefined rules established with input from all stakeholders, including physicians, and published so that physicians and patients are aware of them.

Finally, once the appropriate standard has been identified for prior authorization, such a process will require a demonstration project to learn more about the value to all stakeholders.

2. Finally, we note that the pilot test specified in the MMA is not required if there is adequate industry experience with the standards. In that case, the Secretary may propose them as final standards in a proposed rule, thereby expediting a portion of the standards adoptions process…

Recommendations:

In our experience, one of the greatest implementation challenges for our EMR and ePrescribing clients is integrating with the practice management system so that there is a two-way flow of patient demographic information – including formulary identifiers – between the practice management and clinical system. We strongly encourage HHS to explore the best way to facilitate this information exchange, perhaps by having NCVHS hear testimony from the practice management systems and HL7 about this topic. The fact is, there are 100s of practice management software solutions, many of which use HL7 and many that do not.

The fact is, the primary purposes of practice management systems is billing and scheduling. For that reason, they tend to store the information required to submit a medical claim. It is imperative that those system vendors see the bigger picture, and collect and store information that will make them more interoperable. For example, they do not tend to store pharmacy benefit information. Consequently, even if there was a standard means of interfacing between the PMS and clinical system, the clinical system would not be able to collect the information necessary to link the patient with the appropriate formulary.

A related challenge rests with office staff, who have difficulty collecting this information. HHS could assist in this process by adopting a standard for pharmacy cards, and including the formulary identifier on the card in a clear manner, as we described earlier.

There is also an educational component of this. A key challenge is that the office staff does not know that they need to collect the formulary identifier and put this into the practice management system. To successfully implement Part D with ePrescribing solution partners, an education campaign may need to be launched to explain to physicians' staff the reason for needing this information and what to do with it.

There is also a challenge of integrating with EMR with the ePrescribing systems, which tend to be more innovative and do a better job of delivering the value proposition to all stakeholders. We understand that an ANSI-accredited standard, the Continuity of Care Record (CCR), exists to facilitate this, and that there is a camp that believes the CCR is duplicative to HL7. We do not have an opinion on the two standards, but recommend that formulary and benefit information be part of the flow between the two types of clinical solutions.

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

5. Formulary Exceptions Procedures (423.758) (FR 46719)

(b) Exceptions and Appeals Rules for Non-Formulary Determinations (FR 46720)

Recommendations:

As with prior authorization, we recommend that the rules for exceptions and appeals be transparent and well defined. By transparent, we mean that the exceptions need to be predefined rules established with input from all stakeholders, including physicians, and published so that physicians and patients are aware of them.

MediMedia would be happy to provide additional information or input on any of these issues.

Sincerely,

Brian Bamberger
President
MediMedia Information Technologies
A division of MediMedia USA, Inc.

CMS-4068-P-1002

Submitter : Ann Petersen **Date & Time:** 10/04/2004 05:10:41

Organization : The Law Offices of Ann C. Petersen

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter.

CMS-4068-P-1002-Attach-1.doc

THE LAW OFFICES OF ANN C. PETERSEN

180 EAST PEARSON STREET, SUITE 5103, CHICAGO ILLINOIS 60611-2113

(312.409.4301 / FAX 312.664.6297 / ACPSEN@AOL.COM

October 4, 2004

Via E-mail and USPS

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: Proposed Medicare Program; Medicare Prescription Drug Benefit Regulation
42 C.F.R. Parts 403, 411, 417 and 423

Ladies and Gentlemen:

I am writing in response to the request of the Centers for Medicare and Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS") for comments regarding the proposed Medicare Prescription Drug Benefit regulations, 42 C.F.R. Parts 403, 411, 417 and 423 (the "Proposed Medicare Part D Regulations). I serve as a member of the board of directors of The Board of Pensions of the Presbyterian Church (U.S.A.) (the "Board"), the corporation formed by the Presbyterian Church (U.S.A.) to serve as the administrator of the Benefits Plan of the Presbyterian Church (U.S.A.) (the "PCUSA Plan"), the national employee benefits program for the ministers and lay employees of congregations and related Presbyterian entities. The PCUSA Plan is a church plan as defined under section 414(e) of the Internal Revenue Code. I am the Vice Chair of the Board and a member of its Health Care Committee.

The PCUSA Plan provides medical and prescription drug benefits coverage to over 60,000 active and retired ministers and lay employees of the Presbyterian Church (U.S.A.) and their beneficiaries through a self-funded plan administered by the Board with the assistance of several third party

administrators. The Board has worked diligently to offer comprehensive and cost-effective prescription drug coverage to its retirees as a supplement to the Medicare programs. The PCUSA's prescription drug coverage, administered through Express Scripts, includes a three tier formulary and mail order program. It has served our retirees well. The PCUSA's retiree medical program is financed primarily through subscription dues paid by the retirees but it is also subsidized through dues that congregations continue to make to the Board for Benefits Plan coverage when their pastor's position is vacant.

With respect to my specific comments on the Proposed Medicare Part D Regulations, I support the comments and changes referenced in the comment letter CMS has received on behalf of the Church Alliance.[1] I am writing separately from my perspective as a fiduciary of the PCUSA Plan to emphasize the critical need for CMS to provide relief for church plans.

Specifically, in the short term, the expected timing of the release of final regulations in early 2005 and the awarding of PDP contracts in the Fall of 2005 will make it extremely difficult for trustees of church plans to make prudent decisions which can be implemented to take effect on January 1, 2006. As a trustee, I have the fiduciary obligation to duly investigate and consider the available alternatives for the PCUSA Plan to coordinate with the new Medicare Part D rules. The trustees must consider the best interests of our plan members and the long-term financial stability of our plan. Our board of directors meets three times a year, in February, July and October. Plan changes for the upcoming calendar year are typically considered at the February meeting, presented for advice and counsel to the church entities in various conferences in the Spring and finalized at the July meeting, in time for the compensation and enrollment materials to be sent to congregations in early Fall. Certain plan amendments must also be approved by the General Assembly of the PCUSA, which only meets biennially. Thus, CMS's timeline does not take into account the needs of responsible plan fiduciaries. Plan benefit and financial decisions are based on the results of comprehensive analysis, including the advice of actuaries, legal counsel and other appropriate professional advisors. As noted in the Church Alliance letter, church plans require significant lead time to obtain the approval of the denominational authorities and to properly notify affected employees and retirees. I urge you to consider initial transitional relief for church plans in the form of eligibility for the Federal subsidy until such time as the church plans can make more reasoned decisions about the other Medicare Part D coverage alternatives or change their plan design and financing to qualify for the subsidy under the final regulations.

From a long-term perspective, if church plans that provide retiree prescription drug benefits are not able to qualify for the Federal subsidy, I am

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[1] *See* letter dated October 4, 2004 to CMS from Jean C. Hemphill, Esquire of Ballard Spahr Andrews & Ingersoll, LLP.

concerned that, as a trustee, I will have no alternative but to recommend the termination of our current cost-efficient retiree prescription drug benefit program. The termination of a valuable church-sponsored benefit program is not in the best interest of our retirees or CMS. I also am very concerned that the loss of prescription drug purchasing volumes in our retiree prescription drug coverage will increase the cost of our prescription drug coverage for active employees.

I can appreciate the difficult task that CMS faces in implementing workable rules for Medicare Part D. I hope that you will recognize that church plans such as ours provide valuable benefits, but have special needs that are recognized in other areas of the law. Thank you for the opportunity to comment on the Proposed Medicare Part D Regulations. I would be happy to discuss my comments further at your convenience.

Very truly yours,

Ann C. Petersen

THE LAW OFFICES OF ANN C. PETERSEN

180 EAST PEARSON STREET, SUITE 5103, CHICAGO ILLINOIS 60611-2113

(312.409.4301 / FAX 312.664.6297 / ACPSEN@AOL.COM

October 4, 2004

Via E-mail and USPS

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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I can appreciate the difficult task that CMS faces in implementing workable rules for Medicare Part D. I hope that you will recognize that church plans such as ours provide valuable benefits, but have special needs that are recognized in other areas of the law. Thank you for the opportunity to comment on the Proposed Medicare Part D Regulations. I would be happy to discuss my comments further at your convenience.

Very truly yours,

Ann C. Petersen

CMS-4068-P-1003

Submitter : Mrs. Marilyn Kuna **Date & Time:** 10/04/2004 05:10:05

Organization : Mrs. Marilyn Kuna

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disabillity community.

Submitter : Dr. Connie Kraus **Date & Time:** 10/04/2004 05:10:36

Organization : University of Wisconsin School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

I have been a practicing pharmacist for 28 years and a faculty member and teacher of pharmacy practice for 11 years. I am glad to have this opportunity to share my comments about the proposed Medicare Part D rules and the provision for the medication therapy management(MTM) services. Pharmacists provide important clinical services in a variety of settings. I hope that the Center for Medicare and Medicaid Services will consider providing compensation for all clinical pharmacists providing medication therapy management services.

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

Pharmacy training blends education regarding how drugs work (pharmacology) and how medications are best used to treat illness (pharmacotherapy) with a strong service orientation to patient care by the pharmacist. Pharmacists are well suited to provide medication therapy management in a number of areas such as asthma, diabetes, anticoagulation, hypertension and cholesterol reduction, pain, and others. Pharmacists are invaluable in assessing medication regimens for efficacy and toxicities and potentially reducing use of ineffective or unsafe therapies. In my current practice setting, I oversee the care of patients receiving anticoagulation therapy. I also preview the visits of our patients with diabetes to make recommendations to our providers about necessary laboratory followup as well as suggestions for optimizing the use of medications. I also am frequently asked by patients and their providers to do a comprehensive review of medications to optimize the use of medications that are important to continue and to consider discontinuation of medications that are not working or causing significant side effects. The type of services that I provide in my clinic, which is a family practice residency training site, are services that all of my students have been and will continue to be trained to provide. The training of pharmacists across the country is very similar since schools and colleges of pharmacy are accredited by a single agency. Plan sponsors should allow any pharmacist in any type of practice setting who receives a request from a prescriber to provide MTM services to be able to provide these services and be reimbursed for doing so.

GENERAL PROVISIONS

Pharmacists are uniformly well trained and positioned to provide medication therapy management services. Pharmacists in community practices, clinics, health maintenance organizations,institutional practices sites, and other areas need to be included in the part D benefit to ensure that MTM services are available to patients regardless of where they live. Steps need to be taken to ensure that patients have reasonable access to these services. Particularly in rural counties, patients may find tranportation barriers to accessing this valuable service, so every effort should be made to broaden access rather than limiting it.

CMS-4068-P-1005

Submitter : Dr. Amira Rezk **Date & Time:** 10/04/2004 05:10:05

Organization : VA medical center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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 or,
2. The submitter did not follow through when attaching the document, or submitted only one file or,
3. The document was protected file and would not allow for CMS to attach the ile 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-1006

Submitter : Ms. Mike Fogarty **Date & Time:** 10/04/2004 05:10:41

Organization : Oklahoma Health Care Authority

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The Oklahoma Health Care Authority (OHCA) respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. OHCA is the single state agency designated to administer the Medicaid program in Oklahoma.

CMS-4068-P-1006-Attach-1.doc

MIKE FOGARTY
CHIEF EXECUTIVE OFFICER

BRAD HENRY
GOVERNOR

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

October 4, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: File Code: CMS-4068-P
Medicare Program: Medicare Prescription Drug Benefit

Dear Dr. McClellan:

The Oklahoma Health Care Authority (OHCA) respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. OHCA is the single state agency designated to administer the Medicaid program in Oklahoma.

For your convenience, our comments are organized according to the sections defined in the preamble to the proposed rules.

B. Eligibility and Enrollment

2. Part D Enrollment Process (§ 423.34)

The auto-assignment provision does not clearly define which entity is to perform the auto-assignment. If state Medicaid agencies are to manage the auto-enrollment process, federal financial participation is essential. Federal financial participation for this function should be at the 100% level. Additionally, OHCA believes that states should have the option to manage the auto-enrollment process. This allows a state to determine the feasibility of performing the task based upon existing infrastructure and data processing capabilities. Accordingly, OHCA does not believe that states should be required to manage the auto-enrollment process, but rather, that it should be at the option of individual states.

3. Part D Enrollment Periods (§ 423.36) In accordance with section 1860D-1(b)(1)(C) of the Act, CMS is seeking to establish a process to automatically enroll a full benefit dual-eligible individual [as defined under section 1935(c)(6) of the Act] who has failed to enroll in a PDP or MA-PD plan by either the end of the individual's initial enrollment period or upon becoming dual eligible after his/her initial enrollment period. For full benefit dual eligibles who are eligible to enroll in Part D on November 15, 2005, the initial timeframe runs from November 15, 2005 to May 15, 2006. This leaves a potential gap in coverage from January 1, 2006 through May 15, 2006.

OHCA offers two alternatives to this situation:

1) The first is to delay entry of the dual eligibles until June 2006 at the earliest. This would allow the dual eligible population to continue to receive their medication through the Medicaid program during the implementation of the Part D benefit. This delay would prevent or limit the potential for problems with continuity of care and access to medications for chronic therapies. Delaying the enrollment of the most vulnerable patients will ensure that they are not subjected to unintended consequences of administrative delay.

2) The second suggestion is that all dual eligibles would be automatically enrolled beginning November 15, 2005. Institutionalized dual eligibles have a continuous open enrollment period, so that they could elect to change plans at any time after their initial enrollment. A similar provision is made for automatically enrolled dual eligibles in Section 1860D-1(b)(3)(D) for individuals who are determined full benefit dual eligibles after the initial enrollment period. By extending this special enrollment period to those who are dually eligible during the initial enrollment period, all dual eligibles would be allowed to change plans after automatic enrollment.

The auto-assignment provision at Section 1860D-1(b)(1)(c) includes the use of the term "random" for the enrollment of full benefit dual eligibles. OHCA encourages CMS to develop a detailed algorithm for auto-assignment.

6. Disenrollment by the PDP (§ 423.44(d))

The proposed rules provide under § 423.44(d) that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. According to the rule, an 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 ("SEP") permitting him or her to enroll in another PDP. Since the individual generally will not be able to enroll in either a PDP or an MA-PD until the next annual coordinated election period, he or she may be subject to late enrollment penalties under § 423.46 of the proposed rule. This scenario could be more troubling for dual eligibles in that they would be without drug coverage during the remainder of the plan year. In addition, many members of this population have cognitive impairments coupled with financial limitations that could make them more likely to face involuntary disenrollments than the Medicare Part D population at large. While CMS recognizes the fundamental difference between an MA plan with Medicare fee-for-service as a fall back and the new PDPs that do not have a safety net, they do not propose a fall back for those dual eligibles who are disenrolled from a PDP midyear. OHCA recommends that CMS develop a more stringent standard and/or a fall back plan for involuntary disenrollment for this vulnerable population.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (§ 423.100)

a. Covered Part D Drug.

The definition of a covered Part D drug includes several problematic areas. By including "medical supplies associated with the injection of insulin" the definition is in conflict with the definition given by the FDA. Supplies are defined as "devices" and the FDA is currently working to remove NDC numbers for supplies. This also presents a billing dilemma for pharmacists. It is our understanding of the HIPAA transaction standards that devices and supplies are not to be billed using the NCPDP standards, but are to be billed using the 837 (HCFA 1500) standards.

The second problematic area of the definition of a covered Part D drug is the exclusion of Part B drugs. While coverage for some of the Part B drugs is a black and white issue, coverage for many of these drugs falls into a gray area. In addition, all of the Part B drugs are of a type for which a delay in coverage affects therapeutic outcome. Since Part B does not accept real-time online transactions, a beneficiary may have to wait several weeks to months before it is determined whether Part B will cover the drug. The regulations for Part D should address these situations in order to assure beneficiaries access to this group of pharmaceuticals. One suggestion is to allow PDPs to "pay and chase" the Part B payment. This has been source of concern and significant expense for Oklahoma Medicaid.

b. Dispensing Fees. OHCA supports the use of Option 1 on page 46647 of the Federal Register as the definition of a dispensing fee. This is the commonly understood term for other payer sources nationwide as well as within the pharmacy industry. Supplies and equipment should be billed separately. By including the cost of supplies in the Part D expenditures, the cost to states for the Phased Down Contribution is unnecessarily inflated. Home infusion therapy should not be billed as one lump sum, but should be billed according to product or service type. Many of the home infusion services would be covered under Part A or B and likewise would unnecessarily drive up the cost to states through their contribution. The issue of duplicate and overlapping claims in Parts A, B, and D are also avoided if each component is billed separately.

c. Long-term care facilities

CMS has requested comments as to whether intermediate care facilities for the mentally retarded or related conditions (ICFs/MR), described in §440.150 of the proposed rule, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. OHCA strongly supports the addition of ICFs/MR to the definition of a long term care facility. Since payment for most drugs currently 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. It is our understanding that the ICF/MR facilities also contract with long term care pharmacies for the provision of pharmaceutical products and services.

Additionally, OHCA proposes the inclusion of recipients/beneficiaries covered under §1915(c) Medicaid Home and Community-Based Services (HCBS) Waivers as institutionalized for the purpose of cost-sharing liability as outlined in § 423.782(a)(2)(ii). These individuals meet the requirements for institutionalization in a long term care facility (ICF/MR, NF or long-term acute care hospital) but have chosen to remain in their home and receive the care they require in a cost-effective, community-based setting.

For dual eligibles, pharmacy co-payments under the Medicaid Program are not mandatory but are permitted under Section 1902(a)(14) of the Act. These co-payments are nominal in amount and may be waived by the pharmacy provider if the beneficiary states that they cannot afford to pay them. No such provision is made for the dual eligibles in Part D. While the 2006 co-payments are quite low, they are tied either to CPI or to Part D spending beginning in 2007. These amounts could very quickly escalate beyond the means of the dual eligible population.

3. Establishment of Prescription Drug Plan Service Areas (§ 423.112)
OHCA supports defining a plan service area or region as a single state. Due to the responsibilities of the Medicaid agencies for automatic assignment of the dual eligibles into PDPs, coordinating this assignment will be accomplished more efficiently if the Medicaid and PDP service areas are identical.

4. Access to Covered Part D Drugs (§ 423.120)
a. Pharmacy Access Standards. CMS requests comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies. OHCA has successfully contracted with a number of long-term care pharmacies in the state as well as with independent community pharmacies providing service to residents of long-term care facilities. It has been our experience that long-term care pharmacies are able to purchase drugs at substantially lower prices than traditional community retail pharmacies and as a result, have a higher margin on the ingredient cost. Pharmacy reimbursement should be considered as the sum of the ingredient cost plus the dispensing fee minus any cost-sharing. The ingredient cost is typically based on Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC). A higher margin on the ingredient cost can compensate for lower dispensing fees so that overall, pharmacies in the traditional community setting and those serving long-term care facilities are able to participate under the same terms.

It should be noted, however, that typical third party payers and pharmacy benefit management companies will need to adjust their standard reimbursement schemes in order to attract a sufficient number of participating pharmacies. Due to the expected increase in administrative tasks and coordination of benefits at the dispensing pharmacy, many pharmacies may opt not to participate in the new plans without a significant increase in reimbursement.

CMS has also requested comments regarding the advantages and disadvantages of requiring PDPs to contract with long-term care pharmacies or strongly encouraging PDP sponsors to include long-term care pharmacies in their network. OHCA's experience with pharmacies providing pharmaceutical products to long-term care facilities indicates that while a large number of the beneficiaries are served by these specialty pharmacies, a significant portion of them are served by local independent pharmacists. OHCA believes that it would be best to categorize payment rates by the location of the beneficiary rather than by the stated specialty of the pharmacy. In this way, there is no disadvantage to the local pharmacist who is willing and able to provide the required services for long-term care beneficiaries.

CMS has requested comments regarding the inclusion of I/T/U pharmacies in the PDP networks. It has been the experience of OHCA that the I/T/U pharmacies are very willing to assist their beneficiaries in managing their prescription regimens and will fill those prescriptions that they stock and then send the beneficiary to another pharmacy for the remaining products. The I/T/U pharmacies in Oklahoma are on par with other pharmacies in terms of technology and claims processing capabilities. Alternatively, since claims for tribal members receive 100% federal financial participation, the dual eligibles could retain Medicaid coverage.

CMS has asked for comments regarding access to rural pharmacies. Oklahoma's state employee insurance plan pays different dispensing fees based on location and number of stores within a chain. Individually-owned stores in rural locations are paid a higher reimbursement in order to guarantee

access to pharmacy services for state employees and retirees across the state. Another method to increase or ensure access would be to set a maximum distance that beneficiaries have to travel in order to have their prescriptions filled. In some parts of Oklahoma, the closest pharmacy may be located in an adjacent (bordering) state. Pharmacies within driving distance of their border states should be encouraged to participate in the PDPs that serve their home state and the states they border.

b. Formulary requirements.

OHCA agrees with the CMS interpretation of the binding nature of the P & T Committee's formulary development activities. Any less stringent interpretation would result in a meaningless waste of time for the health care professionals who serve on the Committee. The composition of the P & T Committee should not be specified, other than to enumerate the physicians and pharmacists required. Specialty physicians and pharmacists are not widely available and requiring a certain type of specialist will be unduly burdensome on PDPs.

Formulary development by a PDP will be significantly different than it is currently for payers who are responsible for all health care segments. For example, if OHCA were to restrict access to certain drug products, we would see an increase in hospitalizations. This will not be true for the PDP, who's only responsibility will be the pharmacy benefit. The potential for cost-shifting, unintended or otherwise, is significantly increased for these plans. Due to this potential cost-shifting, CMS must plan to carefully monitor formulary changes by the PDPs.

OHCA is concerned that the standard drug benefit and formulary requirements do not and will not meet the needs of the dual eligibles who currently receive their pharmacy benefit through the Medicaid program. We urge CMS to consider special plans or formularies to address the needs of this population – the frail elderly, the physically disabled, those with serious mental illnesses, the mentally retarded – many of whom require a variety of medications to treat both chronic and acute conditions. We support the use of generic drugs and encourage CMS to consider a minimum formulary of all generic drugs plus two brand name drugs per therapeutic class or category.

Certain categories of drugs should not be restricted. These include drugs used to treat and prevent seizures, anti-retrovirals for HIV/AIDS, antipsychotic and other psychotropic medications, and those drugs that require lengthy periods to determine stable doses or frequent monitoring. For these classes of medications, abruptly changing a beneficiary's medicines due to formulary restrictions or waiting for prior authorization or a formulary appeal could have serious negative consequences to that individual's health and welfare.

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 guidelines that require such flexibility.

While the proposed rules specify the time period for changes to the therapeutic categories and classes, there are no specific time periods stated for changes to the preferred drugs within those therapeutic

categories and classes other than the prohibition against changes during the election period and 30 days after the beginning of the plan year. OHCA's experience with managed care pharmacy plans leads us to believe that the PDPs and MA-PDs will exercise aggressive cost management tools including manufacturer rebates that are likely to lead to significant formulary changes throughout the year. We support the use of these management tools, but in the best interest of the beneficiaries, we suggest a limitation on changes to preferred drugs. Oklahoma's plans were limited to twice-yearly changes in the formulary. With the prohibition against changes during the election period and through the first 30 days of a plan year, this limit would hopefully ensure that beneficiaries are able to get a consistent benefit from Part D. Additionally, the administrative expense of notice and prior authorizations will quickly overcome any savings if formulary changes are allowed to occur too frequently.

CMS has asked for comments regarding the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary. OHCA recommends not less than a quarterly review. We currently review utilization data monthly with our Drug Utilization Review Board. We find it difficult to get through data a month a time and surmise that data for more than a quarter would overwhelm most reviewers.

c. Use of standardized technology.

OHCA submits that the intention of CMS to use identifiers other than a Social Security Number will confound the already convoluted process of coordination of benefits. As stated earlier, pharmacies will be closely scrutinizing contracts with PDPs to ensure that they are adequately reimbursed for their dispensing and administrative tasks. This will also unnecessarily complicate data matching between PDPs and CMS, PDPs and Medicaid, PDPs and any other payer.

One potential problem with out-of-network pharmacy reimbursement was not discussed in the preamble. What happens to dual eligibles when they fill prescriptions out-of-network? What happens to dual eligibles who reside in long-term care facilities? How are pharmacies compensated for the difference between their usual and customary and the negotiated payment rate for the PDP? Is the dual eligible responsible for paying the cost sharing responsibility plus that difference?

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

2a. Cost-effective drug utilization management programs.

CMS has asked for comment on whether there are industry standards for cost effective utilization management. The tools listed are prior authorization, step therapy, and tiered cost-sharing. All of these should be required as program standards by PDPs and MA-PDs.

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S. Special Rules for States – Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

1. Eligibility Determination (§ 423.904)

4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908-423.910)

Under the Act and the Proposed Rule, states will continue to provide a portion of the payment for dual eligible individual's prescription costs. This amount is theoretically equivalent to a state's current contribution toward these individual's drug costs. To calculate the state's share of this cost, CMS has suggested a formula using actual expenditures for covered Part D drugs during calendar year 2003. CMS has previously indicated and the Proposed Rule confirms that CMS plans to use MSIS reported data as the source of prescription drug expenditures for the full-benefit dual eligible population in 2003. The MSIS expenditures will be offset by the amount of drug rebates collected during calendar year 2003.

Our concern with the proposed calculation is that the omission of a few key factors may inadvertently penalize states by requiring more funding than would be necessary for the state to continue to provide their current pharmacy benefits. We ask for CMS to detail their plan to accurately consider drug rebate collections. Specifically, how will CMS account for the fact that drug rebates are invoiced and collected retrospectively? A timely-paid rebate for a drug dispensed the first day of a calendar quarter is not due until six months later. This means that the first and second quarter rebates of calendar year 2003 were based on calendar year 2002 claims and that rebates for the third and fourth quarters of 2003 are not reflected in the rebates collected during calendar year 2003. A possible solution is to use the expenditures for calendar year 2003 and rebate collections from July 1, 2003 through June 30, 2004. This would more closely approximate the rebates as applied to the spending.

Also, Oklahoma has implemented a supplemental rebate program and other cost containment strategies after calendar year 2003. In order to accurately estimate what Oklahoma would spend to provide a pharmacy benefit for the dual eligibles after January 1, 2006, CMS should take into consideration the savings from these programs and apply those to the phased down state contribution calculation.

So that states may more accurately project budgetary needs, CMS should clarify which specific National Health Expenditure projection will be used for the phase-down calculation. We also request clarification as to whether there will be adjustments to the inflation factors included in the clawback calculation. Accordingly, we suggest a modification in this formula to include an adjustment to the average annual change between years. As an example, suppose the National Health Expenditure projected growth for prescription drugs is .384 from 2003 to 2006, by applying an adjustment factor of

75%, the growth factor is reduced to .288. This compensates for the savings in future years for which the state would otherwise not receive credit.

Because of the significance of the base-line number for years to come, OHCA strongly recommends that CMS consider developing an appeals process for the phased down state contribution calculation. This process should enable states to avail themselves of a mechanism to challenge final calculations based on all available evidence and data.

OHCA appreciates the opportunity to submit comments on the Proposed Rule. We would be happy to discuss the comments with you and your staff. Should you have any questions, please contact Nancy Nesser at (405) 522-7325.

Respectfully submitted,

 /e/

Mike Fogarty

MIKE FOGARTY
CHIEF EXECUTIVE OFFICER

BRAD HENRY
GOVERNOR

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

October 4, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: File Code: CMS-4068-P
Medicare Program: Medicare Prescription Drug Benefit

Dear Dr. McClellan:

The Oklahoma Health Care Authority (OHCA) respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. OHCA is the single state agency designated to administer the Medicaid program in Oklahoma.

For your convenience, our comments are organized according to the sections defined in the preamble to the proposed rules.

B. Eligibility and Enrollment

2. Part D Enrollment Process (§ 423.34)

The auto-assignment provision does not clearly define which entity is to perform the auto-assignment. If state Medicaid agencies are to manage the auto-enrollment process, federal financial participation is essential. Federal financial participation for this function should be at the 100% level. Additionally, OHCA believes that states should have the option to manage the auto-enrollment process. This allows a state to determine the feasibility of performing the task based upon existing infrastructure and data processing capabilities. Accordingly, OHCA does not believe that states should be required to manage the auto-enrollment process, but rather, that it should be at the option of individual states.

3. Part D Enrollment Periods (§ 423.36) In accordance with section 1860D-1(b)(1)(C) of the Act, CMS is seeking to establish a process to automatically enroll a full benefit dual-eligible individual [as defined under section 1935(c)(6) of the Act] who has failed to enroll in a PDP or MA-PD plan by either the end of the individual's initial enrollment period or upon becoming dual eligible after his/her initial enrollment period. For full benefit dual eligibles who are eligible to enroll in Part D on November 15, 2005, the initial timeframe runs from November 15, 2005 to May 15, 2006. This leaves a potential gap in coverage from January 1, 2006 through May 15, 2006.

OHCA offers two alternatives to this situation:

1) The first is to delay entry of the dual eligibles until June 2006 at the earliest. This would allow the dual eligible population to continue to receive their medication through the Medicaid program during the implementation of the Part D benefit. This delay would prevent or limit the potential for problems with continuity of care and access to medications for chronic therapies. Delaying the enrollment of the most vulnerable patients will ensure that they are not subjected to unintended consequences of administrative delay.

2) The second suggestion is that all dual eligibles would be automatically enrolled beginning November 15, 2005. Institutionalized dual eligibles have a continuous open enrollment period, so that they could elect to change plans at any time after their initial enrollment. A similar provision is made for automatically enrolled dual eligibles in Section 1860D-1(b)(3)(D) for individuals who are determined full benefit dual eligibles after the initial enrollment period. By extending this special enrollment period to those who are dually eligible during the initial enrollment period, all dual eligibles would be allowed to change plans after automatic enrollment.

The auto-assignment provision at Section 1860D-1(b)(1)(c) includes the use of the term "random" for the enrollment of full benefit dual eligibles. OHCA encourages CMS to develop a detailed algorithm for auto-assignment.

6. Disenrollment by the PDP (§ 423.44(d))

The proposed rules provide under § 423.44(d) that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. According to the rule, an 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 ("SEP") permitting him or her to enroll in another PDP. Since the individual generally will not be able to enroll in either a PDP or an MA-PD until the next annual coordinated election period, he or she may be subject to late enrollment penalties under § 423.46 of the proposed rule. This scenario could be more troubling for dual eligibles in that they would be without drug coverage during the remainder of the plan year. In addition, many members of this population have cognitive impairments coupled with financial limitations that could make them more likely to face involuntary disenrollments than the Medicare Part D population at large. While CMS recognizes the fundamental difference between an MA plan with Medicare fee-for-service as a fall back and the new PDPs that do not have a safety net, they do not propose a fall back for those dual eligibles who are disenrolled from a PDP midyear. OHCA recommends that CMS develop a more stringent standard and/or a fall back plan for involuntary disenrollment for this vulnerable population.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections (§ 423.100)

a. Covered Part D Drug.

The definition of a covered Part D drug includes several problematic areas. By including "medical supplies associated with the injection of insulin" the definition is in conflict with the definition given by the FDA. Supplies are defined as "devices" and the FDA is currently working to remove NDC numbers for supplies. This also presents a billing dilemma for pharmacists. It is our understanding of the HIPAA transaction standards that devices and supplies are not to be billed using the NCPDP standards, but are to be billed using the 837 (HCFA 1500) standards.

The second problematic area of the definition of a covered Part D drug is the exclusion of Part B drugs. While coverage for some of the Part B drugs is a black and white issue, coverage for many of these drugs falls into a gray area. In addition, all of the Part B drugs are of a type for which a delay in coverage affects therapeutic outcome. Since Part B does not accept real-time online transactions, a beneficiary may have to wait several weeks to months before it is determined whether Part B will cover the drug. The regulations for Part D should address these situations in order to assure beneficiaries access to this group of pharmaceuticals. One suggestion is to allow PDPs to "pay and chase" the Part B payment. This has been source of concern and significant expense for Oklahoma Medicaid.

b. Dispensing Fees. OHCA supports the use of Option 1 on page 46647 of the Federal Register as the definition of a dispensing fee. This is the commonly understood term for other payer sources nationwide as well as within the pharmacy industry. Supplies and equipment should be billed separately. By including the cost of supplies in the Part D expenditures, the cost to states for the Phased Down Contribution is unnecessarily inflated. Home infusion therapy should not be billed as one lump sum, but should be billed according to product or service type. Many of the home infusion services would be covered under Part A or B and likewise would unnecessarily drive up the cost to states through their contribution. The issue of duplicate and overlapping claims in Parts A, B, and D are also avoided if each component is billed separately.

c. Long-term care facilities

CMS has requested comments as to whether intermediate care facilities for the mentally retarded or related conditions (ICFs/MR), described in §440.150 of the proposed rule, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. OHCA strongly supports the addition of ICFs/MR to the definition of a long term care facility. Since payment for most drugs currently 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. It is our understanding that the ICF/MR facilities also contract with long term care pharmacies for the provision of pharmaceutical products and services.

Additionally, OHCA proposes the inclusion of recipients/beneficiaries covered under §1915(c) Medicaid Home and Community-Based Services (HCBS) Waivers as institutionalized for the purpose of cost-sharing liability as outlined in § 423.782(a)(2)(ii). These individuals meet the requirements for institutionalization in a long term care facility (ICF/MR, NF or long-term acute care hospital) but have chosen to remain in their home and receive the care they require in a cost-effective, community-based setting.

For dual eligibles, pharmacy co-payments under the Medicaid Program are not mandatory but are permitted under Section 1902(a)(14) of the Act. These co-payments are nominal in amount and may be waived by the pharmacy provider if the beneficiary states that they cannot afford to pay them. No such provision is made for the dual eligibles in Part D. While the 2006 co-payments are quite low, they are tied either to CPI or to Part D spending beginning in 2007. These amounts could very quickly escalate beyond the means of the dual eligible population.

3. Establishment of Prescription Drug Plan Service Areas (§ 423.112)
OHCA supports defining a plan service area or region as a single state. Due to the responsibilities of the Medicaid agencies for automatic assignment of the dual eligibles into PDPs, coordinating this assignment will be accomplished more efficiently if the Medicaid and PDP service areas are identical.

4. Access to Covered Part D Drugs (§ 423.120)
a. Pharmacy Access Standards. CMS requests comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies. OHCA has successfully contracted with a number of long-term care pharmacies in the state as well as with independent community pharmacies providing service to residents of long-term care facilities. It has been our experience that long-term care pharmacies are able to purchase drugs at substantially lower prices than traditional community retail pharmacies and as a result, have a higher margin on the ingredient cost. Pharmacy reimbursement should be considered as the sum of the ingredient cost plus the dispensing fee minus any cost-sharing. The ingredient cost is typically based on Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC). A higher margin on the ingredient cost can compensate for lower dispensing fees so that overall, pharmacies in the traditional community setting and those serving long-term care facilities are able to participate under the same terms.

It should be noted, however, that typical third party payers and pharmacy benefit management companies will need to adjust their standard reimbursement schemes in order to attract a sufficient number of participating pharmacies. Due to the expected increase in administrative tasks and coordination of benefits at the dispensing pharmacy, many pharmacies may opt not to participate in the new plans without a significant increase in reimbursement.

CMS has also requested comments regarding the advantages and disadvantages of requiring PDPs to contract with long-term care pharmacies or strongly encouraging PDP sponsors to include long-term care pharmacies in their network. OHCA's experience with pharmacies providing pharmaceutical products to long-term care facilities indicates that while a large number of the beneficiaries are served by these specialty pharmacies, a significant portion of them are served by local independent pharmacists. OHCA believes that it would be best to categorize payment rates by the location of the beneficiary rather than by the stated specialty of the pharmacy. In this way, there is no disadvantage to the local pharmacist who is willing and able to provide the required services for long-term care beneficiaries.

CMS has requested comments regarding the inclusion of I/T/U pharmacies in the PDP networks. It has been the experience of OHCA that the I/T/U pharmacies are very willing to assist their beneficiaries in managing their prescription regimens and will fill those prescriptions that they stock and then send the beneficiary to another pharmacy for the remaining products. The I/T/U pharmacies in Oklahoma are on par with other pharmacies in terms of technology and claims processing capabilities. Alternatively, since claims for tribal members receive 100% federal financial participation, the dual eligibles could retain Medicaid coverage.

CMS has asked for comments regarding access to rural pharmacies. Oklahoma's state employee insurance plan pays different dispensing fees based on location and number of stores within a chain. Individually-owned stores in rural locations are paid a higher reimbursement in order to guarantee

access to pharmacy services for state employees and retirees across the state. Another method to increase or ensure access would be to set a maximum distance that beneficiaries have to travel in order to have their prescriptions filled. In some parts of Oklahoma, the closest pharmacy may be located in an adjacent (bordering) state. Pharmacies within driving distance of their border states should be encouraged to participate in the PDPs that serve their home state and the states they border.

b. Formulary requirements.

OHCA agrees with the CMS interpretation of the binding nature of the P & T Committee's formulary development activities. Any less stringent interpretation would result in a meaningless waste of time for the health care professionals who serve on the Committee. The composition of the P & T Committee should not be specified, other than to enumerate the physicians and pharmacists required. Specialty physicians and pharmacists are not widely available and requiring a certain type of specialist will be unduly burdensome on PDPs.

Formulary development by a PDP will be significantly different than it is currently for payers who are responsible for all health care segments. For example, if OHCA were to restrict access to certain drug products, we would see an increase in hospitalizations. This will not be true for the PDP, who's only responsibility will be the pharmacy benefit. The potential for cost-shifting, unintended or otherwise, is significantly increased for these plans. Due to this potential cost-shifting, CMS must plan to carefully monitor formulary changes by the PDPs.

OHCA is concerned that the standard drug benefit and formulary requirements do not and will not meet the needs of the dual eligibles who currently receive their pharmacy benefit through the Medicaid program. We urge CMS to consider special plans or formularies to address the needs of this population – the frail elderly, the physically disabled, those with serious mental illnesses, the mentally retarded – many of whom require a variety of medications to treat both chronic and acute conditions. We support the use of generic drugs and encourage CMS to consider a minimum formulary of all generic drugs plus two brand name drugs per therapeutic class or category.

Certain categories of drugs should not be restricted. These include drugs used to treat and prevent seizures, anti-retrovirals for HIV/AIDS, antipsychotic and other psychotropic medications, and those drugs that require lengthy periods to determine stable doses or frequent monitoring. For these classes of medications, abruptly changing a beneficiary's medicines due to formulary restrictions or waiting for prior authorization or a formulary appeal could have serious negative consequences to that individual's health and welfare.

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 guidelines that require such flexibility.

While the proposed rules specify the time period for changes to the therapeutic categories and classes, there are no specific time periods stated for changes to the preferred drugs within those therapeutic

categories and classes other than the prohibition against changes during the election period and 30 days after the beginning of the plan year. OHCA's experience with managed care pharmacy plans leads us to believe that the PDPs and MA-PDs will exercise aggressive cost management tools including manufacturer rebates that are likely to lead to significant formulary changes throughout the year. We support the use of these management tools, but in the best interest of the beneficiaries, we suggest a limitation on changes to preferred drugs. Oklahoma's plans were limited to twice-yearly changes in the formulary. With the prohibition against changes during the election period and through the first 30 days of a plan year, this limit would hopefully ensure that beneficiaries are able to get a consistent benefit from Part D. Additionally, the administrative expense of notice and prior authorizations will quickly overcome any savings if formulary changes are allowed to occur too frequently.

CMS has asked for comments regarding the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary. OHCA recommends not less than a quarterly review. We currently review utilization data monthly with our Drug Utilization Review Board. We find it difficult to get through data a month a time and surmise that data for more than a quarter would overwhelm most reviewers.

c. Use of standardized technology.

OHCA submits that the intention of CMS to use identifiers other than a Social Security Number will confound the already convoluted process of coordination of benefits. As stated earlier, pharmacies will be closely scrutinizing contracts with PDPs to ensure that they are adequately reimbursed for their dispensing and administrative tasks. This will also unnecessarily complicate data matching between PDPs and CMS, PDPs and Medicaid, PDPs and any other payer.

One potential problem with out-of-network pharmacy reimbursement was not discussed in the preamble. What happens to dual eligibles when they fill prescriptions out-of-network? What happens to dual eligibles who reside in long-term care facilities? How are pharmacies compensated for the difference between their usual and customary and the negotiated payment rate for the PDP? Is the dual eligible responsible for paying the cost sharing responsibility plus that difference?

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

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4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908-423.910)

Under the Act and the Proposed Rule, states will continue to provide a portion of the payment for dual eligible individual's prescription costs. This amount is theoretically equivalent to a state's current contribution toward these individual's drug costs. To calculate the state's share of this cost, CMS has suggested a formula using actual expenditures for covered Part D drugs during calendar year 2003. CMS has previously indicated and the Proposed Rule confirms that CMS plans to use MSIS reported data as the source of prescription drug expenditures for the full-benefit dual eligible population in 2003. The MSIS expenditures will be offset by the amount of drug rebates collected during calendar year 2003.

Our concern with the proposed calculation is that the omission of a few key factors may inadvertently penalize states by requiring more funding than would be necessary for the state to continue to provide their current pharmacy benefits. We ask for CMS to detail their plan to accurately consider drug rebate collections. Specifically, how will CMS account for the fact that drug rebates are invoiced and collected retrospectively? A timely-paid rebate for a drug dispensed the first day of a calendar quarter is not due until six months later. This means that the first and second quarter rebates of calendar year 2003 were based on calendar year 2002 claims and that rebates for the third and fourth quarters of 2003 are not reflected in the rebates collected during calendar year 2003. A possible solution is to use the expenditures for calendar year 2003 and rebate collections from July 1, 2003 through June 30, 2004. This would more closely approximate the rebates as applied to the spending.

Also, Oklahoma has implemented a supplemental rebate program and other cost containment strategies after calendar year 2003. In order to accurately estimate what Oklahoma would spend to provide a pharmacy benefit for the dual eligibles after January 1, 2006, CMS should take into consideration the savings from these programs and apply those to the phased down state contribution calculation.

So that states may more accurately project budgetary needs, CMS should clarify which specific National Health Expenditure projection will be used for the phase-down calculation. We also request clarification as to whether there will be adjustments to the inflation factors included in the clawback calculation. Accordingly, we suggest a modification in this formula to include an adjustment to the average annual change between years. As an example, suppose the National Health Expenditure projected growth for prescription drugs is .384 from 2003 to 2006, by applying an adjustment factor of

75%, the growth factor is reduced to .288. This compensates for the savings in future years for which the state would otherwise not receive credit.

Because of the significance of the base-line number for years to come, OHCA strongly recommends that CMS consider developing an appeals process for the phased down state contribution calculation. This process should enable states to avail themselves of a mechanism to challenge final calculations based on all available evidence and data.

OHCA appreciates the opportunity to submit comments on the Proposed Rule. We would be happy to discuss the comments with you and your staff. Should you have any questions, please contact Nancy Nesser at (405) 522-7325.

Respectfully submitted,

 /e/

Mike Fogarty

CMS-4068-P-1007

Submitter : Miriam I. Allen **Date & Time:** 10/04/2004 05:10:21

Organization : Miriam I. Allen

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit. CMS must designate people living with HIV/AIDS as a special population and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

CMS-4068-P-1008

Submitter : Ms. Rev. Carolyn R Palmer **Date & Time:** 10/04/2004 05:10:19

Organization : Special Concerns Ministries

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Plese see attached file from Special Concerns Ministries

CMS-4068-P-1008-Attach-3.doc

CMS-4068-P-1008-Attach-2.doc

CMS-4068-P-1008-Attach-1.doc

Special Concerns Ministries

Elderly ◆ Disabled ◆ Families ◆ Singles

Isaiah 9: 6-7 & 58: 6-12 ◆ Matthew 25: 31-46 ◆ Philippians 2: 1-11

October 1, 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

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

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Targeted and hands-on outreach to Medicare beneficiaries who are seniors and people 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 in each region that incorporates collaborative partnerships with state, local agencies and with physicians and advocacy organizations.

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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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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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. 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 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.

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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 a truly independent review by an administrative law judge (ALJ), and 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; 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.

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Thank you for your consideration of our views.

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October 1, 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

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October 1, 2004

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Phone (503) 231-6640

CMS-4068-P-1009

Submitter : angela davis **Date & Time:** 10/04/2004 05:10:42

Organization : UNC-CH PharmD candidate

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

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

Subpart C: Benefits & Beneficiary Protections
My concern lies with the proposed regulation allowing plans to make distinctions and designate pharmacies within the network as ?preferred? and ?non-preferred?. This plan could reduce a beneficiary?s co-pay at a preferred pharmacy. However, this plan could affect many pharmacists ability to serve their long standing customers. It could potentially drive patients to a particular pharmacy and not the pharmacy or pharmacist of choice because financial restraints. Distinguishing between preferred and non-preferred should only count when evaluating whether a plan?s pharmacy network meets the pharmacy access standard.

In addition, I believe that local pharmacies should be allowed to offer the same benefits as mail order companies such as 90 day supplies. Historically only mail order companies have been allowed to offer this service. However, any price difference should be clarified as a direct relationship with the additional services offered by the local pharmacy and not as an increase cost in drug product.

In conclusion, I urge CMS to revise the regulation to distinguish between preferred and non-preferred pharmacies only in reference to evaluating if the plan?s pharmacy network meets the pharmacy access standard. In addition, I urge CMS to consider allowing local pharmacies to offer the same benefits as mail order companies without any additional costs being tagged with the cost of the product.

Thank you for considering my view.

Sincerely,
Angela Davis
UNC-CH PharmD. Candidate.

CMS-4068-P-1010

Submitter : Mr. Michael Kink **Date & Time:** 10/04/2004 05:10:49

Organization : Housing Works, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

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Please see attached file.

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Housing Works, Inc.

CMS-4068-P-1010-Attach-1.pdf

Housing Works, Inc.
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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 the Centers:

Housing Works is the nation's largest community-based AIDS service organization, and the nation's largest minority-controlled AIDS organization. We currently serve over 2000 homeless and formerly homeless women, men and children living with AIDS and HIV, the majority of whom have multiple co-morbid conditions in addition to HIV, including mental illness, chemical dependency, and histories of incarceration, repeated homelessness, and domestic violence.

We have a number of concerns about the implementation of the prescription drug benefit provided by the *Medicare Modernization Act* (MMA) and appreciate the opportunity to comment on the proposed rule. Hundreds of our clients are Medicaid-Medicare "dual eligibles," and they join with over 80,000 other Americans living with AIDS and HIV who will be impacted by the proposed rule in asking for your urgent attention to the issues raised in these comments – it's a matter of life and death.

In light of the number of questions that the Center for Medicare and Medicaid Services (CMS) raised in the preamble to the proposed rule and the ambiguity that remains in a number of critical areas, we strongly encourage CMS to issue a second notice of proposed rulemaking to provide us the opportunity to comment on the decisions made by CMS regarding these issues.

The development of highly active antiretroviral therapy (HAART) for the treatment of HIV disease over the past decade has led to profound and widespread declines in HIV/AIDS morbidity and mortality. We strongly urge CMS to publish a final rule that ensures that Medicare beneficiaries living with HIV/AIDS at all income levels have affordable access to the full pharmacopoeia of FDA-approved medications.

In a letter to Senator Dianne Feinstein, Secretary Tommy Thompson made assurances that people living with HIV/AIDS would have a comprehensive prescription drug benefit under Medicare Part D. Secretary Thompson pledged that the new Medicare benefit will not result in a loss of coverage for the dually-eligible population and that the Medicare prescription drug plans would not limit drugs for beneficiaries living with HIV/AIDS.

We hope that Secretary Thompson and CMS will keep these assurances in mind when developing the final regulation for the Part D prescription drug benefit.

The following comments represent our highest priority concerns regarding access to life-saving drug therapies for Medicare beneficiaries with HIV/AIDS under Medicare Part D. We hope that CMS will give serious consideration to the issues outlined in this document and will be responsive through publishing a final rule that adequately and appropriately addresses these critical issues.

Housing Works clients, staff and volunteers feel the two issues highlighted below warrant special and serious consideration because of their potential impact on Medicare beneficiaries with HIV/AIDS who access daily life-sustaining drug regimens.

- **DESIGNATE PEOPLE LIVING WITH HIV/AIDS AS A "SPECIAL POPULATION"**

  We strongly encourage CMS to designate "special populations" and require drug plans to exempt these populations from formulary restrictions and grant them special protections from cost-sharing requirements and other cost-containment measures that may impede access to prescription drugs. We strongly recommend that CMS designate people living with HIV/AIDS as a "special population." Please see our comments on page 8 for greater detail on this recommendation.

- **A POTENTIAL LAPSE IN DRUG COVERAGE IS UNACCEPTABLE – DELAY IMPLEMENTATION OF THE MMA FOR DUAL ELIGIBLES**

  We are very concerned that the current proposed timeframe which begins enrollment on November 15, 2005 will not ensure that the nearly 60,000 dual eligible with HIV/AIDS along with more than 6 million other dual eligible individuals are enrolled in a Medicare Part D prescription drug plan before they lose their Medicaid drug coverage on December 31, 2005. The regulations do not appear to ensure that there will be no breach in drug coverage for dual eligibles if these enrollment processes cannot be completed by the last day of 2005. Not enrolling dual eligibles who do not select a plan before they lose Medicaid drug coverage until May 15, 2006 as the regulations would seem to call for is completely unacceptable. The final regulations must ensure that dual eligibles do not lose drug coverage during the transition, even if that requires maintaining individuals with Medicaid-covered drugs—with federal matching funding—until Medicare Part D coverage is in place. It would be far preferable to delay coverage under Part D for this vulnerable group of beneficiaries than to threaten individual and public health by leaving persons with HIV/AIDS and other dual eligibles without any drug coverage for weeks or months.

  Based on our experience, six weeks is not enough time to work with this medically complex and difficult to reach population to ensure that they are enrolled in a prescription drug plan, and if they are not, to conduct a reliable auto-enrollment process that includes educating the beneficiary on the prescription

drug plan that they have been enrolled in and informing them of their right to change plans. It is absolutely critical to the health of dual eligibles with HIV/AIDS that they not experience any disruption in their access to prescription drugs during the transition to a Medicare Part D prescription drug benefit.

We sincerely hope that CMS will work with key stakeholders including Medicare beneficiaries and their health care providers to ensure the implementation of a Medicare drug benefit that delivers on the promise to provide seniors and people with disabilities access to affordable and meaningful prescription drug coverage. We recognize that this delay and many of the issues we raise may require legislative changes; in those instances we hope that CMS will support efforts to remedy these critical issues through legislation.

COMMENTS ON PREAMBLE AND PROPOSED RULE

SUBPART B—ELIGIBILITY AND ENROLLMENT

DUALS ELIGIBLES MUST NOT BE LIMITED TO THE "AVERAGE COST PLAN" (§423.30(D)(1))

The federal premium subsidy for the dual eligible population will be limited to the premium for the average cost plan in their area. The restriction could leave dual eligibles without meaningful access to the full range of prescription drug plans in their area. Dual eligibles are the sickest and poorest Medicare beneficiaries and have extensive prescription drug needs and minimal or no resources to pay for them. It is imperative that the Medicare beneficiaries who are most dependent on drugs have access to the plan that will best meet their needs rather than limiting them to what could be the plan with the weakest drug benefit. Dual eligible individuals should not be charged a premium for enrolling with any plan. At a minimum, if the beneficiary or his or her medical provider can attest that a higher premium plan will better meet their medical needs, then the beneficiary should be allowed to enroll in the plan at no cost to the beneficiary.

PRESCRIPTION DRUG PLANS SHOULD NOT BE ALLOWED TO DISENROLL BENEFICIARIES FOR DISRUPTIVE BEHAVIOR (§423.44(D)(2))

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." In the absence of clearly defining these terms, drug plans would have the latitude to discontinue drug coverage for behaviors that they deem "threatening" and places beneficiaries at risk who simply may be questioning a plan's coverage decision. Most concerning is that there is no protection for individuals who may be exhibiting behaviors that could be perceived as "disruptive or threatening" due to a drug interaction or reaction; untreated or inappropriately treated mental illness or diminished mental capacity due to another condition. We ask that the standard and definitions of these terms be clearly defined by CMS and that the behavior not be due to diminished mental capacity or treatment noncompliance.

STRICT GUIDELINES MUST BE APPLIED TO THE RELEASE OF INDIVIDUAL IDENTIFYING INFORMATION TO PRESCRIPTION DRUG PLANS (§423.50)

We have significant concerns regarding the provision in the MMA statute that allows the Secretary to disclose personal identifying information to prescription drug plans. Disclosure of personal information for these purposes is contrary to fair information practice principles and is particularly unacceptable for Medicare beneficiaries with diseases that carry significant stigma and whose populations experience discrimination, such as HIV/AIDS and mental illnesses. While we understand that the sharing of the information is intended to allow prescription drug plans to assist with outreach and enrollment activities, other opportunities exist for prescription drug plans to assist with these efforts, such as through distributing materials at community health or senior centers.

It is critical that CMS address the provisions below in the final rule to govern the disclosure of individual identifying information to prescription drug plans.

1. Personal identifiable information should only be provided to prescription drug plans that are distributing specific information regarding the plan's drug formulary and associated cost sharing.

2. Personal identifiable information disclosed must be limited to the minimum amount necessary, which would be the potential beneficiary's name and address. Phone numbers must not be disclosed and absolutely no health data or income data should be disclosed to drug plans prior to enrollment. We foresee numerous opportunities for serious misuse of health and financial data and strongly advise CMS to prevent potential negative consequences by explicitly prohibiting the release of this information.

3. If the Secretary decides to disclose individual identifiable information, Medicare beneficiaries must have the option to not have their information disclosed. We recommend an opt-in approach that requires beneficiaries to consent to the sharing of information rather than forcing beneficiaries to request that their information not be shared. The notice requesting a beneficiary's permission to disclose information must be written in plain, easily understood language that clearly specifies the information to be disclosed, who it is being disclosed to and what it will be used for. Furthermore, materials should be printed in large type, written at an 8th grade literacy level and translated into languages appropriate to the community.

Additionally, we have a number of other concerns regarding privacy issues raised by CMS in the preamble to the proposed rule. Since the beginning of the HIV/AIDS epidemic in the United States, people living with HIV/AIDS have been subject to pervasive stigma and discrimination. Inappropriate disclosure of HIV status and other

personal health information has led to lost employment, personal violence, and other serious consequences.

Over the last decade, Housing Works and other organizations have been actively engaged in the policy debate over the establishment of a national floor of privacy protections. Indeed, because of the unique role of people living with HIV/AIDS both as recipients of quality health and medical services that are made possible by the free flow of individually identifiable health information and potential victims resulting from inappropriate disclosures of personal health information, we have been engaged in the policy debate over the Health Insurance Portability and Accountability Act (HIPAA) privacy rule and other privacy issues.

We view the marketing provisions addressed in the proposed rule as inextricably linked to the need for critical privacy protections. These protections cannot be extended to Medicare beneficiaries simply by asserting that prescription drug plans must follow the HIPAA privacy rule. We strongly recommend that prescription drug plans be banned from telemarketing. We also strongly disagree with the CMS suggestion that it could be beneficial for prescription drug plans to be allowed to market other services such as financial services to beneficiaries.

It is inappropriate for private companies to have the opportunity to sell other services to seniors and people with disabilities under the guise of the federal government. We see absolutely no benefit to this approach, but many opportunities for fraud and abuse. We strongly recommend that CMS prohibit prescription drug plans from marketing or providing other goods and services "in conjunction with" with the part D benefit. Finally, we strongly recommend that prescription drug plans and other entities be prohibited from obtaining or using individual identifiable health information collected or maintained by a Medicare Drug Discount Card Program for marketing.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

THE INTERACTION OF THE PART D PROGRAM WITH STATE HIV/AIDS DRUG ASSISTANCE PROGRAMS (ADAPS) REQUIRES THOUGHTFUL CONSIDERATION

While we appreciate the opportunity to comment on possible coordination between HIV/AIDS Drug Assistance Programs (ADAPs) and private Part D plans, we are deeply troubled by CMS' denial of a comprehensive prescription drug benefit to people living with HIV/AIDS. 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 coverage 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.

Congress appropriates federal funds for ADAP programs on a discretionary basis. Notwithstanding the decision by a state to use ADAP funds to subsidize Part D cost-sharing, federal costs do not increase. It makes little sense for the federal government to restrict use of state ADAP funds in this fashion.

Further, ADAP funding has not kept pace with growing need over the past decade, and this has led to increases in the number of individuals on waiting lists for ADAP services, as well as restrictions and limitations in ADAP formularies and eligibility. Regrettably the availability of the Part D benefit will do little to reduce financial pressure on ADAP funds because such funds cannot count toward the catastrophic limit and the benefit itself is too limited to respond to the needs of Medicare beneficiaries with HIV/AIDS. In this environment, federal policy should not create a disincentive for states to wrap-around the Medicare Part D benefit.

When the Medicare prescription drug benefit begins, ADAPs may have several roles to play. While we understand that CMS is hopeful that all prescription drug plans 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 their remaining necessary medications. In addition, even Medicare subsidized cost-sharing for low-income Medicare Part D enrollees could provide a significant barrier to prescription drugs.

This has grave implications both for the medical management of HIV/AIDS in the affected individual, and public health. Treatment interruptions and non-adherence can lead to an increased viral load and a risk of developing resistance to an individual's current treatment regimen and thereby increasing the risk of transmission and starting over with a costly new regimen.

ADAPs will also play a vital role for Medicare beneficiaries living with HIV who have incomes above 150% Federal Poverty Level (FPL). These individuals will most likely need assistance with drug costs during the "donut-hole." Not allowing ADAP expenses spent on premiums, deductibles, cost-shares or the amount spent filing in the donut hole, allows people living with HIV/AIDS who receive Medicare benefits to fall through the cracks.

In several places in the proposed rule, CMS has acknowledged the unique situation of Medicare beneficiaries living with HIV/AIDS. The treatment of HIV disease is extremely complex and specific to the infected individual. Specific drug combinations and adherence to the prescribed medications is essential to the successful treatment of HIV. Disallowing ADAP expenses to count towards "incurred costs" runs counter to CMS' apparent understanding of the circumstances of individuals living with HIV/AIDS.

We are very concerned that the rule 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 help from their state, while allowing people with other medical conditions to benefit from their state dollars. Ironically, persons with AIDS who live in states with SPAPs and who are eligible for their assistance will have SPAP costs count toward incurred costs, while those who rely on ADAP will not.

States recognize the importance of providing prescription drugs to individuals living with HIV/AIDS. In the majority of states, ADAPs are a mix of federal and state dollars. In FY2003 states contributed over $171 million dollars of state general revenue money to their ADAPs, not including required state match dollars. To deny states from using state funds designated to provide drugs to people living with HIV/AIDS in a way that contributes to a Medicare beneficiary's incurred costs overreaches the federal government's authority.

The regulations encourage state ADAPs using a rebate purchasing mechanism to switch to the direct purchase of drugs through participation in the 340B Program. We feel it is inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by the Health Resources and Services Administration (HRSA), the federal agency that oversees the Ryan White CARE Act and the 340B Program.

Approximately half of the states participating in the 340B Program operate a rebate model available to ADAPs under the Public Health Services Act to purchase drugs instead of the direct purchase model. These states, the two largest ADAPs, California and New York, have carefully analyzed the cost-benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study which demonstrates that after calculating rebates, they receive prices for HIV pharmaceuticals comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms. Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size and geography and demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen. ADAPs have and will continue to use every mechanism available to receive the best prices for their HIV-related drugs, including negotiating for supplemental rebates and discounts.

Any coordination between ADAPs and the Medicare Part D prescription drug plans is, under the proposed rule, completely voluntary on the part of the plans. There are several issues that would inhibit the coordination of benefits between ADAPs and prescription drug plans. Most importantly, since ADAPs' expenditures for beneficiaries would not

count as incurred costs, and thereby, not allow many of the HIV-positive beneficiaries' living with HIV/AIDS to reach the catastrophic limit, ADAPs would have no strong incentive to collaborate with private drug plans.

Furthermore, prescription drug plans could charge ADAPs for any coordination between the two entities. The proposed coordination would not result in any significant amount of cost savings and would not be cost-effective for the ADAPs. Finally, it could potentially be very difficult for ADAPs to coordinate with multiple drug plans participating in the Medicare program in a given area. Under these proposed rules, it is not feasible for ADAPs to coordinate with drug plans. However, if CMS would allow payments made by ADAPs to count as incurred costs, coordination between ADAPs and prescription drug plans could result in substantial costs savings and therefore provide incentive for ADAPs to collaborate with the Medicare drug plans.

State HIV/AIDS program staff are interested in exploring methods of collaboration between ADAPs and PDPs that could allow beneficiaries living with HIV/AIDS to benefit from 340B pricing. We understand that several 340B covered entities have begun entering into partnerships with various state and local government programs to provide more individuals access to 340B pricing. However, there are so many complexities and unknowns about the Medicare Part D prescription drug program and its effects on ADAPs that it is premature to comment or offer details on any such collaboration.

§423.120 ACCESS TO COVERED PART D DRUGS

PEOPLE LIVING WITH HIV/AIDS ARE A SPECIAL POPULATION THAT REQUIRE SPECIAL TREATMENT AND ACCESS TO AN OPEN FORMULARY

We strongly support the CMS recommendation to implement "open formularies" for special populations and strongly recommend 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.

Antiretrovirals drugs, the linchpin of successful HIV treatment, are a very unique set of compounds that are not interchangeable even within the same drug class. Positive treatment outcomes depend on people living with HIV/AIDS having access to all anti-HIV drugs available to suppress the virus. If drug plans fail to cover to all anti-HIV drugs and at the lowest tier of cost sharing, it is extremely unlikely that Medicare beneficiaries will have the resources to obtain these life-saving drug therapies.

Furthermore, an "open formulary" that provides access to all medically necessary drugs would serve as a safeguard for Medicare beneficiaries with HIV/AIDS; many whom are dual eligibles. Failure to adopt an "open formulary" for Medicare beneficiaries with HIV/AIDS will make it impossible to guarantee that they maintain the level of access to prescription drugs that is comparable to that provided by Medicaid programs.

In order for the "open formulary" to be meaningful, other protections must be clearly stated in the regulation, including requiring plans to include anti-HIV drugs in the lowest cost-sharing tier and ensuring that physicians are not required to pursue a burdensome prior approval process before prescribing anti-HIV medications.

For Medicare beneficiaries with HIV/AIDS, access to all medically necessary drugs is critical. We strongly recommend that "open formulary" be defined according to a specific population, such as Medicare beneficiaries with HIV/AIDS, rather than a class of drugs such as anti-HIV drugs.

HIV clinicians must take into account drug interactions with therapies for co-morbid conditions when prescribing medications for people living with HIV/AIDS, which necessitates access to particular medications that clinicians deem appropriate for treating serious co-morbid conditions such as hepatitis C, depression, heart disease, diabetes, and liver disease. All of these are increasingly common co-morbid conditions among people living with HIV/AIDS.

As with other complex conditions, successful treatment of HIV disease requires access to all of the drugs necessary to treat an individual's comorbid conditions and side effects. Failure to effectively treat comorbid conditions significantly affects adherence to the HIV therapy regimen[1] and results in more rapid progression of the disease. It is critical that clinicians are not restricted in their ability to prescribe the appropriate medications for all of the medical needs of people living with HIV/AIDS.

As discussed earlier, Medicare beneficiaries with AIDS under 65, who by definition are completely disabled and unable to work do not have the resources to supplement inadequate drug coverage if the drug that they need is not included on the drug plan's formulary.

WE STRONGLY SUPPORT THE NEED FOR SPECIAL PROVISIONS AND PROTECTIONS FOR SPECIAL POPULATIONS WITH REGARDS TO COST CONTAINMENT MEASURES

We appreciate the acknowledgment by CMS that certain populations may be discriminated against and adversely affected by cost containment measures implemented by prescription drug plans. We strongly encourage CMS to learn from the experience of Medicaid programs that have tried to balance containing costs with maintaining access to

[1] Reynolds NR, Testa MA, Marc LG, et al. Factors influencing medication adherence beliefs and self-efficacy in persons naïve to antiretroviral therapy: a multicenter, cross-sectional study. HIV/AIDS Behav. 2004:8(2)141-150.

medically necessary medications. Based on their experience, most Medicaid programs have exempted people living with HIV/AIDS and other complex conditions from cost containment measures such as preferred drug lists or monthly drug limits. [2]

We also appreciate that CMS is recognizing the need for protections for special populations in the context of cost containment measures. Again, we strongly encourage CMS to learn from the experience of Medicaid programs, such as Colorado and Oregon, which had initiated measures such as monthly drug limits or burdensome approval processes that they later rescinded or relaxed. Health services research strongly supports the use of special cost containment measures for public programs serving individuals who have low incomes and/or are disabled that are different from those used by programs in the private market serving a healthier and working population.[3]

We ask that the non-discrimination rule be enforced by ensuring that plans cannot place HIV medications on the higher cost-sharing tiers. Medicare beneficiaries with HIV/AIDS, especially low-income beneficiaries, will not be able to afford their medications if they are not available at the lowest cost-sharing level. If an individual with HIV/AIDS needs an HIV-related medication, or a non-HIV drug, the drug should be available at the lowest cost-sharing tier. We encourage CMS to grant serious consideration to the numerous studies that demonstrate that even modest levels of cost sharing result in low-income individuals, people with chronic illnesses and seniors being deprived of medically necessary prescription drugs.[4]

FORMULARY POLICIES MUST RESPOND TO THE CLINICAL NEEDS OF MEDICARE BENEFICIARIES (§423.120(B)(1))

We strongly support CMS' recommendations to require greater independence and increased specialty representation on the Pharmaceutical and Therapeutic (P&T) Committees and other efforts to enhance their authority.

We support the CMS interpretation of the law that would make formulary decisions made by P&T Committees binding. We feel if the P&T Committees are not granted the authority to make binding decisions that their rigorous evaluations could be rendered

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[2] Kaiser Commission on Medicaid and the Uninsured. Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003. December 2003. Available online at www.kff.org/rxdrugs/medicaid.cfm. Kaiser commission on Medicaid and the uninsured. Model Prescription Drug Prior Authorization Process for State Medicaid Programs. April 2003. Available online at www.kff.org/rxdrugs/medicaid.cfm.

[3] Testimony presented by Health Care Strategies Consultancy to the West Virginia Legislative Panel in July 2003. The testimony is available by emailing info@healthstrategies.net. Additional evaluations of Medicaid programs and preferred drug lists are available from the Kaiser Family Foundation at www.kff.org.rx.drugs/medicaid.cfm.

[4] See: Goldman DP Joyce GF, Escarce JJ et al. Pharmacy benefits and the use of drugs by the chronically ill. Journal of the American Medical Association. 2004;291:2285. Cunningham, PJ. Affording prescription drugs: not just a problem for the elderly. April 2002. Center for Studying Health System Change. Onlne at www.hschange.org. Leighton K. Charging the more for health care: cost-sharing in Medicaid. May 2003. Center on Budget and Policy Priorities. Online at www.cbpp.org.

meaningless if not accepted by the prescription drug plans. Furthermore, prescription drug plans are unlikely to have the expertise to make such decisions and may be unduly influenced by cost as opposed to quality of care.

We do not feel that one independent physician and one independent pharmacist is adequate to ensure a formulary that is based on medical evidence rather than cost. We recommend that CMS require that a majority of P&T Committee members be independent and free of conflict with respect to the PDP sponsor and the prescription drug plan to ensure that recommendations by independent members are not ignored or outvoted.

We also strongly support requiring representation from multiple medical specialties that represent the diversity of people served by the Medicare program on the Committee. Additionally, all HIV-related decisions should be made by or in consultation with an HIV experienced clinician. P&T Committees will play a critical role in determining the prescription drugs available to Medicare beneficiaries with HIV/AIDS have access to, and it is essential that these decisions are grounded in the latest medical evidence and are not compromised by possible conflicts of interest.

We recommend "requiring" instead of "encouraging" P&T Committees to include representation from a variety of medical specialties. In recognition of the fact that it will be impossible for committees to include members from all medical specialties, we also recommend requiring plans to have formal contractual relationships with an HIV experienced provider to advise the P&T Committee on HIV-related treatment decisions and other specialists whose expertise is not represented on the committee.

The requirement that the P&T Committee include one practicing physician member with expertise in the care of elderly and disabled is vague and inadequate. Neither seniors nor people with disabilities are homogenous populations. It is not feasible for one physician to have the expertise to evaluate the prescription drug needs of people with serious conditions such as multiple sclerosis, diabetes, schizophrenia and HIV/AIDS.

We strongly recommend that drug plans be required to cover more than two drugs per category or class for certain categories and for "special populations." Limiting coverage to two per class is wholly inadequate and will result in a federally funded program that does not support the basic standard for HIV care. Drugs within the anti-HIV classes are very different compounds, are not interchangeable, and are not available in generic form.

Furthermore, people living with HIV/AIDS frequently must change the drugs within the HAART regimen multiple times due to drug resistance or toxicity. Failure to require prescription drug plans to cover all anti-HIV drugs will have detrimental effects on Medicare beneficiaries with HIV/AIDS, which for some beneficiaries could include premature death.

We strongly recommend strengthening the CMS reference to P&T Committees' consideration of the Public Health Service guidelines for the treatment of HIV disease

and related opportunistic infections by requiring P&T Committees to cover all drugs referenced in the federal guidelines. The enormous variation in drug resistance[5], drug tolerance and toxicity,[6] drug interactions, co-morbid conditions[7], and virulence of the HIV strain requires that clinicians have access to all of the drug therapies available to treat HIV disease. Requiring drug plans to cover all of the drugs recommended in the federal guidelines is critical to ensuring that all of the prescription drug plans cover the range of anti-HIV drugs that are medically-necessary for successful treatment of HIV disease.

We also support involvement of P&T Committees in designing policies that will be used to encourage use of preferred drugs such as the cost sharing tier structure. It is very important for these decisions to be made with serious consideration given to ensuring that certain populations who have chronic conditions, such as people with HIV/AIDS, who require a daily regimen of prescription drugs, do not face discrimination in regard to cost sharing. P&T Committees would provide the appropriate insight and expertise necessary for making these decisions.

DRUG PLANS SHOULD BE REQUIRED TO COVER PRESCRIBTION DRUGS FOR OFF-LABEL PURPOSES WITHOUT PLACING UNDUE BURDEN ON CLINICIANS

We strongly recommend strengthening the language regarding coverage of drugs for off-label use. We feel it is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label indications that are standard practice in the medical community.

For HIV disease, as with many complex conditions, clinical practice frequently runs ahead of label indications as physicians learn what drug combinations best target their patient's symptoms and side effects. As examples, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV, although treatment for hepatitis B is not an indicated use of the drug. In addition, many protease inhibitors have been shown to be more effective in suppressing the HIV virus if they are boosted with ritonavir (Norvir), although in most cases there is no label indication for this. Atazanavir (Reyataz) and saquinavir (Invirase) are two examples of protease inhibitors that are used in conjunction with ritonavir.

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[5] Fifty to seventy percent of treatment-experienced people living with HIV/AIDS develop drug resistance. Source: Wensing AM, Boucher CA. Worldwide transmission of drug-resistant HIV. HIV/AIDS Rev. 2003;5(3):140-155.

[6] According to HIV experts, fifty percent of people living with HIV develop toxicity that precludes continued use of certain antiretrovirals. Decisions regarding substitutions need to be made from the broad selection of antiretrovirals due to overlapping toxicities.

[7] As examples, 30 percent of people with HIV are co-infected with hepatitis C. Source: Fleming CA, Christiansen D, Nunes D, et al. Health-related quality of life of patients with HIV disease: impact of hepatitis C coinfection. Clinical Infectious Diseases. 2004:38:572-578. At least 50 percent of people with HIV have psychiatric diagnosis. Source: Bing EG, Burnam A, Longshore D, et al. Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States. Arch Gen Psychiatry. 2001:58:721-728.

We also feel it is inappropriate to place undue administrative burdens on physicians by requiring them to "clearly document and justify" off-label drug use if such prescribing is recognized as commonly accepted practice in the medical community. We are concerned that requiring clinicians to "clearly document and justify" off-label prescribing is an attempt to shift medical decision making from clinicians to CMS and/or drug plan sponsors.

REQUIRE DRUG PLANS TO COVER NEW ANTI-HIV DRUG THERAPIES

We strongly recommend that prescription drug plans be required to add new categories or classes of anti-HIV therapies upon approval by the Food and Drug Administration. The standard of care for HIV disease rapidly changes and many Medicare beneficiaries with HIV/AIDS have already exhausted the current drug therapies available. It is critical that they have timely access to the newest therapeutic advances. Federal HIV treatment guidelines are revised quickly when a new HIV drug is approved; the drug plans providing these lifesaving medications to beneficiaries should be required to do the same.

REQUIRE DRUG PLANS TO EVALUATE PROTOCOLS QUARTERLY

We strongly encourage CMS to outline clear requirements regarding prescription drug plans' evaluations of protocols. CMS should define "periodically" to be quarterly and specify criteria for which the drug plans should base their evaluations, e.g., the number of exception requests filed for off-formulary drugs; trends in exception and appeals requests for certain drugs; and the average length of time it takes to process prior authorization requests (if applicable). Additionally, drug plans should be required to have a mechanism for beneficiaries and health care providers to provide feedback which will be incorporated into the evaluation process. Furthermore, we feel it is critical for evaluations to incorporate indicators that ensure a beneficiary's health status is not compromised due to inability to access medically necessary prescription drugs.

REQUIRE A MINIMUM 90-DAY NOTIFICATION FOR FORMULARY CHANGES

We strongly recommend extending the period of time that is required for drug plans to notify affected enrollees and other parties when removing a drug from a formulary to at least 90 days. We feel this is the minimum amount of time required to allow Medicare beneficiaries with HIV/AIDS to consult with their physicians and apply for an exception if their physicians do not think it clinically prudent to switch medications. We also strongly recommend that drug plans be required to provide notice in written format.

PROVIDE BENEFICIARIES WITH DETAILED BENEFIT INFORMATION BEFORE THEY SELECT A PLAN

We strongly recommend that CMS provide detailed information on drug plan formularies to health care providers and beneficiaries before beneficiaries are required to select a plan. The information should be translated into languages based on the needs of the

community. At a minimum, drug plans should be required to disclose and CMS should publicize the prescription drugs and dosages drug plans cover, cost sharing associated with respective drugs and any special cost containment rules that apply to the drug.

We support a model similar to the online database used by the Medicare Drug Discount Cards. However, it is essential that this information is available in other formats such as written mailings to prospective enrollees. Furthermore, Medicare beneficiaries with HIV/AIDS should have the option to request detailed information before they make a selection and not be penalized if the information is not presented in a timely manner.

We strongly recommend that the 24 hour/7 day a week toll free information lines be publicized and available to Medicare beneficiaries before they are required to select a plan to respond to prospective enrollees questions regarding coverage. It is absolutely critical that Medicare beneficiaries with HIV/AIDS know whether a drug plan covers the multiple medications that comprise their lifesaving daily drug regimen and the associated out-of-pocket costs before they are required to enroll in a drug plan.

DO NOT PENALIZE BENEFICIARIES WHEN THEY MUST OBTAIN DRUGS FROM OUT-OF-NETWORK PHARMACIES

We object to the requirement making Medicare beneficiaries responsible for cost differentials if they must obtain drugs from an out-of-network pharmacy. It is inappropriate to penalize the beneficiary – particularly those who are dually eligible – if their condition requires them to obtain medically necessary drugs from an out-of-network pharmacy, whether it is because they become sick when away from home or because an in-network pharmacy is closed. People living with HIV/AIDS may develop complications or experience serious side effects that require immediate attention and should not be penalized if their health status requires them to obtain drugs from an out-of-network pharmacy.

We recommend that the regulation be revised to stipulate that beneficiaries are not responsible for cost differentials if it is medically necessary for the beneficiary to fill the prescription, and there is no access to an in-network pharmacy.

THE US PHARMACOPEIA'S PROCESS FOR DEVELOPING THE "MODEL GUIDELINES" DID NOT PROVIDE SUFFICIENT OPPORTUNITY FOR PUBLIC DIALOGUE AND INPUT INTO THE DEVELOPMENT OF THE "MODEL GUIDELINES"

We were very disappointed in the US Pharmacopeia's (USP) process for developing and soliciting public comment on the "model guidelines." At the one public meeting that was held, less than four hours was devoted to public comment. While we appreciate the opportunity to submit written comments, the lack of an opportunity for dialogue or to publicly voice concerns is very troubling given the magnitude of the decisions made by USP and the millions of beneficiaries who will be affected.

Furthermore, the lack of a transparent and appropriate process is troubling given that prescriptions drug plans that adhere to the recommended categories and classes developed by USP will be virtually free from scrutiny or oversight by CMS. It is completely inappropriate for a drug plan that reflects the USP model formulary to be shielded from potential charges of discrimination against specific subpopulations based on formulary.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

THE PROPOSED REGULATIONS FAIL TO MEET CONSTITUTIONAL DUE PROCESS REQUIREMENTS AND FAIL 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 currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to adequate 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 judge 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 the MMA to provide for an appeals process similar to Medicaid -- is beyond the authority of CMS, but 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. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, adopted 42 C.F.R. 422.626, 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.

THE FINAL RULE MUST PROVIDE FOR AN EMERGENCY SUPPLY OF DRUGS PENDING THE RESOLUTION OF AN EXCEPTION REQUEST OR AN APPEAL

It is unconscionable for CMS to publish a final rule that does not include mandatory, enforceable provisions for preventing treatment interruptions and for requiring plans to dispense a temporary supply of covered Part D drugs pending the resolution of an exceptions request (or in the case of an exception denial, final resolution of an appeal).

For many conditions, treatment interruptions can lead to serious short-term and long-term problems. Successful treatment of HIV disease requires near perfect adherence to a daily regimen of at least three to four drugs. 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 HIV/AIDS develop drug resistance.[8] Failure to prevent treatment interruptions by supplying a temporary drug supply will contribute to the growth of this statistic. Beyond concerns about resistance, treatment interruptions can also lead to serious consequences including irreversible declines in immune functioning, unnecessary hospitalizations, or the development of HIV-related opportunistic infections.

Our concerns over treatment interruptions are heightened due to the absence of adequate protections that ensure individuals can receive a timely resolution of an appeal. It is further heightened since, there is a lengthy period that will pass before an individual has access to a fair and independent review of an appeal by a decision maker completely independent and free of conflict with the plans at the Administrative Law Judge level.

We recognize that the expedited timeframes and the general 72-hour standard are a significant improvement over the standard timeframe of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of the clinical management of HIV infection, 72 hours is an unacceptable delay.

We strongly recommend that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people living with HIV/AIDS 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 in all cases of emergency, including all cases involving people living with HIV/AIDS.

THE PROPOSED EXCEPTIONS PROCESS IS UNWORKABLE AND NEEDS TO BE SIGNIFICANTLY REVAMPED

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 HIV/AIDS and other

[8] Wensing AM, Boucher CA. Worldwide transmission of drug-resistant HIV. HIV/AIDS Rev. 2003;5(3):140-155.

persons with serious and complex conditions receive a quick and individualized coverage determination for on-formulary and off-formulary drugs.

We appreciate that the proposed rule clarifies that non-formulary drugs are eligible for consideration by the exceptions process. 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 achieve the following goals:

- Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
- Minimize the time and evidence burdens on treating physicians. We are particularly troubled that the proposed rule would require treating physicians to assert that an exceptions request is based both on clinical experience and scientific evidence. This is an inappropriate standard that most HIV physicians could not meet because scientific evidence is not always available to support the knowledge they gain through clinical experience treating people living with HIV. We also believe that this requirement goes well beyond the statute, which states, "Under such an exception, a nonpreferred drug could be covered under the terms applicable for a preferred drug if the prescribing physician determines that the preferred drug for the treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both";
- Ensure that all drugs provided through the exceptions process are made available under the terms applicable for a preferred drug for the treatment of the same condition.
- Require reporting to CMS of statistical data related to the exceptions and appeals processes. This including requiring plans to report to CMS the number of exceptions requests, the nature of exception requested and the specific drugs involved, the average time that passes for resolution of an exceptions request and all in-plan steps of the grievance and appeals processes, and the final resolution of each exception, grievance, and appeal request. Furthermore, the final rule should require CMS to annually analyze statistical information and make plan-specific summary information available to the public.

CMS MUST ENSURE DRUGS ARE NOT INAPPROPRIATELY CLASSIFIED AS "EXCLUDED DRUGS" AND COVERAGE DISPUTES OVER EXCLUDED DRUGS MUST BE ELIGIBLE FOR AN APPEAL

The MMA references the Medicaid Act in prohibiting Part D plans from providing coverage for drugs that are excludable under §§1927(d)(2) and (3) of the Social Security Act, except for smoking cessation agents. We are troubled to learn through informal communications that CMS is developing a list of excluded drugs that Part D plans are

prohibited from covering. Many of the categories of excludable drugs in §1927(d)(2) refer to drugs when used for a specific purpose. Therefore, it is inappropriate to simply provide a listing of drugs that Part D plans must exclude because this could include drugs that are excludable or coverable depending on the specific clinical use.

We recommend that the final rule clearly state that Part D plans are only permitted to prohibit coverage for specific drugs when they meet the statutory requirements of §1927(d)(2) and they must provide coverage for potentially excludable drugs when they are prescribed for a clinical use not covered by this section.

We are also deeply troubled that the proposed rule would deny access to the exceptions and appeals process for coverage disputes involving excluded drugs. Experience in the Medicaid program with several high-cost, but clinically important drugs used in the treatment of HIV/AIDS illustrates the risk by not providing Medicare beneficiaries due process with respect to coverage disputes involving excluded drugs. In the past, state Medicaid programs have denied coverage for drugs used to treat HIV/AIDS wasting, a serious, life-threatening condition, by inappropriately claiming that a drug was excludable. It only has been through reliance on access to the Medicaid appeal system and consumer advocacy that Medicaid beneficiaries with HIV/AIDS in some states have gained access to drugs necessary for the treatment of HIV/AIDS wasting.

We strongly recommend that the final rule delete all provisions in the proposed rule that restrict access to the exceptions, grievance, and appeals systems for coverage disputes related to excluded drugs.

SUBPART P –PREMIUMS AND COST SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

DUAL ELIGIBLE BENEFICIARIES MUST NOT BE DENIED MEDICATIONS FOR FAILURE TO PAY CO-PAYMENTS (§423.782(A)(2)(III))

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 medication for failure to pay a co-payment. 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.

LOW-INCOME INDIVIDUALS SHOULD NOT BE DENIED MEDICATIONS FOR FAILURE TO PAY CO-PAYMENTS (§423.782(A)(IV) AND §423.782(B)(2))

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. As previously referenced, a number of 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.

HIV medications are some of the most expensive on the market. 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.

Again, we thank you for the opportunity to comment on this important regulation on the Medicare Part D prescription drug benefit as it impacts people living with HIV/AIDS. We also look forward to the release of the critically important guidelines CMS will utilize in approving individual drug plans, on which we will also put forward comments.

We would be happy to provide further clarification on our comments and recommendations. Please feel free to contact me directly for more information or further comment.

Yours very truly,

Michael Kink, Esq.
Legislative Counsel

CMS-4068-P-1011

Submitter : Miss. Michelle Dooley **Date & Time:** 10/04/2004 05:10:15

Organization : The Arc of Greater Tarrant County

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-1011-Attach-3.doc

CMS-4068-P-1011-Attach-2.txt

CMS-4068-P-1011-Attach-1.txt

Date

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:

The name of organization welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The name of organization is standard description of your organization. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. 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 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 sheer implausibility 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 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.

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

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.

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 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:

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

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. 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 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.

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 a truly independent review by an administrative law judge (ALJ) and 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; 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:

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.

Yahoo! Mail - mich12656@yahoo.com

Yahoo! My Yahoo! Mail
Welcome, mich12656
[Sign Out, My Account]

Mail Home - Help

Mail | Addresses | Calendar | Notepad mich12656@yahoo.com [Sign Out] Check Mail - Compose - Search Mail | Mail Upgrades - Mail Options Free Flip Phone
AT&T Wireless

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Inbox (5) Draft Sent Bulk (1)[Empty] Trash[Empty]

Previous | Next | Back to Messages Printable View - Full Headers
DeleteReplyForwardSpam Move...
This message is not flagged. [Flag Message - Mark as Unread]
Date:Mon, 4 Oct 2004 16:21:32 +0000
From:judy.gutierrez@arcgtc.org Add to Address Book
To:mich12656@yahoo.com
Subject: Fwd: FW: URGENT:Action Needed on Proposed Medicare Prescription Drug Regulations

----- Forwarded message from Mike Bright <Mbright@thearcoftexas.org> -----
Date: Fri, 1 Oct 2004 13:37:50 -0500
From: Mike Bright <Mbright@thearcoftexas.org>
Reply-To: Mike Bright <Mbright@thearcoftexas.org>
Subject: FW: URGENT:Action Needed on Proposed Medicare Prescription Drug Regulations
To: arcgc@swbell.net, wdpower01@shreve.net, "Cynthia King (csking@hal-pc.org)" <csking@arcoffortbend.org>, jfowler@arcoftyler.org, jkantorczyk@thearcofgreaterhouston.com, allens@cablelynx.com, judy.gutierrez@arcgtc.org, kmenger@arc-sa.org, khurt@arcdallas.org, lpadilla@rgv.rr.com, "Marlene Goldstein (E-mail)" <mgold@arcwctx.org>, "Robert Rose (E-mail)" <brose@arcmidlandtx.org>, "Susan Eason (E-mail)" <season@arcofthecapitalarea.org>, tpearson@hot.rr.com

The Arc US really needs help with this one. Please respond by Monday. It is easy to do the electronic response and personalizing the letter

only took a moment.

Thanks.

Mike

-----Original Message-----
From: Brenda Walker [mailto:walker@thearc.org]
Sent: Tuesday, September 28, 2004 9:07 AM
To: Arc Massachusetts (E-mail); Arc Massachusetts (E-mail 2); Arc Minnesota (E-mail); Arc of ND (c/o Upper Valley) (E-mail); Arc of South Carolina (E-mail); Arc/Alaska (E-mail); Arc/Florida (E-mail); Arc-California (E-mail); DC Arc (E-mail); Georgia Arc Network (E-mail); NYSARC (E-mail); Opportunity Village (NV) (E-mail); Rhode Island Arc (E-mail); Arc In Hawaii (E-mail); Arc Michigan (E-mail); Arc of Alabama (E-mail); Arc of Arizona (E-mail); Arc of Arkansas (E-mail); Arc of Colorado (E-mail); Arc of Colorado (E-mail 2); Arc of Connecticut (E-mail); Arc of Delaware (E-mail); Arc of Illinois (E-mail); Arc of Indiana (E-mail); Arc of Iowa (E-mail); Arc of Kansas (E-mail); Arc of Kentucky (E-mail); Arc of Louisiana (E-mail); Arc of Maryland (E-mail); Arc of Maryland (E-mail 2); Arc of Mississippi (E-mail); Arc of Nebraska
(E-mail); Arc of New Jersey (E-mail); Arc of New Jersey (E-mail 2); Arc of New Mexico (E-mail); Arc of North Carolina (E-mail); Arc of North Carolina (E-mail 2); Arc of Ohio (E-mail); Tulsa Advoc. for Rights of Citizens with DD (E-mail); Arc of Oregon (E-mail); Arc of South Dakota (E-mail); Arc of Tennessee (E-mail); Arc of Tennessee (E-mail 2); Mike Bright; Arc of Utah (E-mail); Arc of Virginia (E-mail); Arc of Washington State (E-mail); Arc of Wood County (WVa) (E-mail); Arc of Wyoming (E-mail); Arc-Pennsylvania (E-mail); Arc-Wisconsin (E-mail)
Cc: Cindy Johnson (E-mail); John Dickerson (E-mail); L. Cleveland (E-mail); Lynne Cleveland (E-mail); Michael Mack (E-mail); Mark Russell (E-mail); cynleeowe@aol.com; joyce@arcutah.org
Subject: URGENT:Action Needed on Proposed Medicare Prescription Drug Regulations
Importance: High

TO: State Execs of The Arc

FROM: Liz Savage and Julie Ward, PPC Staff

The proposed regulations issued by the Centers for Medicare and Medicaid
Services (CMS) to implement the new Medicare prescription drug law contains
many critical provisions for Medicare beneficiaries with disabilities, especially those who receive Medicaid benefits (dual eligibles). The PPC
will submit extensive comments on issues affecting our constituents. The
attached model letter focuses on priority issues. Since CMS keeps a count
of all comments on each provision in the proposed regulation, it is important for us to generate as many comments as possible on these priority
issues. Please send this model letter to CMS and forward this

information
to your local chapters and disability advocates in your states. The attached action alert provides substantive background.

Comment Deadline: Monday, October 4, 2004
To send this model letter:
1) transfer it to your letterhead;
2) Fill in the blanks in the first paragraph;
3) Insert a signature line
4) Mail one original and 2 copies to the address on the letter. NOTE: Your
letter must reach CMS by October 4th (a postmark of October 4th is not sufficient).

OR

Submit it electronically to
<http://www.cms.hhs.gov/regulations/ecomments>.
E-mail comments must be received by COB on October 4. Follow these steps
after clicking on this link:

1) Click on the first bullet that says "SEND" ;
2) On the table, find Docket ID-CMS - 4068-P (Medicare Program; Medicare
Prescription Drug Benefit) and then click on "Go";
3) Fill in information (your zip code, etc) on the Docket Management Comment
Form and click "Continue";
4) In the text box under "General Comment" heading, type in "please see attached file from the disability community" and then click on "Continue";
and
5) Follow the instructions for attaching your letter/Word document and then
click the yellow "Attach File" button.

If you have any questions, please contact us (savage@thearc.org) or (jward@ucp.org).

Thank you!

Liz Savage
Director, Health and Housing Policy
The Arc and UCP Public Policy Collaboration
1331 H Street, NW
Suite 301
Washington, DC 20005
Phone: (20) 783-2229
Fax: (202) 783-8250

----- End forwarded message -----

Attachment

Medicare_reg_sample_comment_letter__The_Arc.doc
.doc file

Attachment scanning provided by:

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View Attachment

Attachment

The_Arc__Medicare_reg_action_alert.doc
.doc file

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Calendar Shortcuts

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- Add Birthday
- Day
- Week
- Month
- Year
- Event List
- Reminders
- Tasks
- Sharing
- Synchronize
- Calendar Options
- Calendar Help

Notepad Shortcuts

- Add Note
- Add Folder
- View Notes
- Notepad Options
- Notepad Help

Yahoo! Mail - mich12656@yahoo.com

Yahoo! My Yahoo! Mail
Welcome, mich12656
[Sign Out, My Account]

Mail Home - Help

Mail | Addresses | Calendar | Notepad mich12656@yahoo.com [Sign Out] Check Mail - Compose - Search Mail | Mail Upgrades - Mail Options Free Flip Phone
AT&T Wireless

Folders[Add - Edit]
Inbox (5) Draft Sent Bulk (1)[Empty] Trash[Empty]

Previous | Next | Back to Messages Printable View - Full Headers
DeleteReplyForwardSpam Move...
This message is not flagged. [Flag Message - Mark as Unread]
Date:Mon, 4 Oct 2004 16:21:32 +0000
From:judy.gutierrez@arcgtc.org Add to Address Book
To:mich12656@yahoo.com
Subject: Fwd: FW: URGENT:Action Needed on Proposed Medicare Prescription Drug Regulations

----- Forwarded message from Mike Bright <Mbright@thearcoftexas.org> -----
Date: Fri, 1 Oct 2004 13:37:50 -0500
From: Mike Bright <Mbright@thearcoftexas.org>
Reply-To: Mike Bright <Mbright@thearcoftexas.org>
Subject: FW: URGENT:Action Needed on Proposed Medicare Prescription Drug Regulations
To: arcgc@swbell.net, wdpower01@shreve.net, "Cynthia King (csking@hal-pc.org)" <csking@arcoffortbend.org>, jfowler@arcoftyler.org, jkantorczyk@thearcofgreaterhouston.com, allens@cablelynx.com, judy.gutierrez@arcgtc.org, kmenger@arc-sa.org, khurt@arcdallas.org, lpadilla@rgv.rr.com, "Marlene Goldstein (E-mail)" <mgold@arcwctx.org>, "Robert Rose (E-mail)" <brose@arcmidlandtx.org>, "Susan Eason (E-mail)" <season@arcofthecapitalarea.org>, tpearson@hot.rr.com

The Arc US really needs help with this one. Please respond by Monday. It is easy to do the electronic response and personalizing the letter

only took a moment.

Thanks.

Mike

-----Original Message-----
From: Brenda Walker [mailto:walker@thearc.org]
Sent: Tuesday, September 28, 2004 9:07 AM
To: Arc Massachusetts (E-mail); Arc Massachusetts (E-mail 2); Arc Minnesota (E-mail); Arc of ND (c/o Upper Valley) (E-mail); Arc of South Carolina (E-mail); Arc/Alaska (E-mail); Arc/Florida (E-mail); Arc-California (E-mail); DC Arc (E-mail); Georgia Arc Network (E-mail); NYSARC (E-mail); Opportunity Village (NV) (E-mail); Rhode Island Arc (E-mail); Arc In Hawaii (E-mail); Arc Michigan (E-mail); Arc of Alabama (E-mail); Arc of Arizona (E-mail); Arc of Arkansas (E-mail); Arc of Colorado (E-mail); Arc of Colorado (E-mail 2); Arc of Connecticut (E-mail); Arc of Delaware (E-mail); Arc of Illinois (E-mail); Arc of Indiana (E-mail); Arc of Iowa (E-mail); Arc of Kansas (E-mail); Arc of Kentucky (E-mail); Arc of Louisiana (E-mail); Arc of Maryland (E-mail); Arc of Maryland (E-mail 2); Arc of Mississippi (E-mail); Arc of Nebraska
(E-mail); Arc of New Jersey (E-mail); Arc of New Jersey (E-mail 2); Arc of New Mexico (E-mail); Arc of North Carolina (E-mail); Arc of North Carolina (E-mail 2); Arc of Ohio (E-mail); Tulsa Advoc. for Rights of Citizens with DD (E-mail); Arc of Oregon (E-mail); Arc of South Dakota (E-mail); Arc of Tennessee (E-mail); Arc of Tennessee (E-mail 2); Mike Bright; Arc of Utah (E-mail); Arc of Virginia (E-mail); Arc of Washington State (E-mail); Arc of Wood County (WVa) (E-mail); Arc of Wyoming (E-mail); Arc-Pennsylvania (E-mail); Arc-Wisconsin (E-mail)
Cc: Cindy Johnson (E-mail); John Dickerson (E-mail); L. Cleveland (E-mail); Lynne Cleveland (E-mail); Michael Mack (E-mail); Mark Russell (E-mail); cynleeowe@aol.com; joyce@arcutah.org
Subject: URGENT:Action Needed on Proposed Medicare Prescription Drug Regulations
Importance: High

TO: State Execs of The Arc

FROM: Liz Savage and Julie Ward, PPC Staff

The proposed regulations issued by the Centers for Medicare and Medicaid
Services (CMS) to implement the new Medicare prescription drug law contains
many critical provisions for Medicare beneficiaries with disabilities, especially those who receive Medicaid benefits (dual eligibles). The PPC
will submit extensive comments on issues affecting our constituents. The
attached model letter focuses on priority issues. Since CMS keeps a count
of all comments on each provision in the proposed regulation, it is important for us to generate as many comments as possible on these priority
issues. Please send this model letter to CMS and forward this

information
to your local chapters and disability advocates in your states. The attached action alert provides substantive background.

Comment Deadline: Monday, October 4, 2004
To send this model letter:
1) transfer it to your letterhead;
2) Fill in the blanks in the first paragraph;
3) Insert a signature line
4) Mail one original and 2 copies to the address on the letter. NOTE: Your
letter must reach CMS by October 4th (a postmark of October 4th is not sufficient).

OR

Submit it electronically to
<http://www.cms.hhs.gov/regulations/ecomments>.
E-mail comments must be received by COB on October 4. Follow these steps
after clicking on this link:

1) Click on the first bullet that says "SEND" ;
2) On the table, find Docket ID-CMS - 4068-P (Medicare Program; Medicare
Prescription Drug Benefit) and then click on "Go";
3) Fill in information (your zip code, etc) on the Docket Management Comment
Form and click "Continue";
4) In the text box under "General Comment" heading, type in "please see attached file from the disability community" and then click on "Continue";
and
5) Follow the instructions for attaching your letter/Word document and then
click the yellow "Attach File" button.

If you have any questions, please contact us (savage@thearc.org) or (jward@ucp.org).

Thank you!

Liz Savage
Director, Health and Housing Policy
The Arc and UCP Public Policy Collaboration
1331 H Street, NW
Suite 301
Washington, DC 20005
Phone: (20) 783-2229
Fax: (202) 783-8250

----- End forwarded message -----

Attachment

Medicare_reg_sample_comment_letter__The_Arc.doc
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- Add Task
- Add Birthday
- Day
- Week
- Month
- Year
- Event List
- Reminders
- Tasks
- Sharing
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- Calendar Options
- Calendar Help

Notepad Shortcuts

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- Add Folder
- View Notes
- Notepad Options
- Notepad Help

CMS-4068-P-1012

Submitter : Mrs. Marilyn Kuna **Date & Time:** 10/04/2004 05:10:18

Organization : Parent

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

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 or,
2. The submitter did not follow through when attaching the document, or submitted only one file or,
3. The document was protected file and would not allow for CMS to attach the ile 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-1013

Submitter : Mrs. Nancy Atkins **Date & Time:** 10/04/2004 05:10:57

Organization : West Virginia Bureau for Medical Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The following letter (attachment) in PDF format is comments being submitted for the Medicare Prescription Drug Benefit.

CMS-4068-P-1013-Attach-1.pdf

Bureau for Medical Services
Commissioner's Office
350 Capitol Street - Room 251
Charleston, West Virginia 25301-3706
Phone: (304) 558-1700 Fax: (304) 558-1451

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: Proposed Rule With Comment Period, Medicare Program: Medicare Prescription Drug Benefit

Dear Dr. McClellan:

The West Virginia Bureau for Medical Services (BMS) wishes to submit the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. As the single state agency responsible for providing pharmacy services to dually eligible beneficiaries in West Virginia, BMS has endeavored to provide quality services using limited resources. Realizing the importance of a comprehensive drug program, BMS encourages the Centers for Medicare and Medicaid Services to consider the need for a smooth transition from a traditional fee-for-service Medicaid pharmacy benefit plan to one of limited choices and access. BMS has questions and concerns on several aspects of the Proposed Rule. We thank you for the opportunity to respond and appreciate the many conference calls and other communications from CMS to address the issues.

Enrollment

In regard to enrollment of dual-eligible beneficiaries, it is our understanding that under the Proposed Rule, these individuals will be required to enroll in a Part D plan (PDP) during the period of November 15, 2005 through May 15, 2006. In the event that individuals fail to enroll by the May 15, 2006 deadline, they will be automatically assigned to a PDP. Because these individuals will lose their Medicaid coverage effective January 1, 2006, many beneficiaries may find that they are without prescription coverage for several months. We believe that the January 1, 2006 cut-off potentially puts this already vulnerable population at increased risk. BMS requests that CMS allow

Medicaid coverage to continue with federal financial participation until they have either voluntarily enrolled or until they have been automatically enrolled in a plan. The states' contribution should be adjusted for those dual-eligible beneficiaries who continue to receive Medicaid services. There will be coordination issues that will need to be resolved due to the various ways that Medicare beneficiaries may apply for Part D. State agencies may be in the best position to assist these individuals to select a PDP plan. BMS requests that the states be given the option to perform the automatic assignment function provided federal financial participation is available. We request that this participation be funded at 100%.

In addition, BMS requests that the auto-enrollment process include a detailed algorithm that defines how beneficiaries are assigned to PDP plans. This is essential for beneficiaries who have special needs such as nursing home care or require specialized medications to treat HIV/AIDS, mental illnesses or rare diseases. This vulnerable population requires the assurance of access to necessary treatment.

The statute and regulations are unclear in regard to Medicaid's role in the application process. Beneficiaries may file applications for the low-income subsidy either through the Social Security Administration office or through the state Medicaid agency. Coordination of activities of these two agencies with CMS will be a challenge to state agencies that may have system deficiencies and operating on limited budgets. BMS requests clarification on Medicaid agencies' responsibilities under the new statute.

Phased Down State Contribution

Under the Proposed Rule, states would provide a phased down state contribution to Medicare Part D drug benefit costs. This amount is based on drug expenditures on covered Part D drugs during calendar year 2003, adjusted for drug rebates collected in 2003. BMS requests that CMS clarify how rebates are considered. The inherent lag of the rebate collection process distorts the value of drug rebates that were invoiced for the calendar year 2003. In addition, West Virginia Medicaid implemented supplemental rebates after 2003, which have significantly reduced the overall drug spend. Other cost containment efforts have also been undertaken that are not reflected in the 2003 baseline calculations**.** BMS requests that CMS take this into account when considering modifications to the phased down state contribution to drug benefit costs. In addition, we ask CMS to clarify which National Health Expenditure projection will be used for the phase-down calculation, e.g., national average, Medicaid expenditures or other. Because Medicaid agencies have been aggressive in cost containment of pharmacy programs, using a national average in general could penalize states that have been successful in this regard.

Finally, BMS requests that an appeal process be defined that will allow states to make adjustments to the phase-down state contribution. Uncertainties still exist among state Medicaid agencies concerning the true number of dual eligible individuals for which the

payment will be based. It seems reasonable that states would be allowed to challenge the baseline that will be the basis of future payments.

Involuntary Disenrollment

It is our understanding that individuals may be disenrolled from plans on the basis of nonpayment of premiums, disruptive behavior, or misrepresentation of third party reimbursement. These individuals will not be able to enroll in another plan until the next annual coordinated election period, and he or she may be subject to late enrollment penalties. CMS states that if the individual is prohibited from re-enrolling in each of the plans available in an area, original Medicare is always available to provide and deliver services to that individual. BMS requests that this approach be reconsidered due to the unique aspects of dual eligible individuals. Because Medicaid will no longer be able to receive federal financial participation for paying for prescription drugs, dual eligible beneficiaries who are involuntarily disenrolled may find themselves without prescription drug coverage. BMS recommends that disenrollment, if it occurs at all, be delayed until enrollment in another plan is secured to ensure there is no lapse in coverage. Federal financial participation should be available for drug expenditures through Medicaid should the beneficiary have no other prescription drug coverage options to prevent negative patient outcomes and cost shifting to other sources of care, i.e., emergency rooms.

Definition of Long-Term Care Facility (LTC)

CMS requested comments regarding the definition of the term long-term care facility, particularly if intermediate care facilities for the mentally retarded or related conditions (ICF/MRs) should be included in this definition given Medicare's special coverage related to mentally retarded individuals. BMS recommends modifying this definition to include ICF/MR facilities and other types of long-term care facilities, such as community-based facilities, due to distribution systems needed to serve these types of facilities.

LTC facilities generally contract with a single LTC pharmacy. Therefore, to expect seniors in LTC facilities to access their Part D drugs at another pharmacy, when the LTC pharmacy associated with their institution is not in a plan's network, is unreasonable. BMS is concerned about access to Part D drugs for seniors and disabled individuals in LTC facilities. These beneficiaries do not have the ability to go elsewhere to purchase their medications.

Formulary Issues

CMS has requested that the U.S. Pharmacopeia (USP) develop guidelines of drug categories and classes that may be used by PDP plans. Plans will use formularies based on therapeutic categories either developed by USP or ones developed by the plans. At least two drugs, if available, which have been approved for use by the FDA must be included in each of the categories. BMS has concerns that the limited number of drugs that may be offered by the plans' formularies may be inadequate to meet the

needs of beneficiaries. Should the number of choices be limited to two drugs per category, the exception process must be streamlined to assure access to nonpreferred drugs if needed by the beneficiaries. For those beneficiaries stable on drugs to treat mental health, HIV/AIDS, and epilepsy, BMS recommends that these patients be allowed to continue the use of these medications indefinitely to prevent negative outcomes and shifts to other sources of care, i.e., emergency rooms.

Oversight of formulary decisions and reviews of PDP formularies should be key components in the quality reviews of the designated Quality Improvement Organizations. It is essential that medical and pharmacy claims data be integrated for the Medicare population and be evaluated to determine the performance of the plans and the providers. This quality evaluation is necessary to protect healthcare of Medicare beneficiaries and also provide a therapeutic and cost-effective program.

Prescription Drug Plan Service Areas

The Proposed Rule suggests that prescription drug plan service areas must be established for plans. The regions will be the basis for service areas in which participating plans will offer their access to prescription drug coverage. The regions are also the basis for determining premiums, benefits and payments. A plan must serve an entire region and premiums cannot vary within the region. BMS recommends that plan areas encompass the entire state to avoid having partial state coverage. This will encourage consistency of service within the state and promote access to care in rural areas.

Should you have further questions or require more information, please call me at (304) 558-5956.

Respectfully submitted,

Nancy V. Atkins, MSN, RNC, NP
Commissioner

NVA:pk/lle

CMS-4068-P-1014

Submitter : Ms. Carole Kramer **Date & Time:** 10/04/2004 05:10:50

Organization : Southern Tier Independence Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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:

I welcome the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. We are especially concerned with the 7 million dual eligible who will lose all Medicaid prescription drug benefits they now have. The following are critical recommendations:

DELAY 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. 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, these 7 million people with disabilities the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into nursing homes and mental institutions to get needed medications that have become unaffordable in the community, contrary to the Olmstead and the Freedom initiative supported by CMS.

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM UNTIL ITS IMPACT ON TWWIIA (Ticket to Work/Work Incentives Improvement Act), PASS (Plan for Achieving Self Support) AND OTHER SOCIAL SECURITY WORK INCENTIVES IS DETERMINED.

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.

Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Thank you for your consideration of my views.

Yours sincerely,

Carole J Kramer
BPA&O and Employment Specialist

CMS-4068-P-1015

Submitter : Mr. Paul Pisarzewicz **Date & Time:** 10/04/2004 05:10:50

Organization : Columbia St. Marys Hospitals

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Monday, October 04, 2004

Center for Medicare and Medicaid Services
Dept. Health and Family Services
Att: CMS-4068-P
Baltimore, MD 21244-8014

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As Director of Pharmacy for an integrated health care system that includes hospitals and community pharmacies, I am deeply concerned with the rules as they are currently proposed.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns being expressed by hospital pharmacists around the nation are being considered. All pharmacists want this program to work.

In order for this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all hospital pharmacy providers that perform MTM services.

 CMS rules must allow for hospital pharmacies to be included not precluded. Plan sponsors should be required to establish CMS specified MTM services.

CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

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.

Sincerely,

Paul J. Pisarzewicz, RPh, MBA
Director of Pharmacy
Columbia St. Marys
2323 N Lake Drive
Milwaukee, WI 53211

CMS-4068-P-1016

Submitter : Ms. Dianna Porter **Date & Time:** 10/04/2004 06:10:43

Organization : Alliance for Retired Americans

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,
Attached please find comments from the Alliance for Retired Americans on the proposed rules for the Medicare Part D prescription drug benefit. On behalf of our executive director Edward F. Coyle, president George Kourpias, and Alliance members nationwide, we hope that you will give our comments serious consideration.
Sincerely,
Dianna Porter

CMS-4068-P-1016-Attach-1.doc

October 4, 2004

Mark McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

Attn: CMS-4068-P

Dear Dr. McClellan:

On behalf of the 3 million members of the Alliance for Retired Americans, I am submitting the following comments on the proposed regulations to implement the Medicare Part D prescription drug benefit as promulgated in 69 Fed Reg. 46632 (August 3, 2004).

Overall Comments

We are concerned that many constructive statements in the Preamble do not appear to be reflected in the Proposed Rule. We urge that more be done to reflect the Preamble's good intentions in the actual body of the regulation. 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 only says that notice should be provided, without specifying 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 when an enrollee's plan does not contract with the long-term care pharmacy, which an enrollee in a nursing home must use. The regulatory language does not include the examples CMS discusses in the preamble.

Beneficiary protections in the Preamble have no weight unless specified in the Regulation.

Subpart B-Eligibility and Enrollment

The description of how beneficiaries, especially the low-income, will be enrolled is inadequate. The experience of enrollment in the discount card should be an indication for

the need to do much more outreach and counseling, especially to the hard-to-reach, low-income, and minority populations. Medical Saving Plan enrollees should be automatically enrolled, as well. HHS must commit to better funding of the State Health Insurance Programs and Area Agencies on Aging and to more outreach to limited English proficiency individuals. The provisions in Title I and Title II (relating to managed care plans) making it easier to disenroll disruptive individuals must be deleted as they make it easy for plans to disenroll higher cost patients such as those with Alzheimer's disease and mental illness.

Further, the proposed rule fails to ensure that enough useful information is provided to beneficiaries. Potential enrollees should know the price of drugs on a plan's formulary, and some quality data—even if just a sampling—should be provided prior to the Fall, 2006 open enrollment season. Telemarketing and other high-pressure sales tactics must be prohibited.

There must be no gap in coverage for the 6.4 million dual eligibles. Medicaid coverage needs to be extended to May 15, 2006, or the automatic enrollment of dual eligible individuals must occur on December 31, 2005, with immediate counseling and education about how dual eligibles can switch, without penalty, to a plan that is better for them. As currently proposed, Medicaid drug coverage for Medicare eligible beneficiaries ends on December 31, 2005, but automatic enrollment of individuals who have not chosen a drug plan will not commence until the end of the open enrollment period on May 15, 2006. If the time frame is not changed as we suggest, this most vulnerable population, which includes more than 1.5 million institutionalized individuals, will be left without any drug coverage between January 1 and May 15, 2006.

Subpart C-Benefits and Beneficiary Protections

The regulations must provide that those who are institutionalized, those with complex conditions (like mental health, HIV/AIDS, cancers, etc.), those who have been stabilized on a particular regimen, and those who are fighting shifting viruses and need the latest in medical breakthroughs, have access to needed medications. The use of off-label drugs must be protected. Pharmacy and therapeutic (P&T) committees need more independence, and their recommendations concerning a formulary should be binding. To strengthen the requirement that a formulary must not discriminate against certain beneficiaries or groups of beneficiaries, the final regulations should limit the number of tiers of co-payments a drug plan can use. They should prohibit the inclusion of a tier that requires the enrollee to pay 100% of the cost of a drug, and should list a sample of prohibited activities (such as limits on the number of prescriptions per month, prior approval, etc.). To assist enrollees and pharmacies in understanding the formulary; advice hotlines should be available 24 hours a day, seven days a week.

The final regulations need to do more to assure that people receiving long-term care services in a long-term care facility, in an ICF/MR, or through a Medicaid waiver program have access to all the medicines they require, in the drug forms they use. Such individuals should have access to the pharmacies they utilize without having to pay higher cost-sharing for using a non-network pharmacy.

Subpart D-Cost Control and Quality Improvements for Prescription Drug Plans
The proposed rule contains no restrictions on the ability of plans to use cost-containment tools such as dispensing limits, or prior authorization. The preamble to the proposed rule, on the other hand, appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. The preamble's intent should be included in the regulation.

Subpart F-Submission of Bids and Monthly Beneficiary Premium; Plan Approval
There is nothing in the regulation on eligibility for bidding that precludes a prescription drug plan (PDP) from being owned by or affiliated with a drug manufacturer. The recent history of drug manufacturer and drug delivery firm cooperation shows that this type of relationship invariably leads to the products of the manufacturer being promoted, regardless of whether they are the best product, or the lowest cost. It will be nearly impossible for CMS to prevent such abuses of beneficiaries, and therefore we urge that the regulations prevent groups affiliated with manufacturers from providing the Part D benefit. As the Preamble states in the discussion of fallback plan negotiations, CMS "would also ensure that there is no conflict of interest leading to higher bids." Banning financial relationships between manufacturers and PDPs is the best way to prevent such a conflict.

Subpart J--Coordination Under Part D with Other Prescription Drug Coverage
The Preamble prohibits State Pharmacy Assistance Programs (SPAPs) 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. But despite the Preamble language, the law does not prohibit a State from providing consumer advice to its citizens as to which plan might work best with a SPAP, and which plan offers the best value. Given the intense need for consumer assistance, we urge that the Preamble language be dropped and 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.

Subpart K—Application Procedures and Contracts with PDP Sponsors
We are concerned that some of the minimum enrollment standards being set (5,000 and 1,500 in rural areas) are too low. We do not believe that plans with this small an enrollment base can obtain adequate discounts, maintain 7/24 advice and information lines, and employ the expertise needed for patients with pharmacologically complex conditions. CMS should carefully evaluate minimum enrollment requirements as minimum enrollment should be sufficiently high to ensure that every PDP will have the ability to both negotiate adequate discounts and provide the level of service beneficiaries will require.

Subpart M—Grievances, Coverage Determinations and 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. Dual eligible should have 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 grievance and appeals sections need major simplification and improvement. They weaken

constitutionally protected rights for all Medicare beneficiaries, but particularly for dual eligibles.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals
We support the proposed regulation's limitation of countable resources to liquid assets only. 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 states 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. Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We support the decision reflected in the proposed regulation to deem Medicare Savings Program ("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. Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Plans)
The requirements this subpart impose on those who would be interested in providing a 'fallback plan' to serve an area not served by at least two plans (one of which may be a MA-PD) are so severe that fallback plans will not, in fact, be available. The requirements exceed the statute and basically sabotage this provision of law; they make it entirely possible that some rural areas may have no service except regional PPOs and HMOs.

We believe that Congress did not intend that seniors would have to join a managed care plan for all their health care services in order to get the prescription drug benefit. This section of the proposed regulations should be scaled back to make it more certain that fallback plans will bid and participate.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans
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 Fed Reg.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).

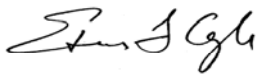
Furthermore, as the Preamble discussion makes clear, accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy

amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

Subpart T-Changes to Part 403. 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.

In conclusion, the Alliance for Retired Americans requests that the Secretary of Health and Human Services institute a second round of comments before issuing final regulations. The proposed regulations express several optional approaches to complicated substantive areas and a second comment period is necessary.

Sincerely,



Edward F. Coyle
Executive Director

CMS-4068-P-1017

Submitter : Mrs. Brianna Hoffman **Date & Time:** 10/04/2004 06:10:19

Organization : West Holt Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please find my attached letter with comments. Thank you.

CMS-4068-P-1017-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

Re: CMS-4068-P

Dear Sir or Madam:

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.

Subpart C: Benefits & 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 plan'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 and that my patients will be able to continue to use my 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. 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 met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress' intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans

- I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

- Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. In my practice we

interact with the physicians in our local clinic to make recommendations on medication changes such as switching to generic drugs or even trying a less expensive drug in the same class. We are also interested in starting an anticoagulation clinic, as well as providing diabetes education. Plans should be encouraged to use my services-to let me help patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to

1) Allow patients their choice of pharmacy by requiring plans to meet the TRICARE pharmacy access requirements on a local level.
2) Require plans to offer a standard contract to all pharmacies and not be allowed to establish preferred pharmacies.
3) Establish pharmacists as the primary providers for medication therapy management services.

Thank you for considering my view.

Sincerely,

Brianna Hoffman, Pharm.D.
West Holt Pharmacy
313 W Pearl St.
Atkinson, NE 68713
(402) 925-2651

CMS-4068-P-1018

Submitter : Mrs. Jacqueline Childers **Date & Time:** 10/04/2004 06:10:26

Organization : Georgia Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments on Medicare Drug Benefit and the Advantage Program Regulations

October 4, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P and CMS-4069-P
PO Box 8014
Baltimore, MD 21244-1814

Ref. File Code CMS-4068-P and CMS-4069-P

Dear Administrator McClellan:

The Georgia Hospital Association (GHA) appreciates the opportunity to comment on the proposed rules implementing the new Medicare Drug Benefit and the Medicare Advantage Program published in the August 3, 2004, Federal Register. We appreciate your ongoing commitment to rural health care, and the GHA looks forward to working with you in our mutual goals of improving access and quality of health care for rural Georgians.

On 10/4/04 GHA held a teleconference with its Critical Access Hospitals to determine how the proposed rules would affect providers. In review of the proposed regulations, we would like to see an emphasis on the impact to the providers as well as, the impact to the beneficiaries. We have two concerns with the regulations as proposed.

a. The prescription drug plan calls for the potential increased use of mail order pharmacies. In many rural areas there is a concern that there may be local independent pharmacists that go out of business with the increased use of mail order pharmacies. In some parts of the country we are told that some of the rural critical access hospitals do not always have a staff pharmacist, and that they rely on a local independent pharmacist to take care of their pharmacy needs. Our concern is that if these rural independent pharmacists go out of business because of the increased use of mail order prescriptions, this would have an impact on the hospital.

b. There is a concern regarding payment to critical access hospitals if they are in the Medicare Advantage Plans. If the beneficiary is out of network, out of the critical access hospital, it is important to assure that the Critical Access Hospital be paid at 100% of the cost as they are today.

The Georgia Hospital Association appreciates the opportunity to submit these comments on behalf of the Critical Access Hospitals in Georgia.. Please do not hesitate to contact Robert Bolden at (770)249-4500 if you have any questions about these comments.

Sincerely,

Jacqueline Childers, MPH, CPHQ
Patient Safety Specialist

CMS-4068-P-1019

Submitter : Ms. Kris Robinson **Date & Time:** 10/04/2004 06:10:37

Organization : American Association of Kidney Patients

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Extended comments from American Association of Kidney Patients

CMS-4068-P-1019-Attach-1.pdf

aakp

The Voice of All Kidney Patients

October 4, 2004

BY ELECTRONIC SUBMISSION

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Baltimore, MD 21244–8012

Subject: CMS CMS–4068–P, Comments Regarding Proposed Rule, Medicare Prescription Drug Benefit—EXTENDED COMMENTS

Dear Dr. McClellan:

On behalf of the American Association of Kidney Patients ("AAKP"), I am writing to comment on the proposed rule for the Medicare prescription drug benefit, published in the *Federal Register* on August 3, 2004. This letter incorporates and extends comments AAKP submitted on September 28, 2004.

About AAKP. The American Association of Kidney Patients (AAKP) (www.aakp.org), founded in 1969, is the nation's only kidney patient-led and managed education and advocacy organization for people with kidney disease. Each year AAKP serves over 12,000 members and, through its programs, hundreds of thousands of other Americans who have either lost kidney function (and live with dialysis or transplant) or have chronic kidney disease (CKD). The *average* life expectancy for individuals following initiation of dialysis therapy is short, about 5 years. But AAKP's membership includes many long-term dialysis survivors, who live full and productive lives only by aggressive attention to their health care, a core mission of AAKP. Indeed, most kidney patients face not only the challenge of kidney disease, but other medical conditions as well, such as diabetes and hypertension.

General Principles. AAKP reviews proposed government policies with respect to several core principles: Will the proposed policy improve access to, and quality of, care, and does the proposed policy respect the principle that *the physician and patient make a joint determination of the care plan best suited for that patient*?

Comments. AAKP submits the following comments:

American Association of Kidney Patients
3505 E. Frontage Rd., Suite 315, Tampa, FL 33607
800-749-2257 · 813-636-8100 · Fax 813-636-8122
http://www.aakp.org E-mail: info@aakp.org

1. General Provisions—Access to Covered Part D Drugs (§ 423.120)—b. Formulary Requirements (FR 46659)—Medicare Members with Kidney Disease Should Be Considered a "Special Population" and Provided "Open Formulary" with Access to All Needed Medications on a Preferred Basis. Medicare drug plans (Part D) can establish formularies that limit the drugs that they will cover. If a sponsor uses a formulary, the formulary must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes.

However, the proposed rule recognizes that special populations may require special treatment:

> We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well as suggestions regarding the particular special populations for whom we may want to make allowances.

FR 46661

In this regard, AAKP respectfully requests that Medicare members with impaired kidney function (chronic kidney disease and end-stage renal disease) be considered a "special population" and that Medicare members with kidney disease should have access to an "open formulary", with all prescribed drugs covered on a preferred basis, for several reasons:

- **Pharmaceuticals Can Have Nephrotoxic Effects.** The kidneys are the primary organs of the urinary system, which purifies the blood by removing wastes and excreting in urine. Accordingly, the kidneys are a major pathway for excretion of pharmaceuticals and pharmaceutical metabolites. However, a wide variety of pharmaceuticals can damage the kidneys (nephrotoxic effects), and accelerate damage to the kidneys. In the worse case, an individual with impaired but functional kidneys will graduate to end-stage renal disease, and require a life-sustaining but expensive and demanding renal replacement therapy (e.g., dialysis or transplant). To avoid or minimize nephrotoxic pharmaceutical effects on individuals with already impaired kidneys, physicians must have the flexibility to prescribe appropriately, and that (at a minimum) any proposed substitution be approved by the patient's physician.

- **Kidney Patients Have Many Co-Morbid Conditions, and Multiple Medications Raise the Risk of Adverse Events.** Kidney patients have high rates of co-morbid conditions, including primary causes of kidney disease such as diabetes and hypertension, and common concomitants to kidney disease, including cardiovascular and other vascular diseases (see 2004 Annual Data Report of the U.S. Renal Data System, at www.usrds.org). Physicians prescribe both to treat a clinical condition and to avoid

adverse interactions. Again, it is imperative that physicians have maximum prescribing flexibility to minimize adverse events.

- **Kidney Disease Patients Require Medications to Treat Ancillary Conditions.** Kidney disease patients frequently require medications to prevent or manage conditions secondary to kidney disease such as cardiovascular disease, anemia (treated with erythropoietin), and secondary hyperparathyroidism (treated with active forms of Vitamin D). It is essential that all medications needed by a kidney patient are covered by a prescription drug plan.

- **Transplant Patients Require Carefully Selected Immunosuppressive Medications.** For individuals who have lost effective use of an organ (such as a kidney or liver), transplantation can be a highly effective form of replacement therapy. AAKP believes strongly that transplant patients should have access to an "open formulary", and that all immunosuppressive drugs should be covered on a preferred basis. The number of Medicare beneficiaries with a kidney transplant is small (about 60,000), and the number of immunosuppressive medications is very limited. Physicians should be able to prescribe the clinically indicated immunosuppressive drug.

Perhaps for certain other medical conditions a trial of a replacement or substitution medication may have few consequences, but for a transplant patient any untoward reaction could lead to catastrophic loss of the organ transplant. The principle of "open formulary" for immunosuppressive drugs for transplant recipients, and the risks of drug substitution (including generics), has been recognized by State pharmaceutical programs (including Medicaid).

2. General Provisions—D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans—1. Overview (§ 423.150)—c. Medication Therapy Management Programs (FR 46668). Medication therapy management is intended to optimize therapeutic outcomes, and includes programs to educate patients on the use of medications, increase adherence to prescription medication regimens, and detection of adverse drug events. AAKP urges CMS to include chronic kidney disease and end-stage renal disease patients for such programs. Kidney patients have high rates of diabetes, hypertension, and cardiovascular and other vascular diseases, among other conditions – and frequently are prescribed medications for each of these diseases. Ensuring that kidney patients understand the need and use of medications, take medications properly, and are informed about adverse events (including drug interactions) would be of immense value.

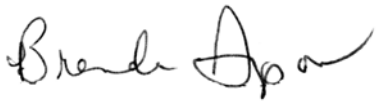
3. Section 101(c) (c), "Study On Transitioning Part B Prescription Drug Coverage". Although this matter is not raised in the proposed rule, the Medicare Modernization Act (MMA) requires the Secretary to submit a report to Congress that makes recommendations regarding methods for providing benefits under Part D currently provided under Part B, no later than January 1, 2005. AAKP believes this report should not be submitted to Congress without opportunity for public comment on a draft, and that no recommendations regarding transitioning Part B covered drugs used by kidney

patients be made until a thorough, independent study is made, including consideration of the financial costs to kidney patients and the impact on access and compliance with medication.

AAKP appreciates the hard work of CMS personnel involved in improving the lives of kidney patients. If you require further information regarding this letter, please contact Kris Robinson, AAKP's Executive Director, at (800) 749-2257.

Thank you in advance for considering AAKP's comments.

Sincerely,



Brenda Dyson
President

cc: Brady Augustine
Barry Straub, M.D.

CMS-4068-P-1020

Submitter : Mr. James Stirling **Date & Time:** 10/04/2004 06:10:06

Organization : Stirling

Category : Health Care Industry

Issue Areas/Comments

Issues 11-20

COLLECTION OF INFORMATION REQUIREMENTS

Very comprehensive proposed regulations. You've covered a lot of questions. My comments are directed to what I believe smaller plans will do. My families business is a 35 employee TPA. We have several clients that sponsor an ERISA plan for their active employees and have 10-100 retirees on their plan.

The application process will probably not be too difficult for small groups. The owners of these firms will sign the forms so long as the focus stays on the facts of their retiree RX plans. Please resist the temptation to make the signature a catch all for other code sections (discrimination testing, funding, or compliance with other rules or regulations). Sponsors of small plans will sign it if they understand it and are representing that these are the facts of their plan.

On the attestation, I think small plans administered by a TPA will have a hard time justifying the cost of the attestation relative to the value of the subsidy. Enrolled Actuaries will be in short supply. The proposed regs envision 850,000 actuarial hours for the 50,000 cases. That's the full employment for actuaries act. A plan with 50 retirees will not likely get a actuary at a reasonable rate to review their design.

As far as the idea that TPA's will get a actuary on staff... I don't think so. The majority of TPA's are privately held with under 100 employees. Most of these are clerical. Bringing on a Actuary, especially since the Act creates a high demand for their services, will not be realistic. The Proposed regs also envision that small plans will band together to reduce the time the attestation takes. Typically, each plan is individual, and unlike those offered by insurance companies (that are similar) even a group of plans through the same PBM will likely need a soup to nuts actuarial study.

Suggestions:
For small plans, offer a streamlined process. Have the plan sponsor sign without a actuarial attestation attached. Instead, require that your form be filled out (require it online, if you want). Let the sponsor give CMS two years of claim data, the number of people covered, and the plan design. Use the gross test to figure if the actual costs exceed the Part D value. Make the historical costs exceed it by 20% so there is a comfort with the numbers. Then have the Plan sponsor provide the employee contributions for two years. Ask the question another way to check the result, ask: what are the monthly contributions. If the numbers make sense, then approve these little plans for the subsidy.

Otherwise,

I suspect that many plans will simply drop coverage. The wrap plans are not that attractive because the wrap carriers will need to make money, too, and so the risk charges and claims overhead will eat away at the benefit. For smaller groups, an employer can pay for the Part D premium, plus put another $1,000 toward their pension, and the average member will come out ahead. Most retirees do not have more than $2,000 of gross drug costs, so the 75% that Part D picks up will satisfy most retirees.

Small cases will be very sensitive to the perception of added work to obtain the subsidy. If you apply one rule to all, the smaller groups will likely drop their plans.

This is a great change in the way Rx is delivered to our elders. Thank you for your work on this issue. If we can help in any way with how this may play out outside the beltway, do not hesitate to ask.

Sincerely yours,
James Stirling

Submitter : Mr. michael godino **Date & Time:** 10/04/2004 06:10:21

Organization : Mr. michael godino

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Michael Godino
104 Tilrose Avenue
Malverne, NY 11565

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:

As a person who is one of the recipients of both Medicare and Medicaid, I welcome the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632.

I am concerned that the proposed rule does
not provide sufficient protections for the 13 million
Medicare beneficiaries with disabilities and chronic health
conditions.

As I applied for the Medicaid Buy in when it became available to people who are disabled and working, I learned how critical good medical insurance is to me as a person with a disability and approaching middle age. I have Multiple Scleroses which I name as my primary disability and a variety of other ?disabilities? that stem from the MS and some that don?t: Blindness, amputee, diabetes and Hypertension just to name some of my disabilities. The medications I take for these ailments, would cost over $1300.00 thirteen hundred dollars per month, however, the Medicaid Buy in as offered me the opportunity to continue working, be it part time, but I keep busy. If I had to pay out of pocket for these medications, I would be better off not working at all and listing myself among the poorest of the poor so the state would have to support me and my medication to stay healthy. As it is now, I pay taxes replenishing some of what I am receiving in benefits.

These proposed regulations will force me and many others like me to make drastic choices not in the best interest of anyone concerned. Please understand, I did not have a vote on this plan and only now can I work with what is available. To better serve me and the millions of others that will be affected by these rules, at the very least, postpone the rules to people who are duel eligible until CMMS has the opportunity to examine the implementation to other less fragile communities.

Thank you for the interest in my concerns,

Sincerely,

Michael Godino

CMS-4068-P-1021-Attach-1.doc

Michael Godino
104 Tilrose Avenue
Malverne, NY 11565

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:

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These proposed regulations will force me and many others like me to make drastic choices not in the best interest of anyone concerned. Please understand, I did not have a vote on this plan and only now can I work with what is available. To better serve me and the millions of others that will be affected by these rules, at the very least, postpone the rules to people who are duel eligible until CMMS has the opportunity to examine the implementation to other less fragile communities.

Thank you for the interest in my concerns,

Sincerely,

Michael Godino

Submitter : Bradley Wooldridge **Date & Time:** 10/04/2004 06:10:00

Organization : Bradley Wooldridge

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist, I would request that patients be able to go anywhere they want to go. Also, we should be able to do a 90 days supply if mail order can for the same dispensing fee and reimbursement rate.

CMS-4068-P-1023

Submitter : Ms. Wendy Tenzyk **Date & Time:** 10/04/2004 06:10:33

Organization : Colorado PERA

Category : State Government

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Re. Retiree Drug Subsidy provisions: Prop. Reg. II.R.3.b.2 re. establishing actuarial equivalency: It would not seem permissible to add a limit test to the 'single prong' approach, based on the definition of 'covered drug costs.' Having a limit test consider 'the amount paid by plan sponsors on behalf of their retirees' would seem to create possibilities that would be complex and unintentional. Also, many sponsors pay for various utilization and disease management programs offered by PBMs. Those programs would not seem to be includible in the allowable cost calculations as defined, but they would seem includable under this description. The 'two prong' approach seems to raise similar issues. Conducting a 'net test' seems contradictory to the definition of 'covered drug costs.' Using the sponsor's after-tax value would pose issues and/or create inequities for governmental plan sponsors. Using a 'net value' test that required sponsors to subtract the retiree premium from the expected amount of paid claims would not seem permissible, and would pose administrative complexities. PBMs maintain records of paid claims, but they have no reason to maintain records of retiree premiums. That information is retained by the plan sponsor or the plan's contracted recordkeeper. Further, retiree premiums are typically premiums that reflect the retiree's costs for both medical and prescription coverage; most plans do not offer or charge for prescription coverage as a separate plan. It would be problematic for plan sponsors to have to change their operations to reflect separate plans and premiums for medical and prescription, and to then compare individual retiree prescription premiums to individual retiree paid claims. Such a system does not exist for us now. It would have to be developed, and it would seem to be a complex effort for sponsors, administrators, and PBMs. Re. Prop. Reg. II.R.3c - Sponsor application for subsidy payment and required information - Having sponsors apply for the subsidy payment by the preceding 9/30 each year would pose timing issues based on the info proposed to be required as part of the app. Enrollments in our plan are not finalized until late December for January 1, thus we have no way of knowing who will be enrolled on Jan. 1 on the preceding 9/30. The proposed information requirement seems reasonable. We maintain that info on each enrollee and could transmit it to CMS, assuming a fairly standard data request format and sufficient 'lead time' for programming. Re. ongoing data updates: Many vendors' systems seem to find working with 'updates only' files problematic. The concept seems logical, but the execution has proven more challenging then we expected. We use both 'updates only' and 'full files' in working with our vendors. Re. a surety bond: This would seem problematic and unnecessary for governmental plans. Re. Prop. Reg. II.R.4 - Retiree drug subsidy amounts - The timing of the indexing calculation seems problematic, and would need to be revised to make it workable for sponsors of large plans. 2007 amounts would not be available until sometime after July 2006, but large plans have already set plan designs and rates by that time, thus if plans did not meet the actuarial equivalency test for the following year based on the indexed numbers, they would be unable to qualify for the subsidy at all for that year. Such an administrative cycle could likely result in large plans not being able to qualify for the subsidy from year to year. Prop. Reg. II.5.b - Payment methodology - The administrative complexities of filing for payments and maintaining 6 years of audit records would suggest that an annual or quarterly filings would be preferable to monthly. The more frequently a PBM or recordkeeper needed to produce reports, the more they would charge a plan sponsor for the service. All of the payment methodologies seem fairly complex and creative, but perhaps unproven and not in use.

GENERAL PROVISIONS

Re. "Definitions" - The definition of "Sponsor" does not seem encompassing enough to include a plan like ours, which is created under state law and administered by Colorado PERA, an instrumentality of state government. Colorado PERA is the sponsor of our retiree plan ("The State" is not). The definition of "allowable retiree costs" includes some wording that would be problematic for many plan sponsors. "Price concessions" are reflected in our PBM contract, and that information would be considered confidential and proprietary. We would have concerns that making this information part of calculations and reporting would make it available to others, including other PBMs who could use it in future bid negotiations. For us, "rebates" are not an identifiable "line item" in our pricing - price concessions take rebates into account, but rebates are not contracted for, nor are they paid to us. Our PBM certainly receives rebates and price concessions related to our business; those are considered in the pricing quoted to us. Rebates are netted out of costs, thus it would seem that they are already netted out of "allowable retiree costs."

CMS-4068-P-1024

Submitter : Ms. Vickie Keys-Lydic **Date & Time:** 10/04/2004 06:10:45

Organization : John Deere Health Care, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment file.

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 or,
2. The submitter did not follow through when attaching the document, or submitted only one file or,
3. The document was protected file and would not allow for CMS to attach the ile 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. brooke klenosky **Date & Time:** 10/04/2004 06:10:53

Organization : VA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 4,2004

Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

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 rule 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 average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) 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.

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.

I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.

A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.

A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.

Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical? pharmacists, as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?

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 should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should 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 populaiton

CMS-4068-P-1026

Submitter : Mr. William Fritz **Date & Time:** 10/04/2004 06:10:00

Organization : University of Arizona Medical Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-4068-P
The purpose of this letter is to provide my opinions and suggestions on several issues related to the proposed rules regarding Medicare Part D. I believe that, while well intended, these rules may have a negative impact on the quality of care provided to Medicare patients.
The two major points that I would like to address are the need to include language that 1) ensures Medicare beneficiaries are able to access medication therapy management (MTM) services from a pharmacist either through their own initiation, a prescriber?s referral or pharmacy initiated processes, and 2) that such services are compensated.
MTM Services
1. CMS rules must allow for all pharmacists to be included not precluded.
? Pharmacists at The University of Arizona Medical Center (UMC) are an integral part of the health care team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary hospitalizations and ER visits.
? All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. All pharmacists practicing within a region (regardless of practice setting) should be afforded the opportunity to provide and be paid for MTM services such that plan sponsors should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service.
? Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services. Identification of targeted beneficiaries should not be left solely to the plan. Plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited a specific pharmacy or a written prescription.
? MTM services should be able to be provided in conjunction with and outside of product dispensing.
? Plan sponsors should be required to establish at CMS-specified set of MTM services. The specified set of services should be a minimum set while additional services should be encouraged.
2. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services.
Additionally, the rules must address Access to Pharmaceuticals
? Plans should be required to offer standard contract language to all pharmacies willing to participate in the program as a prescription and MTM services provider. Plans need to make it easy for patients to have convenient access to their pharmacy of choice. .
? Co-payment reductions should not be provided to coerce beneficiaries into using "preferred" pharmacy providers solely on the basis of pricing or cost. This will provide incentives for beneficiaries to use low cost, low quality providers and ultimately increase the cost of patient care and will disrupt existing pharmacist-patient relationships resulting in improved drug therapy outcomes.
? An adequate reimbursement formula that at a minimum covers the average cost of filling a prescription or providing a service must be established.

? To prevent conflict of interest, plan sponsors should be prohibited from promoting or requiring the use of pharmacies in which they have an ownership interest.
Thank you for your consideration.
William L. Fritz, M.S., R.Ph., FASHP
Associate Director of Pharmacy
University of Arizona Medical Center
1501 N. Campbell Ave.
Tucson, AZ 85724-5009
Phone: 520 694-7015
Email: bfritz@umcaz.edu

Submitter : Miss. Lorraine Cannistra **Date & Time:** 10/04/2004 06:10:33

Organization : Miss. Lorraine Cannistra

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Lorraine Cannistra
1301 West 24th Street C-13
Lawrence, KS 66046

October 4, 2004

CMS, Department of HHS
Attn: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Men and Women of CMS:

I am writing to express my concern about the proposed regulations to implement the Medicare Modernization Act of 2003. As a woman affected by Cerebral Palsy, I require 49.75 hours per week of attendant care and several medications on a daily basis.

Currently, I am dually eligible for Medicare and Medicaid. As I understand it, if the law remains in its current form I will no longer be able to get my prescription drugs covered by Medicaid. The reason I qualify for these programs, in addition to my disability, is because my income is so low. Having to pay a co-pay on every prescription would put a huge burden on my already limited income.

The possibility of not being able to access my medication because I do not have the money to do so is very scary for me. Cerebral Palsy causes many secondary conditions that can only be stabilized when I take medication on a consistent basis. My quality of life will be diminished if this medication is not available to me.

I urge you not adopt the proposed regulations to the Medicare Modernization Act of 2003. My long term health literally depends on this legislation not being passed. Thank you very much for your time.

Sincerely,

Lorraine Cannistra

CMS-4068-P-1028

Submitter : Mrs. Marilyn Kuna **Date & Time:** 10/04/2004 06:10:34

Organization : Parent

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-1028-Attach-1.doc

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS—4068—P

www.ems.hhs.gov/regulations/ecomments

Re: Response to the Medicare Prescription Drug Benefit, Proposed Rule

To Whom It May Concern:

William, my 32-year-old son has developmental disabilities. William is dually eligible for both Medicaid and Medicare and has the following diagnoses: Spastic quadriplegia, mental retardation, scoliosis, gastroesophogeal reflux, requires a wheelchair for mobility and assistance with all activities of daily living. He is taking these prescription medications: Sucralfate, Phenobarbital, Xelnorm, Diazepam and Nexium. William's diapers (Attends) are also covered. He additionally must purchase these prescribed over the counter products: Tylenol, multivitamin, Robitussin, Fergon, Mylanta, and Maltsupex.

I am very worried about the Medicare plans that will change the way William receives prescription medication. Currently, all of his prescription medications and Attends are paid by Medicaid. I am especially worried about the federal government's plans for the Medicare formulary, which will restrict his access to all of the necessary medications.

William cannot afford to pay for these medications if they are not on the formulary. I am worried that when this new Medicare system starts on January 1, 2006, that William won't be able to get all of the medications that he needs, and his health will suffer.

Since William must pay extraordinary costs (currently $375 monthly) for his doctor prescribed over the counter products, it will be financially difficult for him to make a co-payment for each medication under the new Medicare plan. Currently he doesn't have to pay anything to get covered prescribed medications under the Medicaid system. Like the over the counter "prescriptions," the co-pay for medications will probably increase every year.

I don't think that Congress intended to have my son with developmental disabilities to be worse off under this new Medicare drug plan than he was before. But that is what will happen to him and all of the dual eligibles unless you fix the problems that I have described. If the new Medicare drug plan does not cover the specific medications that the dual eligibles need to keep them healthy, then they should be allowed to have their medications continue to be provided through the Medicaid system.

Thank you.
Marilyn M. Kuna

Submitter : Dr. Jay Currie **Date & Time:** 10/04/2004 06:10:41

Organization : Individual

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste

423.153 (d) Medication therapy management program (MTMP)

Having a quality MTMP included in the Part D Plans is essential to assuring quality care and control of waste for the program. Beneficiaries of Medicare Part D Provider Plans will need assistance in getting their mediation-related health care needs met. I am very supportive of the use of `targeted direct patient care? in your description of these services. While PDPs and MA-PDs can and should have some administrative quality control strategies centrally based, quality patient care can only occur at the local level, directly between providers and beneficiaries. Services designed to meet the requirements of the MTMP portion of the rules should meet high standards and should not be allowed to be delivered from a central location by the PDP or MA-PD.

I would urge you to consider the Pharmaceutical Case Management program in Iowa Medicaid as a potential model for the implementation of this portion of the MMA. The program utilizes pharmacists and physicians working together to provide extra care and oversight to high risk beneficiaries. A formula using number of medications and inclusion of defined disease states is used to `target? beneficiaries eligible for this increased care. Adequate documentation and communication between providers triggers billable events in the care of beneficiaries.

I would also urge you to implement the definition and components of Medication Therapy Management put forth by the major pharmacist professional organizations. These include the Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy, American College of Apothecaries, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health System Pharmacists, National Association of Boards of Pharmacy, National Association of Chain Drug Stores, National Community Pharmacists Association, and the National Council of State Association Executives. These recommendations have been provided to CMS for consideration.

I support these recommendations, especially the outlined services, as I have seen these have significant impact on the quality and cost of health care for countless beneficiaries over the last 10 years of pharmacists providing similar services in Iowa.

CMS-4068-P-1030

Submitter : **Date & Time:** 10/04/2004 06:10:02

Organization :

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1030-Attach-1.doc

Confederated Tribes and Bands
of the Yakama Nation

Established by the
Treaty of June 9, 1855

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014.

RE: Comments on Proposed Rule -- Medicare Part D Prescription Drug Benefit
Adverse Impact on American Indians/ Alaska Natives and Indian Health Programs
Notice of August 3, 2004, 69 Federal Register 46632
File Code CMS-4068-P

Dear Administrator:

I am writing to express my strongest opposition to your decision to include Indian Health Programs in your prescription drug benefit program without regard to the Federal Trust Responsibility, the promise of health care in Indian Treaties, the Indian Health Care Improvement Act, and principles of Tribal Self Determination. The proposed regulations will cause a great loss of Medicaid revenue for Indian Health Programs, which will not be adequately replaced by the Medicare drug program, and require many elderly and disabled tribal members to pay significant amounts toward prescription drugs which are now available without charge through Indian Health Programs.

Elderly and disabled American Indians and Alaska Natives should be exempted from the provisions of the Medicare Modernization Act and the proposed regulations that eliminate their Medicaid coverage effective January 1, 2006. The Medicaid system has the flexibility to address uniqueness status of Tribes and Indian Health Programs through state policy and Medicaid waivers. The Medicare Act could remove the ability of states and Indian organizations to negotiate in behalf of Indian Health Programs and their program users in regard to prescription drugs, unless those concerns are adequately addressed in final regulations.

Should the Indian Health Programs and their elderly and disabled patients not be entirely exempted from the Voluntary Medicare Prescription Drug Benefit program, the final regulations should provide for:

1. Exemption for elderly and disabled Indian Health Program users from prescription drug deductibles, premiums, co-payments and coinsurance.

2. Mandatory agreements between prescription drug plans and Indian health pharmacy programs with terms that are responsive to the unique status of each Indian program.

3. 100% reimbursement to Indian Health Programs for prescription drugs provided to elderly and disabled program users who are enrolled, or who are eligible for enrollment, in private prescription drug plans; Medicare reimbursements under the Medicare prescription drug benefit should not be less than current Medicaid reimbursements.

4. Default enrollment of Medicaid and Medicare "dual eligible" American Indians and Alaska Natives in Indian health pharmacy programs, not in private prescription drug plans.

I further incorporate by reference into my comments all of the comments on Part D prepared by the National Indian Health Board and separately forwarded to CMS as part of the comments of many Tribes and Indian Health Boards.

Sincerely,

Linda Pratt, Director Yakama Nation
Vocational Rehabilitation

CMS-4068-P-1031

Submitter : Ms. Mary Dewane **Date & Time:** 10/04/2004 06:10:33

Organization : Schaller Anderson Inc

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached Microsoft Word document

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 or,
2. The submitter did not follow through when attaching the document, or submitted only one file or,
3. The document was protected file and would not allow for CMS to attach the ile 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-1032

Submitter : Mr. Robert Clark **Date & Time:** 10/04/2004 06:10:19

Organization : Bristol Bay Area Health Corporation

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-4068-P-1032-Attach-1.pdf

CMS-4068-P-1032-Attach-2.rtf

COMMENTS REGARDING
PROPOSED REGULATIONS TO IMPLEMENT
THE MEDICARE PRESCRIPTION DRUG BENEFIT UNDER
THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND
MODERNIZATION ACT OF 2003
as published in
69 Fed. Reg. 46,632 *et seq.* (Aug. 3, 2004)
File Code CMS-4068-P

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 D's 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" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

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 D does not result in inadvertent and unintended harm to that system.

The regulations governing the Part D prescription drug benefit must be revised to achieve the following goals:

- Guarantee that AI/ANs have a meaningful opportunity to access the benefit *through the pharmacies of the Indian health delivery system*;

- Require private prescription drug plan sponsors (PDPs) and Medicare Advantage organizations offering prescription drug coverage (MA-PDs) to reimburse or contract with the pharmacies in the Indian health system -- those operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (collectively referred to as "I/T/Us");

- Order Indian-specific terms that must be included in those contracts to guarantee that I/T/U pharmacies can collect from PDPs, building on the experience gained from the Medicare Prescription Drug Discount Card program; and

- Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold harmless" mechanism Congress established for FQHCs

in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D 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 D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid 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. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. 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.

[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 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.
- 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 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. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.[5]

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 IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

[4] U.S. Commission on Civil Rights, A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country, July 2003.
[5] Federal Disparity Index Report for 2002, showing an expenditure of $1,384 per HIS user compared to a benchmark price of $2,687 per user.

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.

Pharmacy Services for Dual Eligibles

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[6] and 30,544[7] 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.[8] 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**[9] **and $53.6 million**.[10] 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 rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

Barriers to Part D access of Indian dual eligibles. There are several reasons why the intended conversion of dual eligibles from Medicaid to Medicare could be extremely problematic in the Indian health system:

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[6] This number represents 85 percent of the three-year total of active users.
[7] This is the number of active users, defined as at least one visit in the past three years.
[8] 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.
[9] 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.
[10] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

- Switching payment sources from Medicaid to PDPs under Part D will hurt AI/AN consumers and Indian health providers because most tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. Dual eligibles in those areas will have difficulty accessing the Part D benefit unless they use an Indian health pharmacy admitted to PDP networks.

- Medicaid revenues have been an important source of income for Indian health facilities. **As drug coverage for AI/AN dual eligibles is removed from Medicaid and placed under Medicare, the amount of revenue in jeopardy is estimated to be between $23.8 million and $53.6 million.** Reductions in reimbursements for pharmaceuticals cannot be absorbed by raising rates for other services, as Indian patients are served without charge.

- The level of revenue an I/T/U would collect under Part D will very likely be less than it currently collects under Medicaid for dual eligible drug coverage. Therefore a "wrap around" payment from Medicare, consisting of the difference between the PDP/MA-PD contract amount and the amount the I/T/U would have received under Medicaid, must be utilized to "hold harmless" I/T/Us, if an I/T/U contracts with a PDP/MA-PD.

- If private prescription drug plans are not required to contract with I/T/U pharmacies, there will be little incentive for them to do so, as the service population of these pharmacies is comparatively small and the Indian population tends to be sicker. Without network status or payment for off plan services, an I/T/U pharmacy will not be able to collect for drugs dispensed to any AI/AN enrolled in a Part D plan. This would produce three negative results: (1) a loss of revenue to the I/T/U pharmacy; (2) no meaningful opportunity for the enrolled Indian to use his Part D benefit; and (3) a windfall for the PDP who collects premiums from CMS for a dual eligible, but pays no claims.

- Even if private plans are required to contract with I/T/U pharmacies, this command will be meaningless unless the regulations set out terms specifically drafted to address the unique circumstances of the IHS, tribal and urban Indian pharmacies.

- Even if an Indian beneficiary is enrolled in a Part D plan, the I/T/U pharmacy may not know what PDP or MA-PD to bill. Particularly with automatic enrollments, the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delay in accessing the benefit if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. This situation mirrors the disastrous consequences suffered by the I/T/Us when State mandatory Medicaid managed care enrollment programs were implemented.

- If delays in implementation occur, it is not clear how the I/T/U pharmacies will recoup payment for expenditures made during the period between when the AI/AN is switched from Medicaid to Medicare pharmacy benefits and when the I/T/U pharmacy is an established network provider or able to bill for out of network services. Even if the I/T/U pharmacy is allowed to bill for services provided from the beginning of 2006, they may not have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to

enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

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 by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS
Comments regarding: Section 423.120: Pharmacy Access Standards

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To guarantee access to Part D prescription drug benefits for AI/AN beneficiaries by requiring private drug plans to contract with those pharmacies which serve the majority of this population -- I/T/U pharmacies.

Access Issue, Pages 46655-57: Should CMS use its authority under Section 1860D-4(b)(1)(C)(iv) of the Act (authorizing the Secretary to establish standards to provide access for I/T/U pharmacies to participate in the Part D program) to *require* or *strongly encourage* private drug plan sponsors (PDPs) and MA organizations offering MA-PD plans (MA-PDs) to contract with I/T/U pharmacies?

Comment: In order to realize its goals (as communicated on pages 46655 and 46633 of the Preamble) of ensuring convenient access to covered Part D drugs to plan enrollees and broad participation by Medicare beneficiaries in the new prescription drug benefit under Part D, CMS must use its authority under Section 1860D-4(b)(1)(iv) of the Act to **require** PDPs and MA-PDs to contract with I/T/U pharmacies. Without this requirement the private drug plans will have little or no incentive to contract with I/T/U pharmacies.[11] This is true because there is no financial incentive for private plans to contract with I/T/U pharmacies since these pharmacies and the AI/AN beneficiaries they serve are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. If PDPs and MA-PDs are merely "*strongly encouraged*" to contract with I/T/Us[12] they will not do so because of the uniqueness and remoteness of Indian health programs the comparatively small and sicker populations they serve, and the perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.[13]

[11] Allowing the private plans to count I/T/U pharmacies toward access standards may provide incentive for private plans to contract with a few I/T/U pharmacies but only where the private plan needs the I/T/U pharmacy to meet the Tricare access standards. It will not be an incentive to contract with all I/T/U pharmacies.

[12] CMS proposes this option in 69 FR at 46657.

[13] One way to decrease administrative costs while at the same time assuring access for AI/AN beneficiaries who use I/T/U pharmacies is to create special endorsement PDPs and MA-PDs to serve AI/AN beneficiaries similar to the mechanism used in the Temporary Prescription Drug Discount Card Program. This matter is discussed further in our comments regarding §423.120(a)(1).

Failure to include language in the rule requiring private plans to contract with I/T/U pharmacies will have the unintended consequence of *denying* access to the benefit for a majority of AI/AN beneficiaries. This would be contrary to the access requirements of the Act. If I/T/U pharmacies are not included in the PDP or MA-PD network, an estimated 26,000 AI/AN beneficiaries who obtain their drugs from I/T/U pharmacies will be unable to access the Part D drug benefit. CMS acknowledges this fact on page 46657 of the Preamble by stating that I/T/U pharmacies may be the only facilities available to AI/AN beneficiaries and recognizes that **access to I/T/U pharmacies should be preserved** because it "would greatly enhance Part D benefits" for AI/AN enrollees.

Access for I/T/U pharmacies to the Part D program is crucial for preserving current revenues. All AI/ANs dual eligibles will lose their Medicaid drug benefits and are required to enroll in a Part D or Part C plan. Those dual eligible who fail to enroll will be automatically enrolled in a private plan. Regardless of such a beneficiary's enrollment in the new prescription drug benefit, an AI/AN beneficiary will continue to utilize his/her I/T/U pharmacy. Absent an agreement with the private drug plans, these pharmacies will be unable to collect reimbursement for prescription dispensed to Medicare beneficiaries. In order for I/T/Us to collect reimbursement for prescription drugs provided to dual eligibles **they must be included in the private plan network.**

Therefore, it is vital that Section 423.120 be modified to include language requiring PDPs and MA-PDs to contract with I/T/U pharmacies, but required contracting is not enough. The unique status of tribes may become an issue in contract negotiations. The standard PDP/MA-PD contract could prove problematic for I/T/Us as CMS acknowledged in the Preamble on page 46657. In order to assist CMS, PDPs, and MA-PDs in resolving this difficulty, we urge that specific contract provisions, which are contained in the draft language below, be required provisions for agreements between PDPs/MA-PDs and I/T/U pharmacies.[14]

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) *Assuring pharmacy access*.

Insert the following new paragraph and re-number all subsequent paragraphs:

> "(2) *Access to IHS, tribal and urban Indian pharmacies.* In order to meet access standards under Section 1860D-4(b)(1)(C)(iv), a prescription drug plan or MA-PD plan must offer to contract with any I/T/U pharmacy in its plan service areas, and such contract must include the elements set out in §423.120(a)(4)."

§423.120(a)(4) *Pharmacy network contracting requirements*.

Insert the following new subparagraph (iv):

[14] We submit as Attachment 1 a model tribal addendum prepared by the CMS Tribal Technical Advisory Group to be utilized by tribal and urban Indian pharmacies participating in the Temporary Prescription Drug Discount Card Program.

"(iv) Must incorporate in all contracts entered into with I/T/U pharmacies, within the text of the agreement or as an addendum, provisions that:

(A) Acknowledge 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) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; 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 the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.

(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including 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) Recognize that I/T/Us are non-taxable entities.

(E) State that IHS, tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.

(F) State that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.

(G) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.

(H) State that an I/T/U pharmacy is not subject to the PDP formulary.

(I) State that the Agreement may not restrict access the I/T/U pharmacy otherwise has to purchase drugs from the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act.

(J) State that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.

(K) Authorize I/T/U pharmacies to establish their own hours of service."

REGULATIONS MUST PROVIDE A MECHANISM TO ASSURE NO REUDCTION IN REVENUES TO I/T/U PHARMACIES

Comments regarding: §423.120: Access to covered Part D drugs and §423.124: Special rules for access to covered Part D drugs at out-of-network pharmacies

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To include in the regulation a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. We provide four options in our comments to achieve this goal:

Option 1: *In-Network Status + Wrap-Around Payment*. One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network

providers and for CMS to provide "a wrap-around payment" modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.

Option 2: *Out of Network Status + Wrap-Around Payment.* In the event that I/T/U pharmacies are not treated as in-network pharmacies, they should be recognized as out-of-network pharmacies eligible for reimbursement from the private plan under §423.124 and receive a supplemental "wrap around" payment from the federal government which would include any increased differential in cost sharing related to use of out of network pharmacies. This supplemental payment would provide reimbursement for the difference between the out of network plan payment and the amount the I/T/U would have received as an in network provider.

Option 3: *Special Endorsement PDP/MA-PD Plans.* Specific PDPs could be designated to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Benefit Discount Card program.

Option 4: *Exemption of AI/AN Dual Eligibles.* Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid. This alternative would allow CMS to avoid the complicated issues of access and revenue loss that we discussed throughout these comments.

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. 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. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for **AI/AN dual eligibles drug costs ranges between $23.8 million[15] and $53.6 million.[16]** 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 rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract

[15] 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.

[16] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

We propose that one of the four "hold harmless" provision options be included in the regulation to maintain the current level of revenue I/T/U pharmacies receive under Medicaid.

Option 1: In-Network Status with Wrap-Around Payment

While it would be the responsibility of CMS to establish ways to prevent loss of revenue at I/T/U pharmacies, we propose that CMS:

(a) Require all PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the appropriate rate[17], ***and***
(b) Provide a "wrap around" payment for drug coverage services similar to the special payment rules for medical services provided at federally qualified health centers (FQHCs) contained in Section 237 of the MMA.

Reimbursement as In-network Provider. We request that the regulations require PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the Medicaid rates. This provision would prevent agreements in which the PDP/MA-PD agrees to pay an artificially low rate to the I/T/U pharmacy, with the knowledge that the I/T/U pharmacy will receive supplemental payments from CMS.

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a "wrap-around payment" to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

We suggest that the following provision or ones similar in nature be added to the Part D rules:

Section 423.120(a)(1): *Convenient access to network pharmacies.*

***

"§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying

[17] 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."

claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy."

The following language should be inserted into Part 423 at the appropriate place:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 2: Out of Network Status with Wrap-Around Payment

In the even that I/T/U pharmacies are not recognized as in-network providers under Option 1, we propose that the regulations recognize these pharmacies as out of network providers under §423.124 and provide a wrap-around payment to supplement the difference between the out of network reimbursement rate and the Medicaid rate.

We suggest that the following sentence be added to Sec. 423.124(a):

Section 423.124(a) ***

"An I/T/U pharmacy that dispenses covered Part D drugs to an American Indian/Alaska Native beneficiary shall be considered an out of network pharmacy for payment of claims."

Additionally, the following provision should be included in Part 423:

§**423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.**

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 3: Special Endorsements with Wrap-Around Payment

Designating private plans to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Discount Card program is an alternative that could encourage PDP contracting with I/T/U pharmacies. Specifically identifying the PDP serving AI/AN will help I/T/Us to identify and bill the correct PDP or MA-PD. Additionally, designating specific PDPs and MA-PDs to contract with I/T/U pharmacies would allow an AI/AN beneficiary to easily identify which plan includes his/her I/T/U pharmacy, avoiding the need for the individual to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. Of course, to ensure that I/T/U revenues do not decrease under this option, the wrap-around payment provision discussed above would be necessary. Designation of specific PDPs would also facilitate development of specific I/T/U contract terms.

If CMS is unable to secure private plans to offer the benefit, then it could either subsidize the benefit or provide a "fall back" plan as authorized by Section 1860D-2(b) of the MMA. The Part D proposed regulations depend on the private market to drive the benefit; however, because of the unique characteristics of Indian health programs, private plans may not have incentive or interest in serving a predominately low-income population. Establishing specific PDPs and MA-PDs to serve the AI/AN population is entirely feasible since PDP and MA-PD regions have yet to be established.[18]

Option 4: Exemption of AI/AN Dual Eligible Individuals from Part D

We offer an alternative that would allow CMS to avoid the complicated issues of access in Section 423.120, revenue loss to I/T/Us and the "wrap around" mechanism discussed on page 11 of these comments -- **Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid**.

We believe that exempting AI/AN dual eligibles from mandatory enrollment is an efficient and effective alternative for the following reasons:

- Exemption of AI/AN dual eligibles from mandatory enrollment will prevent any loss of revenue to I/T/U pharmacies that will result if drug coverage for dual eligibles is switched from Medicare to Medicaid.
- Exemption of AI/AN dual eligibles will eliminate the barriers dual eligibles, as well as AI/AN basic beneficiaries, will face in accessing the Part D benefit. For example, the MMA strategy to use private plans as a vehicle to provide prescription drug benefits severely restricts access for many AI/ANs because tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks.
- Exemption of AI/AN dual eligibles from mandatory enrollment will eliminate the detrimental impact on reimbursement levels and the increase administrative costs that will occur when the I/T/U pharmacy does not know what PDP or MA-PD to bill. This is particularly true with regard to automatic enrollments because the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

It is important to recognize that exempting AI/AN dual eligibles from mandatory participation in Part D thereby allowing them to continue to receive prescription drug coverage through the State Medicaid Program will have **no budget impact.** This is so because prescription drug coverage costs will be paid by the federal government regardless of whether the benefit is provided under Medicaid at 100% FMAP or Medicare Part D subsidy for dual eligibles.

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the

[18] In creating special endorsements for AI/AN CMS could establish:

- A pool of Indian-specific PDP/MA-PD who would serve regions that mirror IHS Areas, or
- Nationwide PDPs/MA-PDs to serve AI/AN in all fifty states

many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)
Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems

Goal: *To ensure that I/T/U pharmacies that participate in PDP pharmacy networks continue to have the option of purchasing prescription drugs for AI/AN Medicare beneficiaries at Federal Supply Schedule (FSS) prices or at the discounts available under the 340B program.*

Terms and Conditions Issue, Page 46658: CMS notes that the proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network. CMS seeks comment on whether it should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.

Comment: As the Preamble recognizes, there are 201 I/T/U pharmacies serving 107,000 elderly and disabled AI/ANs in 27 states (page 46657). These pharmacies currently have access to Federal Supply Schedule (FSS) prices for the prescription drugs they dispense to AI/AN Medicare beneficiaries, or they are covered entities entitled to discounts under the 340B program, 42 U.S.C. 256b, or both. These discounted prices reflect the purchasing leverage of the Federal government and have enabled I/T/U pharmacies to meet the needs of AI/AN beneficiaries, whether or not enrolled in Medicare, in a cost-efficient manner.

We are concerned that PDP sponsors and MA organizations offering an MA-PD plan may require participating pharmacies to purchase drugs through the PDP sponsor or MA organization. This could have the effect of forcing I/T/U pharmacies to choose between participating in Medicare Part D and retaining their current access to FSS prices or 340B discounts, or both. We do not believe Congress intended that I/T/U pharmacies be forced into this choice. We therefore propose that the final rule prohibit PDP sponsors or MA organizations from requiring I/T/U pharmacies to purchase drugs through mechanisms other than FSS or the 340B program. This would not preclude an I/T/U pharmacy that wished to do so from purchasing its drugs through the PDP or MA-PD plan. The option, however, would be that of the I/T/U pharmacy, not the PDP or MA-PD plan.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans should be revised to read as follows (modifications are *italicized*):

"(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;
(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; *and*

(iii) May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b. "

FORMULARY

Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements.

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule.

Goal: *I/T/*Us *should be exempt from formulary requirements and therefore able to utilize permissible substitutes. This exemption is needed to both accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries and to allow I/T/Us to include in their formulary of drugs for which reimbursement will be paid those drugs available through FSS or 340b.*

Comment: Section 423.120(b)(1) permits PDP and MA-PD plans to develop formularies so long as they meet the requirements of this section. We are concerned that plans that develop such formularies will make stocking the drugs in the formulary a requirement of its contracts with participating pharmacies. Many I/T/U pharmacies are small and cannot stock a full range of drugs, particularly if the condition the drug is used to treat is one beyond the scope of the I/T/U clinic and its providers. When establishing their formularies, I/T/U hospital and clinic pharmacies also consider aspects of treatment that may not be generally important, such as the extent of monitoring of the patient that may be required. Since many patients live far from the I/T/U pharmacy, this is an important therapeutic factor. Another factor in whether the I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principle sources of drugs purchased by I/T/U pharmacies. *See* "I/T/U Pharmacies and Federal Supply Schedule (FSS)."

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans in Section 423.120(a)(4) should be further revised to add a new paragraph (iv) to read as follows (new language is *italicized*):

  (v) May not require an I/T/U pharmacy to provide all the drugs in any formulary that may have been adopted by the PDP or MA-PD.

AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U pharmacies are often the only pharmacy providers (page 46657). It is unfair to the AI/AN beneficiaries and to I/T/U providers to limit reimbursement or increase co-pays when a beneficiary is prescribed a drug that is not on the PDP or MA-PD formulary when that may be the only drug available from the I/T/U pharmacy that provides the same therapeutic effect as the formulary drug. In such cases, the PDP or MA-PD should be required to reimburse the I/T/U as if the drug were on its formulary in an amount equal to that the PDP or MA-PD would have paid for an equivalent drug on its formulary. In this way, neither the PDP or MA-PD or the I/T/U pharmacy is disadvantaged financially, and the patients are able to maintain access and continuity of care.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (v) to read as follows (new language is *italicized*):

> *(vi) Must provide for reimbursement to I/T/U pharmacies for all covered Part D drugs whether or not they are on the PDP's or MA-PD's formulary at an amount not lower than the reimbursement that would have been made for an equivalent drug on the formulary.*

BENEFITS AND BENEFICIARY PROTECTIONS
Comments on Section 423.100: DEFINITIONS
"Insurance or otherwise" for purposes of "Incurred costs"

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *To ensure that expenditures by I/T/Us on AI/AN beneficiaries (who do not qualify for the cost-sharing subsidy for low-income individuals) on prescription drugs count toward the annual out-of-pocket threshold ($3,600 in 2006).*

Incurred Cost Issue, Pages 46649-46651: CMS notes that, under the proposed rule, AI/AN Medicare beneficiaries who are not eligible for low-income cost-sharing subsidies may receive drug coverage directly from I/T/U pharmacies or under CHS referrals. While these payments will count toward the AI/AN beneficiary's annual deductible, they will not count as incurred cost toward meeting the out-of-pocket threshold ($3,600 in 2006). The reason, in brief, is that "incurred costs" are defined by section 1860D-2(b)(4)(C)(ii) of the Social Security Act to exclude payments by "insurance or otherwise." But this statutory provision does not expressly include the I/T/U programs in this term. Rather, it is CMS, not the law that has defined what is encompassed by the term "insurance or otherwise". The agency has chosen to include I/T/U health programs as "insurance or otherwise," -- but has not explained the basis for that decision, nor analyzed the impacts of it on the IHS-funded system and affected Indian Medicare beneficiaries, nor acknowledged that failing to count I/T/U pharmacy contributions toward "incurred costs" would be a windfall to the PDP in which an affected Indian is enrolled. Perhaps CMS recognized that this matter requires additional thought, as it asks for comments on "how … IHS beneficiaries will achieve maximized participation in Part D benefits."

Comment: The effect of CMS's decision to treat I/T/U programs as "insurance or otherwise" is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, "most IHS beneficiaries would almost never incur costs above the out-of-pocket limit." (69 FR at 46657). And, as CMS further recognizes, this policy "would likely provide plans with additional cost-savings." (69 FR at 46657). We do not believe that Congress intended Part D to be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as "incurred costs." By using the phrase "not reimbursed by insurance or otherwise," Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not "reimbursed" by their IHS or tribal health care

providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. "fulfills the Secretary's unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes." In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

The proposed rule, however, does not recognize this "unique" legal relationship. Instead, the proposed rule would require those AI/ANs who are Medicare beneficiaries but who are not eligible for the low-income subsidy program to pay substantial amounts out of pocket for their Medicare prescription drug coverage in order to meet the out-of-pocket threshold. In this way, the proposed rule violates the federal trust responsibility, under which AI/ANs are entitled to needed health care services, including prescription drugs, at the federal government's expense.

Section 1860D-2(b)(4)(C)(ii) specifies that costs shall be treated as incurred if they are paid "by another person, *such as* a family member, on behalf of the individual." (*emphasis added*). In the "unique relationship" between the federal government and AI/ANs, the I/T/Us are the functional equivalent of a "family member." Their mission, on behalf of the federal government, is to pay for prescription drugs and other health care services needed by AI/ANs. In terms of paying for prescription drugs, there is no functional difference between I/T/Us fulfilling their obligations to AI/ANs and family members fulfilling their obligations to one other. Again, there is nothing in the concept of family members paying incurred costs to suggest that Congress somehow intended that payments by I/T/Us on behalf of AI/ANs not be treated as incurred costs.

In the preamble, CMS explains that contributions made by charities would be considered "incurred costs" and describes in detail the reasons for a desirable objectives achieved by this decision. Many of the considerations recited there apply to the I/T/U system, particularly the outcome that Medicare beneficiaries who are not eligible for the low-income subsidy would be able to qualify sooner for the catastrophic coverage level. In other words, these beneficiaries would have a better opportunity to fully utilize their Part D benefit.

The outcome is just the reverse with regard to an Indian not eligible for subsidy who is served by an I/T/U pharmacy. That Medicare beneficiary would have to pay the same premium for Part D coverage (or have it paid on his behalf by the I/T/U program as CMS suggests at p. 46651), but the benefit received for that premium would be only slightly more than $1000 -- far lower than that of a non-Indian beneficiary. This is so because this Indian patient would never get out of the "donut hole" and thus would never be able to utilize the catastrophic coverage feature of the Part D benefit.

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

Section 423.100-"Insurance or otherwise" for purposes of "Incurred Costs"

The definition of "insurance or otherwise" used to define "incurred costs" for purposes of meeting the out-of-pocket threshold should be revised to read as follows (modifications are *italicized*):

> "Insurance or otherwise" means a plan (other than a group health plan) or program *(other than a health program operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act , 25 U.S.C. 1603),* that provides, or pays the cost of, medical care…, including any of the following: …(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals *(other than American Indians or Alaska Natives or urban Indians as those terms are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603).*"

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

Comments regarding Section 423.286 Rules regarding premiums.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Tribes/Tribal Health Programs should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.*

Comment: We urge CMS to include I/T/U and/or tribes as permissible payment options and to remove barriers tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules. Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, would elect to pay premiums themselves.

AI/ANs served in an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the IHS based on the Federal Government's obligation to federally recognized Tribes. CMS recognizes this in the Preamble, page 46651, by stating that "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits". It is unlikely that AI/ANs, who are entitled to health care without cost sharing, would elect to pay premiums themselves, therefore, we request that language be included in the regulations recognizing the ability of I/T/Us to pay premiums if they so choose.

WAIVER OF COST SHARING

Comments on Background at 46651 and Section 423.120(a)(4)

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule and Formulary.

Goal. *Assure that I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B (b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.*

Comment: As discussed in the Preamble, the AI/AN beneficiaries receive health services under a unique government-to-government relationship between the United States and Tribes (page 46651). Under this relationship most care is provided directly by or through contract health services administered by I/T/U providers who provide the care without cost to the AI/AN beneficiary. The benefit plans provided under Medicare Part D contemplate patients sharing in the cost of the care they are provided. This is antithetical to the relationship between AI/AN beneficiaries and their I/T/U pharmacies.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (vi) to read as follows (new language is *italicized*):

    (vii) Must authorize I/T/U pharmacies to waive all cost sharing obligations of AI/AN beneficiaries.

CREDITABLE COVERAGE

Comments Regarding Section 423.56: Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *IHS coverage should be deemed "credible coverage" therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.*

Comment: The CMS TTAG strongly supports the decision of CMS to include in the definition of Creditable Prescription Drug Coverage a "medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U)" in the Medicare Prescription Drug Benefit Proposed Rule at § 423.56(a)(9). The Indian Health Service, Tribe or Tribal organizations, or Urban Indian organizations currently provide pharmaceuticals to AI/AN beneficiaries, either through direct care services or IHS Contract Health Services (CHS), at no cost to the beneficiary. For purposes of not being subject to late enrollment penalties, this Proposed Rule will protect those AI/AN beneficiaries who might not initially enroll in Medicare Part D because, for example, they receive their pharmaceuticals from an I/T/U pharmacy but later relocate off reservation and therefore need prescription drug coverage under Medicare Part D.

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

EXCLUDE CERTAIN INDIAN-SPECIFIC INCOME AND RESOURCES FOR CONSIDERATION OF ELIGIBILITY OF AMERICAN INDIANS AND ALASKA NATIVES FOR LOW-INCOME SUBSIDIES

Comments regarding Section 423.772: Premiums and Cost Sharing Subsidies for Low-Income Individuals-Definitions

Goal*:* To exclude from the income and resources tests for determination of an American Indian or Alaska Native (AI/AN) Medicare beneficiary's eligibility for a low-income subsidy under Part D certain income and assets that are excluded from consideration when determining eligibility for Medicaid.

Comment. CMS has recognized that certain Indian-specific income and assets are to be excluded when determining the eligibility of an AI/AN for Medicaid. *See, e.g.*, CMS State Medicaid Manual Part 3 -- Eligibility, §3810. These same exclusions should apply to the determination of whether an AI/AN qualifies for a low-income subsidy under Part D. Since all dual eligibles will be moved from Medicaid to Part D for prescription drug coverage, it is appropriate that the same federally-established exclusions should apply to the affected AI/AN dual eligibles.

In **Sec. 423.772,** the definitions of "income" and "resources" should be revised to exclude income that derives from tribal lands and other resources currently held in trust status, from judgment funds awarded by the Indian Claims Commission and the U.S. Claims Court, and from other property held in a protected status, as specified in the Medicaid Manual. In addition, cultural objects, as specified in the Medicaid Manual, should also be exempted from the definitions of these terms.

ELIGIBILITY AND ENROLLMENT

Comments regarding Section 423.48: Information about Part D.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.*

Comment: Without outreach, education and enrollment assistance from Indian health programs, AI/AN are unlikely to enroll in Medicare Part D or Part C. AI/AN are entitled to receive free health care at I/T/Us and through Contract Health Services, thus they have no incentive to enroll in programs requiring premiums and cost sharing. I/T/Us know who may be eligible for new Medicare programs and how to contact them. AI/ANs trust I/T/U health workers. Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to I/T/U at no cost. As CMS states on Page 46642 of the Preamble, “we would undertake special outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries.

Materials and information would be made available in languages other than English, where appropriate." In implementing this provision CMS must reach out to AI/AN beneficiaries.

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Plan" or Plan Sponsor") and _____ (herein "Provider") for administration of Transitional Assistance under the Prescription Drug Discount Card program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 at pharmacies and dispensaries of Provider. To the extent that any provision of the Special Endorsed Plan Master Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Special Endorsed plan Master Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Plan Sponsor" means _____ which operates the Prescription Drug Discount Card Plan defined in subsection (b).

(b) The terms "Prescription Drug Discount Card Plan" and "Plan" means a Prescription Drug Discount Card Plan operated by Plan Sponsor that is approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and holds a special endorsement from CMS to administer the Transitional Assistance feature of the Prescription Drug Discount Card program at pharmacies or dispensaries operated by the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations (hereafter "I/T/U endorsement").

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Co-pays, deductibles.

The parties agree that the Provider may waive any co-payments for any Indian who is enrolled in the Plan when such Indian receives services pursuant to the Plan at any pharmacy or dispensary of Provider.

5. Persons eligible for services of Provider.

(a)The parties agree that the persons eligible for services of the Provider under the Special Endorsed Plan Master Agreement and all addenda thereto shall be governed by the following authorities:

(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations
(2) Sec. 813 of the Indian Health Care Improvement Act, 25 USC §1680c
(3) Part 136 of Title 42, Code of Federal Regulations
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Special Endorsed Plan Master Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.;*
(2) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;

(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;

(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

Provider is a non-taxable entity and as such shall not be required by Plan or Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. A Provider which is an urban Indian organization which holds designation as a Federally Qualified Health Center shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify Plan or Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located, and shall be deemed qualified to provide services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided that such employee is currently licensed to practice pharmacy in any State. To the extent that any State exempts from state regulation a direct employee of Provider, such employee shall be deemed qualified to perform services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements pursuant to 42 CFR §431.110, the Provider shall not be required to hold a State license to receive any payments under the Special Endorsed Plan Master Agreement and any addendum thereto.

11. Re-Enrollment Period.

The Centers for Medicare and Medicaid Services has established as a matter of policy that an enrollee eligible for services from an I/T/U pharmacy shall be permitted to disenroll from a prescription drug discount card plan that does not hold a special I/T/U endorsement and to re-enroll in a plan that has received such endorsement at any time during the life of the Medicare Drug Discount Drug Card Program. Nothing in the Special Endorsed Plan Master Agreement or any other addendum thereto shall be interpreted to impede this right of re-enrollment.

12. Dispute Resolution.

Any dispute arising under the Special Endorsed Plan Master Agreement or any other addendum thereto shall be resolved through negotiation rather than arbitration. The parties agree to meet and confer in good faith to resolve any such disputes.

13. Governing Law.

The Special Endorsed Plan Master Agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between the Special Endorsed Plan Master Agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

14. Pharmacy/Dispensary Participation.

The Special Endorsed Plan Master Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum.

15. Acquisition of Pharmaceuticals.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in the Special Endorsed Plan Master Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

16. Formulary.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's formulary. The Provider is exempt from any provision of the Special Endorsed Plan Master Agreement and all addenda thereto requiring compliance or cooperation with the Plan Sponsor's or Plan's formulary, drug utilization review, generic equivalent substitution, and notification of price differentials.

17. Transitional Assistance Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim. When the toll-free number is used for non-electronic claims, Plan will verify the balance of an enrollee's Transitional Assistance subsidy remaining as of that time and obligate funds from that subsidy for payment of the Provider's claim at the point of sale. Instructions for filing and adjudicating non-electronic claims are attached as Schedule C.

18. Payment Rate.

Claims from the Provider for Transitional Assistance benefits shall be paid at the same rates as the State Medicaid program fee-for-service in the State where the Provider's pharmacy or dispensary is located, pursuant to Schedule A of this Addendum.

19. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Plan shall be supplied by Plan to Provider in paper and electronic format at no cost to the Provider. Provider shall have the right to convert such materials as it deems necessary for language or cultural appropriateness.

20. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Plan, Provider shall provide written notification of its hours of service to the Plan.

BRISTOL BAY AREA HEALTH CORPORATION

Kanakanak Hospital
P.O. Box 130 • Dillingham, Alaska 99576
(907) 842-5201

October 4, 2004

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

via electronic delivery: <http://www.cms.hhs.gov/regulations/ecomments>

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)
File Code CMS-4068-P

Dear Administrator:

On behalf of the Bristol Bay Area Health Corporation (BBAHC), I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program. BBAHC operates the Indian Health Service-funded health program serving the Alaska Natives in the Bristol Bay region of Alaska and serves a geographic area equivalent to the size of the state of Ohio.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

Please keep in mind that delivery of health services to Alaska Natives is fraught with extreme challenges. Most of the communities we serve cannot be reached by surface transportation; small aircraft or boat must be used to supply health services to residents in those communities. Because of this circumstance, most -- and in some communities, the only -- health care available is provided by Community Health Aides/Practitioners who must receive intensive training to carry out this vital health care mission.

We ask that you recognize that the small, very dispersed population in our State does not make it an attractive area to be served by the PDPs envisioned by the law and regulations. Thus, Alaska Natives are unlikely to have a reasonable choice of PDPs to provide prescription drug coverage under Part D. BBAHC, like other IHS-funded programs, provides prescription medications to Alaska Natives without charge to the patient, but we can and do bill Medicaid for drugs dispensed to our dual eligibles. We are very concerned about how we will maintain the revenue we receive from Medicaid for these prescriptions when we have to try to enroll these patients in a Part D program by 2006. That is why we urge CMS to assure that our program, and all IHS-funded programs, do not suffer a loss of revenue under the new program. You must also guard against the increase in pharmacy drug prices that occurred after the Temporary Drug Discount Card program was put into effect.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

Robert Clark/bjf

Robert Clark, CEO
Bristol Bay Area Health Corporation

Attachment -- Part D Comments

CMS-4068-P-1033

Submitter : Nora Dowd Eisenhower Estelle B. Richman **Date & Time:** 10/04/2004 06:10:43

Organization : PA Departments of Aging & Public Welfare

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please See Attached

CMS-4068-P-1033-Attach-1.doc

COMMONWEALTH OF PENNSYLVANIA

October 4, 2004

Dr. Mark McClellan, 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

Dear Dr. McClellan:

Thank you for the opportunity to provide comment on the above referenced proposed rulemaking for the Medicare Prescription Drug Benefit pursuant to section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). On behalf of the Commonwealth of Pennsylvania, we are pleased to provide the enclosed comments for your consideration. Please feel free to contact us with any questions.

Sincerely,

Estelle B. Richman
Secretary
Department of Public Welfare
Box 2675
Harrisburg, PA 17105
(717) 787-2600

Nora Dowd Eisenhower
Secretary
Department of Aging
555 Walnut Street, 5th Floor
Harrisburg, PA 17101-1919
(717) 783-1550

Subpart A. General Provisions

423.4 Definition of State Pharmacy Assistance Program (SPAP) – See comments below regarding Subpart J.

Subpart B. Eligibility, Election and Enrollment

Comments Relating to the Enrollment of Dual Eligible Individuals

1. Preventing gaps in Coverage for Dual Eligible Individuals: Section 423.34 provides for automatic enrollment of dual eligible individuals only at the end of their initial enrollment period, which for currently enrolled individuals is May 15, 2006 – while Medicaid drug coverage is eliminated as of January 1, 2006. Based on our experience in enrolling Medicaid enrollees in managed care plans, it is foreseeable that many will not exercise their choice, will not do so in a timely manner, or will have difficulty doing so. It is essential that there be no coverage gap for dual eligible individuals in order to ensure continuity of care for a highly vulnerable population with substantial prescription drug needs. We recommend that CMS revise its implementation timeline to automatically enroll all dual eligible individuals who have not made a PDP or MA-PD selection by no later than December 1st, 2005.

2. Automatic Enrollment for dual eligible individuals in PDPs on a "Random basis": Section 423.34(d)(2) provides that, if there is more than one PDP in a region with a beneficiary premium at or below the subsidy amount, dual eligible individuals will be automatically enrolled in one of such PDPs "on a random basis." The statute also provides for "random" assignment (section 1860D-1(b)(1)(C)). In this context, where differences in Part D plan formularies, pharmacy networks, or other plan features may impede meaningful access to life-saving drugs, "random" assignment should be interpreted to mean "assignment among all such PDPs in the region that are appropriate for the beneficiary's particular needs."

Accordingly, States should be permitted to develop automatic assignment methodologies that would advance care coordination and continuity of care for dual eligible individuals if there were more than one PDP in the region for which automatic enrollment would be appropriate. For example, as part of the automatic assignment process, we recommend that CMS allow States to automatically enroll long term care residents in the same facility to the same Part D plan in order to assist with ongoing care coordination.

3. State option to perform the automatic enrollment process: The preamble specifically seeks comment on what entity should perform the automatic assignment/enrollment process. We recommend that CMS allow States the option of performing the automatic assignment using the assignment methods described above.

States should be fully compensated for their automatic enrollment activities, either through 100% FFP or through a contractual relationship with CMS. The MMA assigns the responsibility for automatic enrollment of dual eligible individuals to the Secretary of HHS, 1860D-1(b)(1), and therefore States should not be required to finance those activities. The

statutory provision does not reference or amend Title XIX of the Social Security Act, and therefore the preamble's proposal to make automatic enrollment a requirement of a State Medicaid plan is inappropriate.

4. Automatic Enrollment for Individuals becoming eligible after January 1, 2006: Section 423.36 discusses establishing three enrollment periods: initial, annual coordinated, and special enrollment periods. When a person becomes a dual eligible individual – whether that means that an individual is newly enrolled in Medicaid, newly eligible for Medicare, or both that occurrence should initiate a special enrollment period under section 423.36(c) to ensure that dual eligible individuals will have prescription drug coverage immediately. Because enrollment in Medicaid is often initiated when an individual has immediate medical needs, the special enrollment process for dual eligible individuals should ensure that immediate prescription needs can be met. The Office of Income Maintenance recently surveyed local Medicaid eligibility offices on their experiences issuing "interim cards" – temporary cards that can be issued immediately to new Medicaid enrollees. It was found that on the average, the Commonwealth issues 350 to 400 cards a month to meet immediate medical needs. The majority of immediate medical need requests are for prescription drug coverage.

Typically, once an individual enrolls in Medicaid, the permanent plastic PA ACCESS card is mailed to the Medicaid beneficiary and, depending on location and mail service, is received after computer generation within 2 to 3 days. When an individual has an immediate need, an interim card is issued so the individual does not have to wait for the ACCESS card to obtain services. Interim cards are issued the same day that the individual is determined eligible and are valid for a limited period of up to 7 days, becoming void after the issuance of the actual ACCESS card.

Because the Medicaid agency will no longer be able to provide interim cards covering prescription drug expenses to individuals who are just becoming eligible for Medicaid after January 1, 2006, there needs to be an expedited process to provide coverage under Part D for immediate medical needs.

5. Opt-out Provision for Dual Eligible Individuals: Section 423.34(d)(3) provides that an automatically-enrolled dual eligible individual may choose to decline enrollment in any Part D plan, essentially opting out of Part D coverage altogether. Because States will no longer have the option of providing Medicaid drug coverage for people eligible for Part D, the dual eligible individual who opts out of Part D will likely be left with no prescription drug coverage at all. Furthermore, if s/he tries to reenroll in a Part D plan at a later time, s/he will be subject to a late enrollment penalty. Persons without drug coverage end up as heavy users of hospital emergency rooms, costing both Medicare and Medicaid additional dollars. Due to illness, language barriers, health literacy or mental incapacity, these individuals may also not appreciate the potentially harmful consequences of declining enrollment in any Part D plan. Therefore, dual eligible individuals should not be allowed to completely opt out of the Part D coverage except in limited circumstances. For example, a dual eligible individual might be permitted to disenroll from any coverage if s/he had alternative coverage; if enrollment would disqualify him/her from other benefits; or if enrollment itself would result in out-of-pocket spending, for example if a late

enrollment penalty applied. Of course, dual eligible individuals should remain free to disenroll from any particular Part D plan in favor of another plan.

Comments Relating to Enrollment Generally

6. Outreach/Brokerage Effort: Although the preamble asserts that CMS will implement a national education and outreach effort, we are concerned that the regulations do not explain CMS's planned enrollment assistance or brokerage function. It is clear that consumers will be making difficult and potentially confusing choices between various Part D plans, in some cases prior to automatic assignment and in some cases after. No matter when consumers choose to exercise their right to switch plans, some process must be in place to provide support for their decision-making. Furthermore, for those consumers who are automatically assigned to a plan, there will be a significant need to educate them, their physicians and their pharmacies about the new rules of their prescription drug coverage in order to ensure that they have meaningful, and not just hypothetical, access to needed drugs. Many Medicaid programs, including Pennsylvania's, employ enrollment brokers to assist consumers making a selection among managed care organizations. We have found this function invaluable in assisting consumers matching their medical needs with the appropriate managed care organization. We urge CMS to create and administer an enrollment education or brokerage function for the Part D program.

7. Automatic Enrollment for Individuals Enrolled in SPAPs: The proposed regulation should explicitly permit automatic enrollment of SPAP beneficiaries into Part D plans, as long as beneficiaries have the ability to opt out of automatic enrollment. Section 423.42(a) provides that enrollment can be effected by an individual filing an enrollment form or "through other mechanisms CMS determines are appropriate"; the final rule should specifically approve an SPAP automatic enrollment mechanism. This approach is consistent with the statutory requirements of the MMA, and the MMA Conference Report explicitly envisions an enrollment function for SPAPs, providing that SPAPs are permitted "to act as administrative intermediaries for the purpose of facilitating enrollment of SPAP members in prescription drug plans and in the discount card program."

This kind of automatic enrollment process was successfully used in the Medicare Drug Discount Card program and should be repeated in Part D. Before automatic enrollment was authorized, very few SPAP beneficiaries had elected to receive Transitional Assistance or a Medicare Discount Card, and there is little reason to believe that the experience with the Part D benefit would be significantly different. However, because of automatic enrollment, PACE successfully enrolled approximately 110,000 beneficiaries into Transitional Assistance and the discount card. Likewise, with automatic enrollment, SPAP beneficiaries could experience a smooth and hassle-free transition to Part D. Enrollment of approximately 100,000 PACE beneficiaries in Part D would be assured, and PACE could coordinate wrap-around coverage for non-low-income subsidy eligible individuals with a minimum of administrative burden to the PDP or to the beneficiary. Providing auto enrollment with an opt out capability would ensure the Part D enrollee the choice of plans that is required by the rules.

8. Late Enrollment Penalty: Section 423.46 provides that all Part D eligible individuals are subject to the late enrollment penalty if they were eligible for, but did not enroll in, a Part D plan and they did not have creditable coverage for any period more than 63 days after the end of their initial enrollment period. This presumably applies to individuals eligible for low-income subsidies ("LIS"), including dual eligible individuals, though the amount of the penalty that they would have to pay out of their pockets is reduced compared to non-LIS enrollees. CMS should exempt new dual eligible individuals from the late enrollment penalty entirely, because the late enrollment penalty could result in extreme hardship and/or a total lack of coverage for dual eligible individuals who generally have very low incomes and, for those who are in institutions, may not have enough disposable income to pay the late enrollment penalty. Dual eligible individuals will be automatically enrolled in Part D plans, but many low-income individuals may become dually eligible long after they are first eligible to enroll in a Part D plan. These people would not have had a facilitated enrollment process and may have been unable to afford the Part D benefit or simply been unable to complete the enrollment process. Many of these individuals who become dually eligible after they become Medicare beneficiaries suffer from serious mental or physical impairments.

9. Notice of creditable coverage for Medicaid Programs: Proposed section 423.56 provides that prescription drug plans must provide notice to enrolled and potentially enrolling beneficiaries as to whether the plan's coverage is "creditable" under the terms of the MMA. Section 423.56(a)(2) lists "Medicaid coverage under title XIX" as one of the kinds of coverage that might be "creditable" and therefore, under 423.56(b), it would appear that States must provide notice of actuarial equivalence to any Part D eligible individual seeking to enroll in Medicaid. This burdensome requirement makes no sense considering that Medicaid drug coverage will effectively terminate for dual eligible individuals beginning on January 1, 2006. After January 1, a State Medicaid program would be permitted to cover only a small number of drugs that are excluded from coverage under Part D for dual eligible individuals. This kind of coverage would never be actuarially equivalent to Part D coverage. At the same time, the burden to States of having to provide creditable coverage notices to every dual eligible individual prior to their enrollment in Medicaid would be significant; it also might dissuade eligible individuals from enrolling in Medicaid for the other benefits it provides. CMS should explicitly exempt States from this notice requirement (unless the State operates a Medicaid waiver program that provides meaningful drug coverage to Medicare beneficiaries).

Subpart C. – Benefits and Beneficiary Protections

1. Definitions: Long-term care facility: Under the definitions in proposed section 423.100, only nursing facilities are considered "long-term care facilities," and therefore, only those facility residents are entitled to low-income subsidies for the full amount of any prescription drug cost-sharing. This definition should be expanded to include ICF/MRs and assisted living facilities and other facilities in which dual eligible individuals would be limited to a monthly "personal needs allowance" that would limit their ability to pay any prescription cost-sharing.

2. Pharmacy access standards: Section 423.120 does not require Part D plans to contract with institutional pharmacies or to guarantee that they can effectively distribute drugs to long term care facility residents. CMS explicitly sought comment on whether long-term care pharmacies had to be part of a Part D plan's network. We recommend that, at a minimum, CMS require Part D plans to submit as part of their application to CMS their plan for distributing drugs to long term care residents, whether or not this plan involves contracting with long term care pharmacies. CMS should not approve a pharmacy network if it does not adequately provide for the distribution of drugs to long-term care residents. We do not believe that using the "out of network" exception for long term care facility residents is a reasonable solution, since that could leave residents who are not dual eligible individuals financially responsible for certain additional costs under 423.124(b).

3. Determination of Regions: Proposed rule 423.112 provides that CMS will determine PDP and MA regions. We understand that several options are under consideration, including 50 state-based regions and fewer multi-state regions (10, 11, 24 and 41 multi-state regions). In the options providing for 24, 41 and 50 multi-state regions, Pennsylvania, as well as many other States, would stand alone as separate regions. Pennsylvania views these three options as the preferable choices and advocates for the creation of more, rather than fewer, regions. Creating more regions with the opportunity for Pennsylvania to stand-alone as a region acknowledges the reality that health care is a local matter and would best allow existing State-based programs and institutions to work effectively within the new Part D system. We are particularly concerned that PACE, our very successful State Pharmacy Assistance Program, be able to work effectively with new health care organizations and partners, and this will be most easily accomplished if the new organizations – PDPs, MAPDs, and MA organizations – operate within the same geographical and jurisdictional boundaries as PACE.

4. Continuity of Drug Therapy for Dual Eligible Individuals: The draft regulations on formulary access, 423.120(b), do not require the PDPs or MAPDs to provide access to drugs not on their formulary for dual eligible individuals who are taking those non-formulary drugs at the time of enrollment. We have serious concerns about the potential harm to dual eligible individuals who may be required to change multiple prescriptions within a very short period of time when they transition to Part D coverage. Dual eligible individuals include many heavy prescription drug users with complex medical conditions; many people with mental illness; HIV/AIDS; and disabilities. Furthermore, because Pennsylvania Medicaid's fee for service program does not prior authorize behavioral health drugs or operate a preferred drug list program, our dual eligible individuals are not currently experienced with navigating formulary restrictions. Accordingly, we recommend that CMS treat dual eligible individuals as a special population, envisioned in the proposed rule preamble that would not be subject to formulary restrictions. Alternatively, we would recommend that CMS treat dual eligible individuals as such a special population at least for the first six months of the new benefit, so that they and their physicians have a reasonable period in which to consider changes in drug therapies or to pursue coverage determinations or appeals.

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

1. Quality Assurance: Quality assurance (QA) requirements in 423.153(c) should include data sharing between Part D plans, CMS, and Medicaid and SPAP programs. Quality assurance and evaluation are the most critical components of an effective drug benefit program and must result in quality improvement. It does not matter if beneficiaries can purchase affordable drugs if medications are not being prescribed or if beneficiaries are receiving medications inappropriate to their individual needs. QA and evaluation must be viewed in an integrated manner to ensure that not only are we accessing and collecting appropriate data on the benefit plans, but also that data is being properly analyzed and then used to improve program performance.

Currently, Pennsylvania is the only State that has full access to the Medicare database. Pennsylvania pays for the Medicare data and finds it very valuable in evaluating whether State programs are actually helping individuals by keeping them healthy and out of hospitals. There is no other current mechanism in place for the drug benefit program to be evaluated on a regular basis to assess what is and is not effective in the program. That information needs to be used by programs to make on-going quality improvements.

CMS should improve quality assurance programs in Part D by sharing CMS Medicare data, without charge, with SPAPs and Medicaid programs. CMS should also issue annual reports assessing the effectiveness of the Part D drug benefit program and its impact on other aspects of Medicare and Medicaid programs. Those aspects include, but are not limited to, beneficiary access to medications, patient hospitalizations and nursing facility residencies, utilization of home and community based services, and fiscal implications of the drug benefit. There should be a quality improvement process for Part D that comes from the evaluation and information gathered from the CMS annual reports, and SPAPs should have a role in that larger quality improvement process.

2. Care Coordination of Dual Eligible Individuals: Proposed section 423.153(d)(4) requires Part D plans to develop medication therapy management programs that are, among other things, coordinated with care management plans for targeted individuals established under section 1807 of MMA, but it does not require coordination with any other entities. Care coordination is vital for Medicaid programs to ensure effective management and quality care for dual eligible individuals. This provision should include requirements that Part D plans be required to execute care coordination agreements with each State that it operates in for dual eligible individuals. These agreements would require data sharing and coordinated care management plans for eligible individuals. 423.153(d)(2) should be revised to include dual eligibility for Medicare and Medicaid as a factor that qualifies an individual for medication therapy management programs.

Subpart I. Organization Compliance With State Law and Preemption by Federal Law

1. State Authority to Require Coordination as Condition of Licensure: Proposed section 423.410 provides that CMS may waive State licensure requirements under various circumstances. The circumstances listed are broad and vague, suggesting that State licensure is easily avoided by plans. In particular, 423.410(c)(2) provides that CMS may grant a waiver of

licensure if the State has denied a license on the basis of "material requirements, procedures, or standards…not generally applied to other entities engaged in a substantially similar business." Because there is no "substantially similar business" as that contemplated by Part D plans, this provision could be read as an extremely broad prohibition on State licensing conditions on Part D plans. Pennsylvania is considering requiring as a condition of licensure of Part D plans that the plans agree to care coordination arrangements and data sharing, with appropriate protections, with State health programs, like Medicaid, to ensure the highest quality care for Pennsylvanians enrolled Part D. The proposed regulations should be revised to permit this State licensure requirement.

Subpart J. Coordination under Part D with Other Prescription Drug Coverage

1. SPAPs and Preferred Prescription Drug Plans: Proposed Section 423.464(e) provides that an SPAP is a program that "provides assistance … in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." This language is more restrictive than the statutory language in the MMA 1860D-23(b)(2), which provides that an SPAP "in determining eligibility and the amount of assistance to part D eligible individuals . . . does not discriminate based upon the part D plan in which such individual is enrolled." Under the controlling statutory definition, an SPAP would not be prohibited from recommending, steering, or automatically assigning its enrollees to a preferred part D plan, as long as SPAP enrollees would remain eligible for the same amount of assistance if they opted to enroll in a different Part D plan. CMS' proposed interpretation of the MMA provisions would not allow SPAPs to develop a relationship with a preferred PDP. Not only is CMS' proposed interpretation not supported by the language of the MMA, but it would limit the ability of Pennsylvania's PACE program to ensure maximum Part D enrollment, facilitate a smooth transition for its enrollees, and negotiate the most generous benefit plan for its enrollees. The final regulation should not unnecessarily restrict SPAPs from facilitating the kind of automatic enrollment that was so successful in the Discount Card context.

2. Definition of "Cost management tools" and Coordination Requirements: The proposed section 423.464(d) does little to clarify or explain how CMS will implement, or allow PDPs to implement, a very general statutory provision providing that coordination requirements "shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments) under all methods of operation." 1860D-24(c)(1). It is foreseeable that Part D plans and SPAPs or other prescription drug plans will have different views on whether certain forms of coordination will "impair" the application of "cost management tools." CMS should at least provide more detailed standards and establish a procedure for resolving disputes relating to this provision. Absent such guidance, PDPs or MAPDs may claim to have veto power over any coordination arrangement that provides cost-sharing assistance or expanded formulary access, with significant consequences for beneficiaries and the operation of the Part D program.

Subpart K – Application Procedures and Contracts with PDP Sponsors

1. Termination of Contracts: Proposed section 423.509(a) provides a list of bases for CMS' termination of a contract with a PDP or MA organization. We recommend adding to the lengthy list termination for failure to adhere to the requirements of Subpart J, or otherwise impeding the coordination of benefits between the organization and SPAPs, employer-sponsored prescription drug plans, or other defined "Rx plans." Because of the Part D benefit design, enrollees who are not eligible for low-income subsidies will still be subject to substantial financial exposure for prescription drug costs. The success of the Part D benefit depends on the coordination of Part D with other third-party payors – payors who can help fill in some of Part D's gaps. If plans are unwilling to cooperate with these other payors, it could have seriously damaging consequences for beneficiaries and for the viability of the Part D benefit.

Subpart P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals.

1. Interaction with Social Security Administration and Extending the Comment Period: Because the MMA establishes parallel low-income subsidy eligibility determination processes performed by States and by the Social Security Administration, it is very difficult to comment meaningfully on proposed regulations that only provide guidance to States, and not regulations guiding the SSA process. Understanding the interaction between the two eligibility determination processes is of critical importance to States and to beneficiaries. Accordingly, we would ask that the comment period for this portion of the proposed regulation remain open until comments are due on SSA's proposed regulations. Only by looking at the two sets of regulations together can we understand how the low-income subsidy eligibility determination process is likely to work and can we provide meaningful comments on the regulations and their interactions.

2. Family size/Income Determinations: When States have to determine eligibility for low-income subsidies, the proposed rules, section 423.772, provide that States can only count a person (other than the spouse) for household size purposes if the applicant provides at least one-half support for that person. The Medicaid program has no such one-half support test, so if State agencies have to determine eligibility for the Part D subsidy, they will have to calculate household size differently for the Medicaid Program than for Part D. This raises personnel training and automated systems concerns and will be burdensome to implement.

The regulations should also clarify if income such as Supplemental Security Income (SSI) and Temporary Assistance for Needy Families (TANF) of other family members will impact eligibility.

3. Resources: The regulations at section 423.772 should clarify if "liquid resources" would include those resources that can be converted to cash within 20 days, but would require a monetary loss, such as a tax payment or penalty payment, to applicant. We would suggest that a resource should be excluded if liquidating that resource would result in a financial loss (penalty) to the individual.

The preamble States that the Secretary proposes to decline using his statutory authority to permit States to use the income and resource methodology flexibility available to them in

determining eligibility for Medicare Savings Programs when making low income subsidy eligibility determinations under Part D. The final regulations should reverse that decision and permit States to use existing systems to determine eligibility for Part D low-income subsidies.

4. Data sharing between Medicaid programs and SSA for Verification: The preamble discusses a data sharing system between State Medicaid agencies and SSA that can be used to verify eligibility for low-income subsidies. For such a data sharing system to be implemented efficiently, CMS or the Department of Health and Human Services (HHS) should enter into a memorandum of understanding with SSA to provide for this data exchange. Individual States should not be required to negotiate and enter into agreements with SSA. Development of a data-sharing information exchange between SSA agencies and Medicaid agencies will be useful to States in identifying current Part D beneficiaries and providing information on PDP coverage to beneficiaries. Also, data sharing could be used by SSA to notify Medicaid agencies of potential Medicaid beneficiaries. This could streamline the Medicaid application process because the Part D application information can be used to determine Medicaid or Medicare Savings Program eligibility. Data-sharing requirements will need to be provided to States as soon as possible to allow time for system modification and development.

Subpart S. Special Rules for States - Eligibility Determinations for Low-Income Subsidies and General Payment Provisions.

1. Eligibility Determinations by States: The preamble suggests that the Social Security Administration and CMS are developing a simplified model application form and a process that States could use in making eligibility determinations. Because the details of the application form and the SSA's proposed process have not yet been published, it is difficult for us to comment or even predict whether or not Pennsylvania would take advantage of a process that relied on SSA's model form. We hope that after SSA publishes proposed regulations and finalizes a draft application that CMS and SSA will have a joint open comment period in which the public could revisit comments to CMS on its LIS determination proposed rules. It would be best if a prototype notice was provided to States but States would be permitted to modify it to work in their Medicaid eligibility and notification systems.

2. Timeframe for renewals: Proposed section 423.904(a) suggests that States will follow their current timeframes for redeterminations/renewals, while the timeframe for SSA renewals is left uncertain. Proposed section 423.774(c)(2) provides that SSA will do redeterminations "in the manner specified by the Secretary." In our experience, the population this type of benefit is intended for – low-income elderly and disabled individuals – is less likely to have changes in their eligibility than other low-income populations. Therefore, Pennsylvania would propose to use a passive redetermination (renewal) process for this population, requiring the State to mail a snapshot of the individual's reported circumstances to him/her each year and only requiring the individual to respond if there are changes to report. A recent review of case data involving older and disabled households revealed that the most frequent reason why this population loses eligibility for Medicaid at the time of renewal is failure to provide information (i.e., they have difficulty complying with the process), not because they have had a change in circumstances that affects their eligibility. Additionally, because the Conference Report urges the use of multi-year

renewals, the same timeframe should apply to any renewals the State is responsible to complete. Having different renewal timeframes would add to the likelihood of inconsistent results depending on whether a beneficiary applied with Medicaid or with SSA. Furthermore, the proposed regulations provide no information about what the SSA redetermination/renewal process will look like. If possible, a standard "passive renewal" process should be developed by CMS or SSA that States are encouraged to use that only requires an individual to report changes in their circumstances.

3. Notification of Eligibility: 423.904(c) specifies that States must notify deemed subsidy eligible individuals of their subsidy eligibility. Clarification is needed on the notification process that States should use. Will States do this through the current Medicaid notification process or will special notices be developed for States to use?

4. Low-Income Subsidy Applications: Proposed 423.904(d) provides that States must make LIS application forms available, provide information on the requirements on the subsidy program, and provide assistance to Medicare beneficiaries in completing applications. In order to develop a timeframe and plan for implementation, States need to know if CMS intends to develop the materials for States to provide to individuals on the program or if CMS will provide guidelines for States to develop their own materials, including applications, notices, and other materials. If States are required to develop materials, they need to be informed as soon as possible to allow time for development and distribution to field offices. If States are going to be required to assist low-income subsidy applicants with a new application, actually determine eligibility based on the application, verify the information on the application, input the benefits into the State and a federal eligibility system and send notification of the eligibility decision, this will be extremely burdensome to local office staff. We estimate that, depending upon the size of the local office, a minimum of one to three staff in each local office would have to be dedicated to Part D low-income subsidy application processes. Pennsylvania has over 100 local offices. Additional headquarters staff would be used to develop materials, modify the eligibility system, and complete necessary reports. Additionally, sufficient time does not exist for automated eligibility systems to be modified, interfaces to be developed, and training and communication mechanisms to be developed before July 1, 2005.

5. Eligibility Verification: Section 423.904(d) provides direction on the process used to verify eligibility for low-income subsidies. The verification requirements and process should be the same for both SSA and Medicaid agencies to provide consistency in the Part D application and approval process. Pennsylvania agrees with the concept that allows using data exchanges, applicant/recipient collateral statements and information known to agencies for eligibility verification. We would prefer to minimize the verification burden on the client because most sources of income and resources could be verified through third-party sources.

Comments Relating to 423.902: Determining the State Contribution Payment

1. Calculating the Base Year Rebate Percentage: Proposed section 423.902 defines the "Rebate adjustment factor," which is a critical element in calculating the State's significant "contribution payment" to the federal government. The proposed method for calculating the

base year rebate percentage would divide rebates received by the State in CY 2003 by total drug expenditures made by the State in CY 2003. This approach will understate the true rebate percentage that the State is entitled to based on its 2003 expenditures, because a significant portion of rebates received in 2003 were for drug claims/expenditures from CY 2002. Since drug expenditures grew at double digit rates, 12% in 2002-03, using rebates collected from (smaller) 2002 expenditures as the numerator and the total (larger) expenditures from 2003 will understate the true rebate percentage by several percentage points.

We urge CMS to allow States to identify the amount of rebates collected related to 2003 drug claims in calculating the rebate percentage. We believe that only this approach would accurately determine the rebate percentage for CY 2003 and that it is well-supported by the statutory language of the MMA, which provides that the amount of rebate payments "for 2003" (it does not talk about payments made "in 2003") can be based on information in the four CMS-64 for calendar year 2003 "and such other data" in the discretion of the Secretary. Section 1935(c)(3)(B)(iii) of the Social Security Act. Alternatively, we would urge CMS to calculate the rebate percentage using a blending of CY 2002 and CY 2003 expenditure/claim costs for the denominator in the calculation to match the effective blending of the related CY 2002 and 2003 rebates.

2. Calculating the Drug Costs of Dual Eligible Individuals in Managed Care: Proposed section 423.902 defines the actuarial value of capitated prescription drug benefits provided to dual eligible individuals in managed care as an "estimated" actuarial value determined using data the Secretary determines appropriate. Pennsylvania has 125,000 full benefit dual eligible individuals in its Medicaid program, 44 percent of who are enrolled in managed care plans through the Commonwealth's mandatory HealthChoices program. Therefore, a large part of Pennsylvania's "State contribution" will be based on the Secretary's "estimate" of the actuarial value of capitated drug benefits. The current regulations do not provide specific details as to how the managed care calculation will be performed or what data it will be based on. We recommend that the regulations require CMS to accept state-specific methodologies for this calculation, and, specifically, to allow states to use either actual pharmacy claims encounter data from managed care plans or plans' summary cost data for the dual eligible population. This type of data is available to Pennsylvania's Medicaid program.

CMS-4068-P-1034

Submitter : Pat O'Neal **Date & Time:** 10/04/2004 06:10:53

Organization : Arlington Clinical Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-4068-P-1034-Attach-1.doc

Arlington Clinical Pharmacy, 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.

Arlington Clinical Pharmacy, Inc., is an independent home infusion pharmacy and home health nursing management company serving the island of Hawaii since 1991. Arlington Clinical is a preferred provider for all health plans in Hawaii, including the Blue Cross affiliate, which manages the only Medicare HMO in the islands. We specialize in providing state-of-the-art infusion services in patients' homes in virtually all treatment modalities, and treat an average of 75 infusion patients per year. Hawaii has a long history of being a preferred retirement location. As such, Arlington Clinical services a large population of Medicare beneficiaries. Virtually every week we are asked to provide services for a patient with only Medicare insurance benefits and must break the unexpected and unwelcome news that our services are not covered by Medicare. Virtually all of these patients cannot afford to pay for infusion services at home. They remain in the hospital to receive their therapy at a huge cost to Medicare, the hospital, and ultimately our community. For these patients to remain hospitalized is a gross misuse of valuable and scarce resources.

Arlington Clinical Pharmacy 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,

Pat O'Neal, R.Ph.

Managing Director of Pharmacy

Arlington Clinical Pharmacy, Inc.

CMS-4068-P-1035

Submitter : Ms. Vickie Keys-Lydic **Date & Time:** 10/04/2004 06:10:46

Organization : John Deere Health Care, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comments for Title I.

CMS-4068-P-1035-Attach-1.txt

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

Thank you for the opportunity to submit comments on Title I and Title II of the Medicare Modernization Act of 2003. Please find them listed below.

Sincerely,
Lois Boyer, Manager,
Medicare Managed Care
boyerloisl@johndeere.com
309-765-1491

Comments – Title I and Title II

Title I: Subpart C - Benefits and Beneficiary Protections
The proposed regulations stipulate an MA organization must provide access to negotiated prices for covered Part D drugs included in its plan's formulary. Because of the complexity of making lists of actual prices available, is it sufficient to provide members with the percentage off AWP at which a participating pharmacy is contracted, perhaps via a website? 423.120 The proposed regulations require that plans include at least two covered Part D drugs within each therapeutic category and class, and one Part D drug in each if only one drug exists. This two-drug rule would require automatic inclusion of any newly released drug in a class or category where previously only one existed. This would not allow for P&T committees to assess the efficacy or safety of a newly released drug, nor would it promote cost control. Indeed, this could promote rapid development of new drugs to "fill" categories where currently only one drug exists at costs plans would have little ability to control. Currently, many plans have expertise in developing and maintaining formularies via their P&T committees, who are separate entities from the plan. Allowing more leeway for that process to continue to choose appropriate medications, even when only one exists or is deemed appropriate by the P&T committee, seems prudent and in the best interest of the Medicare beneficiary.

Subpart D – Cost
Control and Quality Improvement Requirements 423.153 Carriers will be unable to ensure that pharmacists address issues with members at the point of service regarding therapy management, drug interactions or adverse events. Elderly members typically have several medications, which can cause the drug benefit to be exhausted quickly. Carriers cannot capture information on medications paid for out of pocket (even when members are encouraged to continue using their coverage card to obtain the carrier's discount, many do not) so tracking drug interactions will be very difficult. In today's world where pharmacies are swamped filling hundreds of prescriptions every day, pharmacists do not consistently have the opportunity to counsel patients about drug interactions. They may have some edits built into their systems, but they are not always able to counsel the member.

In addition, what are the HIPAA implications when a hearing impaired elderly patient is at the dispensing window and the pharmacist is trying to counsel about drug interactions? And in that setting, how helpful is it, or how much does the member absorb? Drug over and under-utilization is monitored in disease

management programs. The extent of this monitoring depends upon the disease and the initiatives in place. Subpart J –Coordination Under part D With Other Prescription Drug Coverage 423.464 John Deere HealthWe would support CMS acting as a "clearinghouse" for SPAP claims. Enabling plans to download or otherwise capture this information from one central spot will somewhat reduce the burden of having to accumulate and calculate.

Title II: Subpart C – Benefits and Beneficiary Protections 422.101
If an HMO wants to contract on a regional basis, what rules apply compared to ? The same as all regional PPOs, with the addition of the quality assurance requirements in section 1852(e) of the Act? Please help clarify the addition to paragraph (a). If a POS benefit is not available or not purchased by the member, then there would be no out-of-plan cost sharing, only in-plan cost-sharing. Shouldn't members with a POS benefit have the same financial protections when using contracted providers as those members without a POS benefit?

Also, please comment on the policy that members cannot be held financially liable when contracting providers fail to follow or adhere to plan referral or prior eauthorization rules in comparison to the CMS model EOC for CY 2005. Section 2 of the EOC stresses that if the member doesn't have a referral before receiving services from a specialist, the member may have to pay for the services himself/herself. Section 5 of the EOC that contains exclusions for services received without a referral from a PCP orand services without prior authorization, when either or both may be required for coverage.

Finally, Section 9 of the EOC states the member has the responsibility to get familiar with his/her coverage and the rules he/she must follow to get care as a member. Please help clarify the CMS policy, especially in context of gatekeeper model networks. 422.105 Please define or further clarify a POS-LIKE benefit for MA regional plans. 422.111 We encourage CMS, when considering the requirement that all MA plans set up an Ineternet Web site, to also consider enhancements to marketing guidelines for the Web. Today, CMS considers the Web just another marketing vehicle, requiring the same guidelines as all other marketing mediums. We ask that CMS accommodate its marketing guidelines for this real-time medium. How should a carrier demonstrate its "good faith" effort in attempting to contract with a hospital to be designated as an essential hospital? MA Regional plans have the option of designating an essential hospital, but not MA Local plans. This puts plans who choose to become MA Local plans at a distinct disadvantage. MA Local plans, realistically, would have a greater need, especially in rural areas, for the capability to designate an essential hospital.

How will CMS address this? Subpart D – Quality Improvement Program
The purpose of a PPO is to give members access to providers and coverage of services. A PPO environment is not conducive to monitoring and promotion of continuity and integration of care since providers in a PPO are not held to the same contractual requirements as providers contracted with an HMO. If an organization has been deemed under NCQA for CMS, this accreditation/deeming includes continuity and integration of health care services; therefore, the carrier should receive automatic credit and not be separately held to or audited on these standards.

John Deere Health, John Deere Health Plan, Inc. - A Health Maintenance Organization
John Deere Health Care, Inc. - A Manager of Health Benefit Services
1300 River Drive, Suite 200

Moline, IL 61265
www.JohnDeereHealth.com

CMS-4068-P-1036

Submitter : Mr. John Coster **Date & Time:** 10/04/2004 06:10:08

Organization : National Association of Chain Drug Stores

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please accept the following attachments as written comments on behalf of the National Association of Chain Drug Stores.

CMS-4068-P-1036-Attach-2.doc

CMS-4068-P-1036-Attach-1.doc

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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: Medicare Program; Medicare Prescription Drug Benefit, CMS 4068-P, RIN 0938-AN08

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) is providing extensive written comments to the proposed regulation published August 3rd that would implement Title I of the Medicare Modernization Act (MMA) of 2003. This Title establishes the voluntary Medicare Part D prescription drug benefit program that will begin in 2006.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS represents more than 200 chain pharmacy companies that operate nearly 35,000 community retail pharmacies. NACDS member companies fill more than 71 percent of the approximately 3.2 billion prescriptions that are provided annually in the United States. We are a major provider of pharmacy services to elderly and disabled Medicare beneficiaries, and will continue to do so under this new benefit program. We provide comments in each section in the order in which they appear in the regulation. In these comments, references made to Part D plans refer to Prescription Drug Plans (PDP) and Medicare Advantage – Prescription Drug Plans (MA-PD).

NACDS will work with CMS, plans, providers, and beneficiaries to assure the success of this program. However, we ultimately believe that this program will only be successful if beneficiaries believe and actually can continue to use the pharmacy provider of their choice to obtain their medication and medication therapy management services.

We appreciate the opportunity to submit these comments and look forward to continued dialogue with CMS to assure that the Part D prescription drug program is implemented consistent with Congressional intent. Thank you.

Sincerely,

John M. Coster

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Fax (703) 836-4869
www.nacds.org

John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs

Comments of the National Association of Chain Drug Stores (NACDS)
Medicare Program; Medicare Prescription Drug Benefit, CMS 4068-P, RIN 0938-AN08

I. General Provisions (Includes Comments on Subparts A-J)

Sections 423.30-423.50 - Issues Relating to Eligibility and Enrollment (Subpart A)

Information Provided by CMS and Part D Plans to Beneficiaries: Sections 423.30-423.50 and 69 Fed. Reg. 46635-46646 describe proposed regulations relating to eligibility and enrollment of Medicare beneficiaries in Part D plans. NACDS generally agrees with the proposed rule's requirements regarding the type of information that beneficiaries have to receive both from CMS and individual Part D plans. However, we believe that it is important for beneficiaries to know the network status of each of the pharmacies in the particular plans that they are considering so they can make an informed determination regarding which plan they may want to choose.

The network status of pharmacies is likely to be very confusing to beneficiaries under the scheme that CMS has constructed. Pharmacies can be considered preferred, non-preferred or out of network. Plans must specify the status of specific pharmacy locations, not just note whether a particular chain is in the network. In addition, beneficiaries should know the exact cost sharing amounts involved with using particular pharmacies in the network. Plan materials should be carefully reviewed by CMS to assure that plan designs do not steer beneficiaries to mail order pharmacies.

Beneficiaries should also be told up front in both the CMS and individual plan educational materials that they have the option of using a preferred or non-preferred retail pharmacy in the network to obtain a maintenance supply of their medication. Plan educational materials should be reviewed carefully by CMS to assure that plans do not say or imply that maintenance medication can only be obtained through mail order. This requirement should extend to CMS education materials as well as plan specific educational materials. These materials should also provide general information about the types of medication therapy management (MTM) services being offered by the plans.

We do not encourage CMS to require, or plans to provide, actual prescription pricing information in written format to beneficiaries. NACDS supports prescription drug price transparency on both the manufacturer and retail level. Beneficiaries can obtain real-time pricing information about prescription by calling their local pharmacy, but prices that are provided in written format several months before a benefit program may actually begin will likely be outdated by the time that a beneficiary actually starts using the benefit on January 1, 2006. This will cause confusion and disappointment for the beneficiary. That is because prescription prices at retail change consistent with changes in costs to pharmacies, primarily increasing manufacturers' product prices. Beneficiaries may enroll in a plan based on these written prices, but these prices could change between the time they enroll and the time they fill their first prescription.

Certainly, price increases are likely during the calendar year in which the beneficiary is enrolled, and plan educational materials should communicate the potential for such changes to beneficiaries. The bottom line is that pharmacies cannot be expected to hold constant these prices for any period of time, given the fact that pharmacies are low-margin businesses, and cannot and should not absorb manufacturer price increases.

It is important that all beneficiaries who are enrolled in a Part D plan have a standard benefit card issued by a plan that the pharmacist can use through the online real-time claims adjudication system in the pharmacy to determine whether the beneficiaries are eligible for benefits under the plan. All information needs to be provided to the pharmacist through this system, such as if the person is eligible for benefits, if eligibility has expired, and the beneficiary's cost sharing status (i.e. whether the individual is in the donut hole, or has exceeded the out of pocket maximum, etc.) The pharmacist cannot be held responsible for filling prescriptions for beneficiaries who are no longer enrolled in a plan if the information provided through the system indicates that the individual is eligible at that point in time. The pharmacist cannot be held responsible for delayed updates by the Part D plan sponsor regarding prescription claims for enrollees if eligibility has been voluntarily or involuntarily terminated.

Role of Pharmacy in Educating Beneficiaries: NACDS encourages CMS to recognize that many beneficiaries rely on pharmacists to help them understand how to most effectively use their prescription drug benefit plans. Moreover, it is common for individuals to talk with their pharmacist during "open enrollment" periods to help them determine which particular plan they should choose. CMS should consider preparing educational materials that would help pharmacists understand the benefit, and other material that they can use to educate Medicare beneficiaries.

CMS should recognize that if a particular pharmacist assists a beneficiary in sorting through various Part D drug plans that may be offered in an area, such help does not represent an improper "endorsement" of the plan. It simply represents an attempt by the pharmacist to help the beneficiary determine which particular plan may best suit their needs.

Given the difficulty that Medicare has experienced with enrolling beneficiaries in the discount card program, as well as the Part B replacement demonstration program, CMS should consider allowing Part D plans to pay pharmacies for educating beneficiaries about plan options in their region. We do not necessarily believe that a pharmacy has to promote a specific plan option. However, we do believe that beneficiaries will spend more time talking with their pharmacist about their options than any other health professional. Pharmacies can be critical to the success of this program, given that pharmacists interact with millions of Medicare beneficiaries each day. We also believe that states should be allowed to use part of $125 million in funds that they will receive over the next two years to educate pharmacists about changes in their state pharmaceutical assistance programs so that they can help educate beneficiaries.

Impact on Dual Eligibles: NACDS is particularly concerned about the impact of this Part D drug benefit on dual eligible Medicare beneficiaries who have traditionally received their drug coverage through the Medicaid program.

The Medicaid program in each state has traditionally offered a relatively uniform drug benefit for all participants, has not required mail order for maintenance medications, has allowed freedom of choice of pharmacy, and has not subjected beneficiaries to strict formularies. Requiring dual eligible beneficiaries to make these complex choices among Part D drug plans in their region may result in many not making a choice of drug plans.

Many of these dual eligible enrollees that do not choose a drug plan will likely have to be automatically enrolled in the early part of 2006, but we are concerned that many dual eligibles will find themselves without prescription drug coverage on January 1, 2006. In fact, automatic enrollment of dual eligibles will not begin until the end of the initial enrollment period on May 15, 2006. This can create serious health implications for Medicare dual eligible beneficiaries, and CMS should allow these dual eligible beneficiaries to have a transition period of no less than six months into 2006 to allow for a transition to this new drug benefit.

We would urge that automatic enrollment of these individuals begin no later than December 1, 2005 to be certain that these individuals will have drug coverage on January 1, 2006. We also urge CMS to include pharmacies in any educational efforts that may be started next spring to reach these dual eligible individuals. This will help assure that dual eligible enrollees can both obtain the subsidies for which they might be eligible, as well as get enrolled in a Part D prescription drug program.

States should continue to receive FMAP during this transition period to assure that pharmacy service to this critical population is not disrupted. NACDS is also seriously concerned about the potential disruptions in care that may result in 2006 by transitioning these low income individuals from drugs that they have been receiving from their Medicaid program to drugs that are on their new Part D plan's formulary. This could involve hundreds of thousands of calls to physicians to obtain authority to switch drugs, further justifying some type of special transition period for dual eligible Medicare beneficiaries who are transitioning from the Medicaid program.

As an alternative, CMS should consider requiring Part D plans to pay for a continuation of a dual eligible's existing drug therapy through the first six months of 2006 or until the individual can select a plan that is appropriate for them in terms of the drugs covered on the formulary. This extended time will also allow for the pharmacist to work with the physician to execute any formulary switches that are necessary, and to exhaust any appeals process that might be initiated. This will also allow for a gradual switching of medications in the most logical clinical order if the dual eligible has to be switched from several existing drug therapies to several new drug therapies.

Section 423.48 – Part D Information that CMS Provides to Beneficiaries

Continuation of Prescription Pricing Website: In its discussion of the information that CMS would propose to provide beneficiaries to make choices among Part D plans, CMS suggests that it will want to continue its prescription pricing website that it established for the Medicare-approved prescription drug discount program. The purpose of this website is to help beneficiaries select a discount card by comparing negotiated prices that are being offered for covered drugs by the various card sponsors at various pharmacies.

In its proposed regulation, CMS indicates that it proposes to "*build on our experience in implementing the drug discount card price comparison website as we develop requirements for the Part D price comparison, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings*." We agree that Medicare beneficiaries should take the most cost-effective prescription medications.

Comparing the prices of medications is one way to help beneficiaries make Part D plan decisions, but there are many practical, administrative and operational issues that could make this interactive website unworkable and overly confusing for patients. Moreover, beneficiaries should be choosing plans based on other criteria as well, such as covered Part D drugs included in the plan's formulary, the pharmacy network (especially if they are snow birds), the scope and nature of medication therapy management services that are offered, out of network pharmacy policies, and other items. CMS should encourage beneficiaries to use prescription price as <u>one</u> factor in determining which Part D plan best fits their needs.

There are many significant challenges to creating a pricing website given that there are tens of thousands of prescription drugs with different dosage forms, strengths and package sizes. The retail prices of the medications change frequently due to manufacturer price increases. In addition, prices for the same dosage form and strength of drug may be lower if ordered in larger quantities, making it more difficult for beneficiaries to know exactly how much they might pay for a drug at a pharmacy. This is unfair to the beneficiary and unfair to the pharmacy. Given that Part D is a coverage program, beneficiaries will also have to know how to compute their out of pocket cost based on the prices reported on this website, given that cost sharing of some type – whether coinsurance or copayments – will apply.

It would be very costly and time-consuming for CMS to keep up with and maintain the changes on the website. Moreover, consumers may not understand that variations in prices, even across the same chain of pharmacies, may reflect different costs of doing business in particular parts of the country. Given the frequent changes in manufacturers' prices for drugs, CMS and beneficiaries cannot realistically expect that any posted price could remain the same for any significant period of time.

If CMS requires that plans posts the "maximum price" that could be charged, then it may not provide the correct information to seniors because that price is typically the pharmacy's "usual and customary" cash price. This price probably will not reflect the actual price that would be paid at the counter which is likely based on the negotiated price. Even if the price was accurate, beneficiaries may only be paying a cost sharing amount, which may have little or no impact on their out of pocket costs.

CMS needs to assure that any website includes pricing comparisons about generic drugs compared to their innovator brands, as well as generics compared to other brand name drugs in a similar therapeutic class. For example, there are now two generics available in the SSRI class of antidepressants. Individuals going to the pricing website should be able to find this information. This will encourage the use of generics in therapeutic categories where one or two such versions might be available.

In addition, unlike the current Medicare approved discount card website, CMS must post the prices on the website of retail pharmacies that offer maintenance supplies of medications. This will assure that beneficiaries will know by consulting the website that they can also obtain maintenance quantities of medications from the retail pharmacy, as required under MMA.

Posting the actual contracted prices could be problematic for pharmacies and plans because it could reveal confidential proprietary information about a particular plan's negotiations with pharmacies regarding prices. Similar to how specific rebate and discount information from manufacturers to plans is protected from disclosure, and can only be reported in the aggregate, CMS will be creating a double standard for the revelation of proprietary contracting and pricing information if it creates a website that discloses this proprietary information from pharmacies.

If the posted prices for a particular plan were to include negotiated price concessions from manufacturers as well (which is allowed under the regulation, since plans can pass these through in the form of lower prices), it could also be a back door way of revealing drug specific manufacturer discounts that are not supposed to be revealed under the statute.

Section 423. 100 - Definition of Covered Part D Drugs

In Section 423.100, the proposed regulation defines covered Part D outpatient drugs. NACDS supports the definition of covered outpatient drugs specified in the statute and the regulation. We understand that the definition will allow for the coverage of oral medications, self administered injectable drugs, infusion drugs that may be delivered through equipment such as a drip apparatus, vaccines, and insulin (as well as related injection supplies).

Benzodiazepines: We are concerned that the benzodiazepine category of drugs may be excluded by Part D plans. The MMA law and regulation consider these drugs to be "excludable." Many Medicare beneficiaries take these medications because they are safe and cost effective to treat such conditions as insomnia and anxiety. It is not clear what physicians might substitute for these drugs, which may be more costly and have more side effects that benzodiazepines. Beneficiaries can obtain these medications if they pay for them or if they purchase (or are offered through an employer or state-based program) a supplemental Part D plan or wrap around that covers these drugs. We interpret the regulation as allowing state Medicaid programs to pay for these medications and collect Federal matching funds to help defray the cost.

Medically accepted indications: Medically accepted indications of Part D drugs will be covered as well by Part D plans, consistent with these indications appearing in the listed published compendia. We are concerned however that the pharmacist will not know that a medication is being prescribed for an off label use. In that case, the pharmacist should not be penalized for dispensing a prescription for a covered drug used for an indication that is not medically accepted.

The pharmacist cannot be expected to be in a position to contact each physician for each prescription in question to determine whether the drug has been prescribed for such an off-label indication. Physicians are often reluctant to put any indication on the prescription for various reasons, including patient privacy concerns.

CMS may want to require plans to require physicians to obtain a special code from the Part D plans that can be communicated to the pharmacist when the prescription is filled to indicate that the plan has approved the medically accepted use of that drug. This would be especially important for certain classes of drugs, such as cancer drugs antipsychotic, antiepileptics, and pain medications.

Interaction of Part B and Part D Coverage: NACDS encourages CMS to require plans to put a hard stop or edit in their system to avoid Medicare Part D plans paying for Part B covered drugs for beneficiaries that are eligible for payment under that part of the program. We assume that if a beneficiary had both Part B and Part D coverage that Part D could not pay for the 20 percent cost sharing that might be payable for a Part B drug. (That is, Part D would not provide the wrap around, although we encourage CMS to address this issue.)

We are also concerned that the fragmentation of Part B and Part D coverage could compromise quality of care for Medicare beneficiaries. The systems used by pharmacies to bill for Part B drugs (i.e., DMERC carriers) and the systems used to bill Part D drugs (i.e., PBMs, health insurance) may not communicate with each other. This makes it difficult for the pharmacist to check for drug interactions or other medication use problems. Thus, beneficiaries taking Part B drugs should be encouraged to use one pharmacy for all their Part B and Part D drugs.

Options for Dispensing Fees: In its discussion of covered outpatient drugs at 69 Fed. Reg. 46647-48, the proposed regulation presents different options for payment of dispensing fees for covered Part D drugs. NACDS expects that Part D plans will pay pharmacists a reasonable dispensing fee for providing these medications. The statute and regulation clearly envision that such a fee will be paid by plans. However, the regulation's background is clearly concerned about plans paying appropriate dispensing fees to long term care pharmacies, but does not engage in the same discussion regarding the adequacy of dispensing fees paid to retail pharmacies. We encourage CMS to monitor the scope and nature of dispensing fees paid by plans to retail pharmacies to assure that there is appropriate community-based access to pharmacy services for Medicare beneficiaries.

We believe that the plan should pay the basic dispensing fee to cover the pharmacy's routine cost of dispensing, as well as overhead. We also believe that plans should consider the use of differential fees to encourage the use of generic drugs. Some recent studies regarding the cost of dispensing illustrate that a reasonable fee would be in the following range:

- Texas, Myers and Stauffer, August 2002: Myers and Stauffer (M&S) determined the weighted median (i.e., the midpoint) cost of dispensing a prescription in Texas to be $5.95. The weighted mean (i.e., the "average") was $6.16. The unweighted mean was $6.96. M&S notes generally higher costs in urban areas, primarily due to labor-related costs.

- California, Myers and Stauffer, June 2002: M&S determined the weighted median (i.e., the midpoint) cost of dispensing in California to be $6.95. The weighted mean (i.e., the "average") was $7.21. The unweighted mean was $7.87. These figures are much higher than the dispensing fee paid by Medi-Cal at the time, which was $4.05.

M&S indicates that the cost of dispensing in California is higher than observed in other states, primarily due to higher pharmacist salaries.

- Kentucky, Myers and Stauffer, October 2003: M&S determined the weighted median (i.e., the midpoint) cost of dispensing in Kentucky to be $5.72; they also provide an adjusted figure that supposedly takes into account response bias (over-sampling of chain and institutional pharmacies), which is $5.76. The weighted mean (i.e., the "average") was $5.86. The unweighted mean was $6.40. M&S notes generally higher costs for institutional pharmacies, chain pharmacies (partly due to higher labor costs for employee pharmacists), and pharmacies in urban areas. M&S notes that labor costs from increasing pharmacist salaries, particularly in chains, were putting inflationary pressure on the cost of dispensing. They attribute the rising labor costs to a perceived pharmacist shortage.

While these are recent cost of dispensing studies, an analysis conducted by the University of Texas at Austin Center for Pharmacoeconomic Studies found that these studies have generally understated the cost of dispensing. That is because they did not account for other important overhead factors, such as corporate overhead costs, costs of professional licensure maintenance for practicing pharmacists, owners compensation costs allocation, and others. Therefore, to assure beneficiary access to retail pharmacies and well as institutional pharmacies, we urge that CMS monitor the adequacy of the dispensing fees paid by Part D plans.

For the purpose of defining a dispensing fee for Part D drugs, NACDS believes that Option 1 of the proposed rule's definition of dispensing fee should be adopted. This includes, according to the preamble, charges associated with mixing the drugs, delivery and overhead. Third party payers in almost all circumstances reimburse the pharmacist for the cost of the product as well as dispensing the prescription. Because pharmacists in the retail setting generally do not "administer" drugs to beneficiaries, the act of providing patients prescription drugs is generally defined as "dispensing" the drugs. NACDS has included a summary of the important components involved with dispensing a prescription (see Appendix 1). These components are recognized by most cost of dispensing prescription surveys that are done to determine a pharmacy's actual cost of dispensing.

We agree that the definition of dispensing fee as envisioned in the statute and the regulation would not normally include the costs of professional services, such as medication therapy management services. However, the dispensing fee should include the costs of counseling provided by the pharmacist to the patient. The simple act of transferring the prescription to the patient is an important part of dispensing, but a basic component of transferring that prescription involves helping the beneficiary take the medication correctly. This occurs through the basic counseling requirements that are included in almost all pharmacy practice acts, if the patient agrees to such counseling by the pharmacist.

A general dispensing fee as defined in Option 1 should require plans to provide various levels of dispensing fees depending upon the complexity of the preparation required to dispense the prescription. For example, beyond a fee paid for dispensing, a plan may also establish another additional fee for compounding a prescription.

CMS appears to envision such a payment when it refers to the act of "mixing" a drug as part of its definition of dispensing fee in Option 1. ("Compounding" should be distinguished from the process known as "reconstitution", which simply requires the pharmacist to add sterile water to a powder preparation. Compounding can involve several complex steps regarding the weighing and mixing of multiple ingredients.)

An additional dispensing fee could be established for the preparation and dispensing of infusion drugs, such as antibiotics, covered under Part D. These drugs are usually prepared as "admixtures", which can involve additional costs, such as the use of a laminar flow hood. Finally, many drugs need to be prepared in special packaging, such as blister packs or "bingo" cards, which can help enhance medication compliance. While payment for these services is envisioned under the medication therapy management section, this type of packaging may be required for individuals who do not qualify for MTM services. Therefore, plans should consider payment for this special packaging to enhance medication compliance by beneficiaries. CMS should require plans to develop dispensing fee schedules depending on the complexity of tasks required to deliver or dispense the drug to the patient.

We also believe that plans must reimburse pharmacies for value added or professional services relating to dispensing the prescription. CMS should understand that many of the formulary management and drug utilization techniques that will be used by Part D plans are performed by pharmacists. As such, plans should indicate as part of their bid submission how they intend to compensate pharmacists for performing these valuable cost management and quality improvement functions. This compensation must be provided in addition to the product reimbursement and dispensing fees that have to be paid to the pharmacist. CMS envisions that pharmacies would be paid for these functions (e.g., formulary compliance and generic drug substitution) because they are described as part of "performance based measures" under the definition of "insurance risk". These professional intervention service payments should be consistent with the time needed to perform them and should be updated each year to account for increasing costs to the pharmacy operator.

Because the new Part D benefit appears to include coverage for self injectable drugs and other self-administered infusion drugs, there is a need to reimburse for the services and setups required for the safe and effective use of these medications.

Section 423.104 – Requirements Relating to Qualified Prescription Drug Coverage

Availability of 340B Pricing to PDP Plans: At 69 Fed. Reg. 46651, CMS asks for comments about how to maximize savings for people in need of HIV/AIDS medications under the 340B program. In particular, CMS wants to know whether it is feasible for ADAP programs to participate with prescription drug plans so that drugs offered to individuals with HIV/AIDS can be offered at 340B pricing. CMS also solicits comments regarding the coordination of ADAP and Medicare Part D benefits. NACDS supports the ability of individuals with HIV/AIDS to continue to obtain their necessary medications. Successful treatment of HIV/AIDS requires access to patient-specific combinations of select drugs, which need to be taken regularly in order to treat the condition.

We are not sure what CMS is considering when it asks whether 340B pricing can continue to be offered to these individuals. If Part D plans are administering these programs, and all pharmaceutical price negotiations must occur between these entities and manufacturers, then it is not clear how 340B pricing would be made available.

If CMS wants pharmacies to charge ADAP beneficiaries lower prices equal to 340B prices, and thus lower any cost sharing that these individuals might have, then manufacturers of 340B drugs dispensed to ADAP individuals must provide rebates back to plans equal to 340B pricing, and pass those rebates through to the pharmacies. Pharmacies will not keep separate sets of inventory for different groups of patients (i.e. 340B drugs), so any plan that would allow ADAP beneficiaries to access these prices at retail pharmacies must be done through some real time reconciliation process that does not require keeping of separate inventory by pharmacies.

Moreover, if ADAP programs want to "wrap around" the Part D benefit and provide supplemental coverage for drugs not covered on a Part D formulary, or provide cost sharing, we assume that these expenses are not counted toward the true out of pocket costs, known as the TrOOP. However, the Part D plan needs to establish a process – similar to those established for other plans that wrap around – that would allow the pharmacy to know in real time at the point of care the amounts that should be collected from the ADAP beneficiary for the covered Part D drugs, if any.

Access to Negotiated Prices: At Section 423.104(h), the proposed regulation defines "negotiated prices" (also found at 69 CFR 46654-5). Part D plans are required to provide enrollees with access to negotiated prices used for payment for covered outpatient drugs during the periods when benefits are not provided for these drugs, such as after the first coverage limit is reached (e.g, $2,250 in total spending for 2006). These prices are also to be passed through on a drug that is within a tier in a plan's formulary for which no benefits may be payable. Beneficiaries are responsible for 100 percent of these costs, but would be charged only the "negotiated price."

The proposed regulation indicates that "negotiated prices" shall take into account negotiated price concessions such as discounts, direct or indirect subsidies, rebates, and direct or indirect remuneration, and shall include dispensing fees. Negotiated prices are essentially the contract rate that the plan will pay the pharmacy for a prescription drug. We consider the requirement that pharmacies pass through negotiated prices during the coverage gaps and for non-covered formulary drugs to be price controls on retail pharmacies. Pharmacies should not have to shoulder the burden of these discounts when the regulation fails to spell out whether and how manufacturers' price concessions and reductions are also to be passed through in these cases.

Part D plans should be required to pass through all, and not just "take into account", manufacturer and pharmacy price concessions and rebates when determining the negotiated rate. These include formulary placement fee discounts, market share movement discounts, and any administrative fees paid by the manufacturer to the PBM. The pass through of these amounts will lower the overall cost of the drug benefit for Medicare and potentially reduce the amount of cost sharing that a Medicare beneficiary would have to pay. It will also help lower beneficiaries' out of pocket costs and reduce the rate at which beneficiaries will reach the initial plan limit.

It is consistent with the intent of this prescription drug program that discounts and rebates from both pharmacies and manufacturers be passed through. These negotiated discounts from manufacturers should be passed through during the periods of coverage as well as the coverage gaps. CMS should assure that plan bids do not allow PBMs to retain any rebates, discounts or price concessions they obtain during the coverage gaps.

Pharmacies are responsible for passing through of manufacturer price concessions at the point of service. Pharmacies should expect that the PDP or MA-PD plans will reimburse pharmacies for any manufacturer price concessions that are passed through by the pharmacy in a timely manner, but no later than one week after submission of the claim. Pharmacies cannot be expected to "float" for the Part D plan a significant amount of reimbursable costs for product inventory.

Part D plans should not be able to keep any pharmacy spreads on prescriptions provided for brands and generic drugs. For example, plans should be prohibited from paying the pharmacy a lower rate than they are charging the plan for filling the prescription, thus retaining some of the pharmacy spread. This negotiated rate should be passed through in full to the beneficiary. CMS should require plans to report the extent to which they retain any spread on pharmacy reimbursement.

Section 423.120- Access to Covered Part D Drugs

Section 423.120(a)(1)-(5) - Issues Relating to Access to Pharmacies

The standards for Medicare beneficiary access to pharmacies are being implemented in a manner that is inconsistent with Congressional intent and will significantly reduce Medicare beneficiary access to and interaction with their local community pharmacy. We believe that it was Congress' intent to protect and enhance, rather than jeopardize, the health of Medicare beneficiaries by creating access standards to retail pharmacies.

Congress required Part D plans to comply, at a minimum, with the Department of Defense's (DOD) TRICARE pharmacy access standards, as well as required plans to establish access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906-03-R) by the Department of Defense on March 13, 2003, for the purposes of TRICARE retail pharmacy programs.

These standards require on average that 90 percent of Medicare beneficiaries in urban areas have access to a pharmacy within 2 miles; 90 percent in suburban areas have access to a pharmacy within 5 miles; and 70 percent in rural areas have access to a pharmacy within 15 miles**.** The solicitation requires that a "contractor shall maintain a pharmacy network which minimizes the number of eligible beneficiaries who will have to change pharmacies…".

Averaging Access Standards: The TRICARE access standards are the minimum standards that plans must meet. Under the proposed regulation, Part D sponsors are allowed to average each of the standards across all urban areas, all suburban areas and all rural areas for each plan in each region in which they offer a Part D plan.

We believe, however, that plans should be required to meet these standards in each state in which they operate. While the proposed regulation does not specify the regions or service areas, using an "average" could allow plans to permit much greater access for beneficiaries in certain urban areas of the region, while reducing access in other urban areas of the region. The same is true for the suburban and rural areas of the region. Here are some examples of how such "averaging" affects beneficiary access to pharmacies:

- Using an "averaging" approach, a PDP plan could allow for greater than 90 percent access by offering a program in New York state with greater than 90 percent urban pharmacy access in New York City and Albany, but much less than 90 percent access in Syracuse, Buffalo, and Rochester. On average, across all the urban areas in this service area, this PDP might meet the 90 urban access requirements, but would not have done so in each urban area. The same averaging could apply to suburban and rural areas.

- Similarly, a PDP offering a plan in contiguous New England states such as Vermont, Massachusetts, Maine, and New Hampshire could meet the card sponsor pharmacy access requirements, on average, by exceeding the 90 percent urban standard in certain cities of these states but falling short of that requirement in other urban areas. Thus, Medicare beneficiaries in Boston could have an over abundance of pharmacies from which to choose, while those in Manchester, Burlington, and Portland might have a difficult time finding a retail pharmacy that is in the network. In addition to creating uneven access, this would obviously create an incentive for card enrollees to use mail order pharmacies, disadvantaging enrollees who want to continue to use their local retail pharmacies.

Creating "Preferred Pharmacy" Network: The proposed regulation also allows plans to totally circumvent the TRICARE standards by creating "preferred pharmacies" and "non-preferred" pharmacies. Thus, a PDP or MA-PD plan could include the minimum number of pharmacies in its overall network to meet the TRICARE access standards, and then create a defacto smaller network by allowing some of the pharmacies in the general TRICARE network to offer lower cost sharing to beneficiaries than the non-preferred pharmacies. The proposed regulation does not specify how many pharmacies would be able to offer such lower cost sharing or the extent to which the cost sharing might differ.

This proposal allows Part D plans to create a smaller network than TRICARE that was simply not envisioned by the statute. In effect, it renders the TRICARE standards meaningless because it allows plans to create much smaller networks than are allowed by the statute. Note that the DOD TRICARE program uses only an "in-network" pharmacy and non-network pharmacy program. The in network pharmacy meets the TRICARE access standards, and has uniform cost sharing for all these in network pharmacies. DOD has not created a smaller "exclusive provider organization" type network as created by CMS under these proposed rules. Thus, CMS application of the TRICARE pharmacy access standards is inconsistent with DOD's application of the standards, and the application of the TRICARE standards by CMS establishes rules that are less favorable than those required under the March 13, 2003 statement of work solicitation. This is inconsistent with Congressional intent.

Taken together, the legislation and the report language do not support CMS' interpretation regarding this type of network structure. In 1860D-4(b)(1)(A) of MMA, it indicates that Part D plans have to permit the participation in the network of "any willing pharmacy" that meets the terms and conditions of participation. The next subsection indicates that, not withstanding the fact that a plan has to allow any willing pharmacy to participate, plans can reduce cost sharing for individuals for covered Part D drugs dispensed through in network pharmacies.

Later, in section 1860D-4(b)(C)(ii), it clearly states that the Secretary has to establish rules for convenient access to "in network" pharmacies that are no less favorable than TRICARE. Thus, any reduced cost sharing that is allowable in the previous subsection, we believe, applies in relation to all pharmacies that are able to participate, not in relation to the pharmacies in the TRICARE network. This reduced cost sharing should only apply to in network pharmacies, where that network of such pharmacies cannot be any smaller than TRICARE.

The report language accompanying the statute (see pp. 451-452 of Conference Report to H.R. 1, Report 108-391) supports this interpretation, and makes it clear that plans cannot create "smaller networks" than the TRICARE access standards. It indicates that the "…minimum in network pharmacy for each plan offered by a PDP or MA in a geographic area must provide access to pharmacies that is not less restrictive than the TRICARE access standards." The report language further states that "*plan sponsors cannot create any pharmacy networks that are more restrictive than the TRICARE access standards.*" CMS basically ignores this intent of Congress with how it is implementing the program.

CMS admits to the negative impact of such a network by writing that:

> *"We recognize the possibility that plans could effectively limit access in portions of their service areas by using the flexibility provided in…our proposed rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a plan could establish a differential between cost sharing at preferred pharmacies versus non-preferred pharmacies – while still meeting the access standards in our proposed rule – that is so significant as to discourage enrollees in certain areas (rural or inner cities, for example), from enrolling in that plan. Our intent is to use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process described in § 423.272 of our proposed rule, the design of proposed prescription drug plan and MA–PD plan designs to ensure that they are not likely to substantially discourage enrollment by certain part D eligible individuals. Such a review would preclude the approval of bids submitted by plans that attempt to use strategies such as that outlined above to limit enrollment in portions of their service areas that are more difficult or costly to serve."*

Thus, CMS itself indicates that it is allowing plans to create "in networks" of pharmacies that will be more restrictive than TRICARE, directly contravening Congressional intent. Moreover, implementation of the TRICARE access standards established in the DOD solicitation of work create much more access to retail pharmacies than the way that CMS is implementing these standards, which is also contrary to Congressional intent.

We believe that for each plan being offered in each state in each region, Part D plans must establish the same cost sharing requirements for all TRICARE pharmacies, and cannot create lower or different cost sharing requirements among "in network" TRICARE pharmacies. Lower or different cost sharing amounts for some preferred pharmacies in the TRICARE network would only be accessible by some Medicare beneficiaries, creating a defacto smaller pharmacy network.

Driving Distances to Pharmacies: The proposed regulation also fails to indicate that, in determining distances to pharmacies required under the TRICARE standards, plans must apply the standards using "commercially traveled routes." These are the actual travel distances for beneficiaries to these pharmacies, not just the distances between the beneficiary and the pharmacy. For example, a beneficiary may only be geographically two miles from a pharmacy, but because of the way that the road system is structured, the beneficiary has to travel or drive five miles to reach that pharmacy. The actual driving distance should be used to determine whether the TRICARE access standards are being met.

Taken together, all these loopholes mean that millions of Medicare beneficiaries will not be able to obtain their needed medications from their local pharmacies at the best cost sharing rates possible:

- For example, a Medicare beneficiary living in an urban area may be within 2 miles of a network pharmacy (the pharmacy that she has been using for multiple years). However, because it is a non-preferred pharmacy, the beneficiary may find that she has to pay $10 rather than $5 for her medications, and cannot afford to do so. The nearest preferred pharmacy may be in an urban area many miles away, because this plan's urban access average includes more pharmacies in another urban area rather than this beneficiary's urban area.
- In another example, a Medicare beneficiary in a different urban area in the same region may be 4 miles from the nearest network pharmacy. This beneficiary still meets the TRICARE access standards because of the "averaging" allowed for the urban areas in this region. However, this pharmacy is not a preferred pharmacy, but the nearest preferred pharmacy in 6 miles away. This beneficiary is also disadvantaged from using her local pharmacy because of the incorrect interpretation of the statute regarding the TRICARE access standards.

CMS indicates that it will waive the pharmacy access standards under certain conditions. This includes MA-PD plans that provide access through pharmacies owned and operated by the MA organization that operates the plan. NACDS believes that such a waiver should only apply to staff model HMO plans that are also MA-PD providers. These types of plans typically own their own buildings, including pharmacies, where health care services are delivered. However, a MA-PD plan that is a regional or local PPO should not be allowed to own one pharmacy to evade the pharmacy access requirements. We encourage CMS to only allow this waiver to be applicable only to HMO staff model MA-PD plans.

Definition of Pharmacy: The regulation indicates that Part D plans can only consider to be part of their networks retail pharmacies that are "licensed pharmacies from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services related to that particular covered Part D drug from a provider or institution affiliated with that pharmacy." In our view, Part D plans can only count traditional community retail pharmacies that are accessible to the general public when determining whether they meet the TRICARE access standards. That means that only those pharmacies licensed in the state where any individual can take a prescription in order for that prescription to be filled should count toward the TRICARE standards.

As such, plans cannot count mail order or central fill pharmacies, closed door pharmacies (such as nursing home or institutional pharmacies), PHS clinic or IHS pharmacies, or pharmacies in bordering states (unless in the region), hospital outpatient pharmacies, dispensing physicians, infusion pharmacies or other pharmacies that are not accessible to the general public.

Plans can include home infusion pharmacies in their networks, but these should not count toward the TRICARE access standards because these pharmacies typically provide special types of drugs and supplies (i.e. intravenous antibiotics, TPN, etc), that are not found in traditional retail pharmacies. Only patients eligible to receive drugs from Indian Health Service pharmacies should receive drugs from such pharmacies under this program if the pharmacies are included to meet access requirements. In its definition of long-term care pharmacy, CMS should recognize that some long-term care pharmacies might be subsidiaries of corporations that own both a LTC and retail pharmacy establishment.

We believe that plans should contract with pharmacies outside their service area (who would then become network pharmacies) to provide pharmacy services to beneficiaries that travel (i.e. snow birds). However, as the proposed regulation indicates, these pharmacies cannot count toward the TRICARE access standards for that region, unless the pharmacies are in the same region.

In summary, the final rule must not allow plans to average access requirements across urban, suburban, or rural areas in each region. The final rule must specify that each Part D plan must meet the TRICARE access standards in each state in each region in which they offer such plans. Plans cannot create any networks that are smaller than TRICARE. The final rule must specify that only traditional retail pharmacy should be counted by plans toward meeting the pharmacy access requirements. To achieve access to pharmacies consistent with Congressional intent, the final rule must specify that the TRICARE access standards can only be met by counting "preferred pharmacies" not "non-preferred pharmacies." The final rule should require that "commercially traveled" routes be used by plans to determine whether the TRICARE access standards are being met.

Standard Pharmacy Contract: The background to the proposed regulation asks whether CMS should require Part D plans to make available to all pharmacies a standard contract for participation in their plan's networks. CMS indicates that such a contract could be varied with terms and conditions that would only have to be made available to a subset of pharmacies.

We believe that such a model contract should be made available by plans to any pharmacy willing to participate in the plan's network.

In addition, in order to avoid any issues regarding whether a pharmacy is still in operation and actually participating in a Part D plan's network, CMS should require that all pharmacy contracts be done by plans through an "active" process rather than a "passive process."

In other words, plans should not use "all products" clauses in existing third party contracts to assume that a pharmacy will also be in the Part D plan's network. This situation occurred in the process by which plans contracted with pharmacies to form their discount card networks.
Some of these networks included pharmacies that were no longer in operation, or had not "actively" accepted a contract to participate in the discount card sponsor's network. Part D plans should be required to demonstrate that they have negotiated separate contracts with pharmacies specifically related to participation in these networks.

We believe that these contracts should, among other items, specify the terms and conditions of payment. Contracts between pharmacies and Part D sponsors should clearly define terminology and descriptive criteria associated with the terms used in the agreement, as well as operational processes and procedures to assure efficient administration of the program. These would include the following:

- *Real Time Adjudication:* All information regarding the adjudication of the prescription claim, including eligibility information, copays, formulary coverage status, other liable third party payers, TrOOP calculations, and claims payment status must be provided by the plan to the pharmacy through an online, real-time claims adjudication system.
- *Define Average Wholesale Price (AWP):* The contract should indicate the source of the AWP, how often the plan's AWP files are updated, what AWP is used, what "current" AWP means, and designate the package size on which the AWP is based.
- *Define Brand Name Drug:* Because both single and multiple source products have brand names, the term brand name either needs definition or should not be used. If brand name means single source, then the contract should say single source. If brand name also refers to multiple source products with brand names, then the contract should so state.
- *Define Generic Drug:* All drugs, both single source and multiple source drug products, have a generic name. If the contract is referring to a product available and marketed from multiple sources, then it should be referred to as a multiple source drug.
- *Identify Compensation:* The contract should identify the compensation formula for paying pharmacies for prescriptions, as well as any payments for other services and incentives for performance. The other services and incentives, and the requirements for pharmacies to receive compensation, should also be defined.
- *Maintenance Supply of Medications:* The contract should specify that a network pharmacy can provide a maintenance quantity of medication and the specific differences in prices, if any, that a beneficiary would have to pay at the retail pharmacy. The contract should also allow the pharmacy, at its option, to accept the mail order reimbursement (i.e. negotiated rate) for a similar quantity of medication if it is lower than the negotiated rate for the retail pharmacy.

- *No Acceptance of Risk:* As required under law, pharmacies cannot be required to accept risk. This should be stated in the contract. The contract should also preclude other forms of potential risk transfer, such as terms that would institute fixed fee amounts for drugs that are prescribed in specific drug classifications, fixed amounts of reimbursement per patients or capitated payment amounts, delayed reimbursement, or other forms of financial hardships because of the inability of plans to control costs.
- *Co-Payments:* Often patients' co-payments differ depending on the drug prescribed or "tier" in which the drug is located. All contracts should carefully describe the various co-payments and tiers, as well as how and when they apply.
- *Covered Services:* The contract should describe covered services, restrictions and exclusions.
- *Eligibility and Identification Cards:* Contracts should identify the criteria for coverage, and specify that the Part D plan's identification card meet the NCPDP standards for identification cards. There should not be a multitude of dissimilar looking cards containing varying and inconsistent information.
- *Maximum Allowable Cost (MAC):* A MAC schedule is often a component of the pharmacy compensation methodology. It is important that the source and the method that the sponsor uses to determine MAC be identified in the contract, and that processes are in place to assure that MACs are adjusted in a timely manner to reflect changes in the market place.
- *Policy and Procedures:* The contract and plan material provided to pharmacies should completely define the processes and procedures to be used when submitting claims, for seeking prior authorization, and for responding to electronic communications from the processor.
- *Payment for Services:* Contracts should specify who pays the pharmacy and when. Since claims are to be submitted electronically, payers should be able to make payment to pharmacies within 7-10 days. Pharmacies should not be subjected to bearing large and costly receivables and having their cash flow jeopardized because of payers' delayed payments.
- *Late or Non-payment:* The contract should address the processes and procedures that pharmacies are to follow should a plan be delinquent in payment, or unable to meet its financial obligations.
- *Patients' Records:* It should be made clear that patient information and prescription records are the property of the pharmacy and payers and that sponsors cannot use that data for purposes other than processing and paying claims. The pharmacy will allow records to be copied for meeting regulatory requirements.
- *No Retroactive Recoupments:* Plans must be prohibited from requiring pharmacies to retroactively recoup from other third party payors that were later determined to be liable for all or part of the prescription claim after the prescription claim was adjudicated.
- *Auditing and Record Reviews:* Contracts should include a description of the processes used for audits, including what can be audited, how an audit is conducted, providing prior notification, appeals processes, etc.
- *No Passive Contracting Changes:* Any and all changes to a contract between a plan and a pharmacy should be required to be negotiated. Plans should not be able to make material changes to a contract by simply indicating in the contract that pharmacies agree to any and all changes made in the plan's provider manual.

- Plans often seek to circumvent the need to negotiate significant benefit design or plan participation requirements with pharmacies by simply indicating that the pharmacy agrees to any change made by the plan in the provider manual. We do not believe that CMS should allow any plan to make material changes in this manner, given that it may affect the ability of plans to maintain networks.
- *Usual and Customary Price:* NACDS supports CMS' definition of "usual and customary" price as the price the pharmacy charges a customer who does not have any form of prescription drug coverage. That is, this is the price for a prescription that would be paid by a cash-paying customer. This is an industry standard, and should be included in the standard model contract developed by plans.
- *Termination of Contract:* The plan must give pharmacies 90 days notice that it intends to terminate its contract with CMS, and assure that payment for all prescription claims filled during the remainder of the contract period are paid within one week after the contract date ends.

Issues Relating to Low Income Individuals: Part D plans are prohibited from establishing different deductible or cost sharing requirements other than those established by law for subsidy-eligible Medicare beneficiaries below 150 percent of poverty (i.e., $1 generic/$3 brand for those up to 135 percent of poverty; $2 generics/$5 brands for those up to 150 percent of poverty). That is, plans are prohibited from creating actuarially equivalent benefit plans for these individuals. For that reason, because there cannot be differential cost sharing or "actuarially equivalent" plans for these individuals, any pharmacy (preferred or non-preferred) that wants to provide prescription services for these individuals should be able to do so, as long as they meet the other terms and conditions of the contract.

Allowing dual eligible Medicare beneficiaries to obtain their prescription drugs from any pharmacy in the network (preferred or non-preferred) will help assure appropriate pharmacy care for these individuals, many of whom do not have the means to travel long distances to select retail pharmacies to obtain their prescription medications and pharmacy services.

Plans should be discouraged from using mail order pharmacies for these low-income populations, and should be prohibited from varying the cost sharing amounts for these individuals to encourage the use of mail order pharmacy over retail pharmacy. There should be no additional payment required from these individuals to obtain the same benefits (same quantity of medication) from retail pharmacy as through mail. That is because co-payment amounts for these populations – as well as any future year increases – are fixed by law.

We agree with CMS assertion on 69 CFR 46793 regarding the ability of low-income individuals to obtain their prescription drugs in larger quantities from retail pharmacies (either preferred or non preferred) as they do from mail order. The economic analysis indicates that "there is likely to be no effect on mail order use by beneficiaries who qualify for the low-income subsidy because nominal cost sharing exists regardless of where the beneficiary purchases the prescriptions…". Thus, these individuals should pay the same cost sharing whether they obtain their medications from preferred or non-preferred pharmacy providers.

Essential Rural Provider: The proposed regulation asks for comments on how beneficiaries that reside in rural areas might be assured of access to a retail pharmacy. The TRICARE access standards require that 70 percent of beneficiaries in rural areas live within 15 miles of a network retail pharmacy. CMS has interpreted this as allowing plans to "average" this access requirement among all the rural areas in this region.

This could mean that a beneficiary in a rural are could have to travel more than 15 miles before they find a preferred pharmacy in the plan's network. This would create uneven access for Medicare beneficiaries to retail pharmacies and create unfair incentives for them to use mail. Such a result would essentially nullify an important policy component of the Medicare law; that is, giving beneficiaries the choice of obtaining pharmacy services from the provider of their choice if they are in the network.

There are likely to be rural communities where there is only one pharmacy for many miles, making it the only location within reasonable traveling distances for many beneficiaries. CMS should assure that these pharmacies are included as preferred pharmacies in the plan's network, at the lower cost sharing amounts that are established. While we strongly oppose the concept of preferred pharmacies and non-preferred pharmacies, rural beneficiaries may have to travel much longer distances than 15 miles to find a preferred pharmacy. CMS should create a similar concept as an "essential rural provider" designation for rural pharmacies that are clearly critical to providing community-based pharmacy services to Medicare beneficiaries.

Section 423.120(a)(4) – Contracting Terms with Pharmacies and Prohibition on Transferring of Insurance Risk

Section 423.120(a)(4) describes pharmacy network contracting requirements for Part D plans. Under these requirements, plans cannot require pharmacies to accept insurance risk as a condition of participating in these plans. The proposed regulation defines "insurance risk" as risk that is the type commonly assumed only by insurers licensed by a state and does not include payment variations designed to reflect performance-based measures within the control of the pharmacy, such as formulary compliance and generic drug substitution, nor does it include elements potentially in control of the pharmacy for example labor costs and productivity. While these types of performance-based programs do exist in the market today, payments for these performance-based measures are generally made in addition to, not instead of, payment for dispensing the prescription. They represent additional payments for meeting certain incentive measures.

Consistent with legislative intent, the final regulations should prohibit plans from forcing pharmacies to accept any contractual terms that require them to accept lower payment rates as a result of plan cost overruns. These terms would include fixed fee amounts for drugs that are prescribed in specific drug classifications, fixed amounts of reimbursement per patient or capitated payment amounts, delayed reimbursement, or other forms of financial hardships because of the inability of plans to control costs.

These unexpected cost increases can result from, among other factors, unexpected cost overruns for drug spending under the plan resulting from insufficient premium bids, the introduction of costly new drugs, insufficient incentives to use lower-cost generics, overuse of brand name drugs in mail order, or other cost increase factors not under the pharmacies' control as specifically defined by the contract.

Part D plans should be required to clearly identify for CMS as well as pharmacies the pricing source that they will use as the basis of paying for covered outpatient drugs provided under their program. For example, plans should indicate whether they are using First DataBank, Medi-Span, or another pricing source, and indicate how often this information will be updated.
Changes in data sources should be prohibited contractually until the contract between the pharmacy and the Part D plan expires or through bilateral contract negotiations. Plans should also be required to publish their Maximum Allowable Cost (MAC) list for generic drugs, update the list frequently, and use the list to reimburse both for retail prescriptions and mail order prescriptions. Plans should also indicate how and when new generics will be added to their MAC list.

Section 423.120(a)(6) – Level Playing Field between Mail Order and Network Pharmacies

This section implements statutory requirements relating to Part D plans allowing enrollees to obtain covered Part D drugs from retail pharmacies in the same amount, scope and duration that they provide from mail order pharmacies. We believe that it was the intent of Congress to assure that Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from their pharmacy provider of choice. As such, we believe that Part D plans have to permit Medicare beneficiaries to obtain the same amount, scope, and duration of covered outpatient drugs and medication therapy management services at any community retail pharmacy that is in the plan's pharmacy network (which include those that are in the preferred network and non-preferred network) as they offer through mail order pharmacies.

The 90-day supply quantity mentioned in the law is only an example of the type of benefits that Part D plans have to allow retail pharmacies to provide to Medicare beneficiaries if they are also provided through mail order pharmacies, and we believe that the proposed regulation agrees with that interpretation. Entities that are administering the Part D prescription drug coverage programs should do all they can to make any cost differences between mail order and retail pharmacy minimal for the beneficiary.

Based on legislative history and Congressional intent, plans cannot create artificial cost sharing structures to create incentives for beneficiaries to use a particular source to obtain their covered outpatient drugs.[1] That is, plans cannot create differential cost sharing requirements to shift beneficiaries to mail order. The only difference in cost between a retail and mail order prescription for a beneficiary should be the net cost, if any, of the difference between negotiated prices as explained below.

[1] Note that the provision that would require plans to allow Medicare beneficiaries to obtain maintenance quantities of medications from their retail pharmacy provider if also offered by mail order passed as an amendment to the Senate Medicare Modernization bill by a unanimous vote of 95-0.

In fact, a colloquy between Senator Enzi, the provision's sponsor regarding retail and mail order equity, and Senate Finance Chairman Grassley provides clear Congressional intent regarding how this provision should be implemented:

> ***Senator Enzi:*** *"My intent in offering this amendment was to prohibit plans from implementing restrictions that would steer consumers to mail order pharmacies…My concern is that any differences in charges between mail order and retail be reasonable differences, based on the actual cost of delivering the service. I would be concerned if differences in charges were used as a method of steering seniors and disabled to mail order pharmacies."*
>
> ***Senator Grassley:*** *"I say to my colleague from Wyoming that Medicare drug plans and Medicare Advantage organizations should not force seniors or the disabled to choose a mail order house when they would prefer to patronize their local community pharmacy…it is my expectation that any differential in charge be reasonable and based on the actual cost of providing the service in or through the setting in which it is provided.*
> *I would also expect that the Secretary of Health and Human Services would disapprove of any plan that would impose a differential charge that was intended primarily to steer Medicare beneficiaries to mail order pharmacies versus retail pharmacies"* [2]

In a February 10, 2004 appearance before the House Ways and Mean Committee, Secretary Thompson said the following in response to a question raised by Congressman Phil Crane:

> ***Congressman Crane:*** *…It was clearly the intent of Congress to improve seniors' choices by creating a level playing field between local pharmacies and mail order. I hope that when HHS implements the drug coverage portion of this law, that you'll work to make sure that drug plans do nothing to intentionally discourage seniors from choosing a 90-day supply of drugs from their local pharmacies. I am especially concerned that drug plans may attempt to steer seniors to their mail order businesses by requiring higher copays or other cost sharing just for choosing to obtain a 90-day supplement from their neighborhood pharmacy. That was not the intent of this Committee, and I urge you to be vigilant in preventing plans from doing this. And do you have any specific plans for preventing this from occurring?*
>
> ***HHS Secretary Tommy Thompson:*** *We're going to be very vigilant as you have admonished us to be Congressman Crane, and we are going to use procedures to make sure that does not happen, we have to be very aggressive in making sure that seniors are treated properly and correctly and we want to make sure that we carry out the will of the Congress and will and intent of this Medicare Modernization Act and we will do everything we possibly can to prevent any kind of scamming that may possibly be considered.*

Regarding this provision, in a March 8, 2004 letter to Secretary Thompson, Congressman Joe Barton (R-TX), Chairman of the Committee on Energy and Commerce of the House of Representatives, indicated that:

[2] Congressional Record, Senate, November 24, 2003, p. S15744

"…the provision indicates that any differential in charge between mail order prescriptions and prescriptions filled by community pharmacies will be paid by enrollees. To ensure a level playing field between mail order and retail pharmacies any such additional charges should be reasonable, and should not exceed the additional direct costs associated with dispensing the drugs through a community pharmacy. To permit large differences in charges would have the undesired effect of steering enrollees away from community pharmacies and toward mail order pharmacies."

Under the law, Medicare beneficiaries are required to pay any difference in "charge" for obtaining their covered outpatient drugs through retail pharmacy rather than mail order.
The proposed regulation interprets the phrase "difference in charge" by indicating that the enrollee pays for any "differential in the negotiated price for the covered Part D drug at the network retail pharmacy and mail order pharmacy." This interpretation is consistent with an August 2, 2004 communication from Secretary Thompson to House Energy and Commerce Committee Chairman Joe Barton, which responded to his letter of March 8, 2004. In that letter, Secretary Thompson says that:

"We appreciate your concern that any such differential be reasonable and not exceed the additional direct costs associated with dispensing the drugs through a retail pharmacy…Plan enrollees would only pay the difference between the negotiated price a retail pharmacy would have charged them for an extended (i.e. 90 day) supply of a covered Part D drug and the negotiated price of a mail order pharmacy would have charged for the same covered Part D drug."

"Negotiated prices" according to the regulation, should take into account "price concessions, such as discounts, direct or indirect subsidies, and direct or indirect remunerations, for any covered Part D drugs, and include any such dispensing fees for such drugs."

Consistent with this definition, the "negotiated price" should only reflect the net direct cost to the Part D plan, net of rebates, discounts or other price concessions, for the same quantity of medication dispensed to the patient through retail pharmacies versus mail order pharmacies. That means the cost difference to the senior should only reflect the net cost to the plan of paying for the prescription through retail versus mail, net of any manufacturer rebates, discounts, or price concessions paid to the plan for a similar quantity of the drug dispensed through retail versus mail order, with those various price concessions applied directly to reducing the cost of the retail or mail order prescription.

Plans should not be allowed to use rebates that are provided to them for prescription drugs that are dispensed through retail pharmacies to artificially lower the cost of providing mail order prescriptions. This makes it appear that mail order is less expensive, so they can make higher profits and dispense larger quantities of prescription drugs by steering beneficiaries to mail.

Moreover, to make an "apples to apples" comparison, plans must use the same AWP basis to determine the reimbursement rate for mail order and retail, and not use artificially-inflated or repackaged product AWPs for mail order, which generally overstate the AWPs as compared to retail package AWPs.

Moreover, reimbursement rates for generic drugs should be the same whether provided through retail or mail. That is, if a plan uses an AWP discount rate to reimburse mail order for generics, it should use the same method for retail. Similarly, if the plan uses a MAC (maximum allowable cost) for generic reimbursement for retail, it should use the same for mail order. Moreover, plans should pass along any spread between the rate they pay to pharmacies and the rate they charge the beneficiary. Plans should not be allowed to keep the spread (and thus make the retail price higher) by passing along the spread on the mail order side, but retaining it and charging the higher price on the retail side.

Given that subsidy-eligible low income individuals cannot have any difference in copayment amounts for their medications (i.e. $1 for generic; $3 for a brand in 2006) these individuals should be able to obtain larger quantities of medications from their local retail pharmacies, whether preferred or non-preferred, without having to pay any difference in price for their prescriptions.

Avoiding Conflict of Interest in Mail Order Services: We also believe that CMS should not approve any Part D plan that proposes to administer both the retail network and the mail order program in the same region. Such an arrangement reflects an inherent conflict of interest and is anti-competitive because the plan has an incentive to steer beneficiaries away from using a retail pharmacy toward their own mail order operation. This is more commonly known as PBM "self dealing".

A landmark study of the cost of PBM "self dealing" under a Medicare prescription drug benefit was released in September, 2003. The study estimated that the cost to the Medicare program resulting from situations where the PBM is both the plan administrator and seller of drugs through its own mail order pharmacy were an extra $30 billion over the period 2004-13.[3] The study determined that various factors were responsible for this increased cost to the Medicare program resulting from this conflict of interest.

These factors include that mail order dispensing is more profitable to the PBM than receiving payment for administering retail drug claims, creating incentive for it to create artificial plan designs (i.e., higher cost sharing at retail pharmacies) to shift beneficiaries to mail order; that PBMs receive larger rebates from drug manufacturers for shifting beneficiaries to higher-priced single source drugs, larger quantities of which are dispensed through mail order; and that PBMs often repackage prescription drugs and sell them to plans at a higher cost than if they used equivalent retail pharmacy packaging. For these reasons, we believe that Part D plan should be prohibited from being the retail plan administrator and mail order provider.

Beneficiaries will also pay more in cost sharing by using mail order pharmacies because use of lower-cost generics in mail order pharmacies is lower than in traditional retail community pharmacies. Data from NDCHealth, a healthcare information services company, indicate that mail order pharmacies use generics in less than 30 percent of the prescriptions they fill. This is quite low compared to retail pharmacies, which use generics for 55 percent of the cash prescriptions that they fill and over 47 percent in the Medicaid prescriptions that they fill.

[3] James Langenfeld and Robert Maness, "The Cost of PBM Self-Dealing Under a Medicare Prescription Drug Benefit, September 9, 2003.

Reluctance by mail order pharmacies to dispense generic drugs at a higher rate further contributes to the wasteful spending of benefit program funds.

In conclusion, we believe that the final rule must specify that plans cannot use differential cost sharing to steer beneficiaries to mail order pharmacies. The final rule must specify that, in calculating the difference between the negotiated price for the same quantity of prescription dispensed through retail pharmacy as compared to mail order, the price in each case reflects the rebates or discounts earned for that particular drug by the PBM in each channel in which they are earned.

The final rule should specify that any differential in price paid by the enrollee for a prescription obtained from a retail pharmacy versus a mail order pharmacy, or vice versa, should be considered an "incurred cost," and count toward the beneficiary's out of pocket spending thresholds.

Section 423.120(b) - Drug Formulary Requirements

Community retail pharmacy works with millions of patients each day to help provide them their prescription medications consistent with their plan's drug formularies. Formulary "enforcement" generally occurs at the retail pharmacy and often involves significant administrative hassles for the patient and pharmacist with little or no compensation. In fact, often times the rebate credits are earned by the PBM or health insurance plan for a formulary-based drug switch that was executed by the retail pharmacy provider.

The MMA allows Part D plans to use drug formularies and allows plans to create tiers within their formularies. Given that this new Part D program will affect the prescription patterns of millions of elderly individuals, including millions of low income Medicaid recipients, the potential for tens of thousands of drug switches to comply with new Part D drug formularies is possible, especially in the early months of 2006. This will create significant administrative hassles for pharmacists and beneficiaries, since almost all of these switches will likely require physician approval.

As part of its review process of a plan's formulary, CMS has indicated that it will also examine other utilization management strategies that are tied to appropriate drug use, such as tiered cost sharing, step therapy and prior authorization. All these mechanisms are integral to appropriate drug use and cost containment, and in almost all cases they are implemented through the retail pharmacy provider. We agree that CMS should review these mechanisms in conjunction with the plan's formulary, as well as extent to which the plan is using tiered cost sharing to encourage the use of certain medications.

NACDS believes that drug formularies developed by Part D plans should include covered Part D drugs that reflect contemporary medical practice. Having said that, we believe that beneficiaries should be started on the most cost effective drug that is available on the formulary to treat their medical condition, and that plans and formularies should encourage the use of generic or lower cost multiple-source drugs where possible.

Beneficiaries should be able to obtain specific brands when necessary, but we are concerned that direct to consumer advertising of prescription drugs may result in excessive brand drug usage where more cost effective generics might be available. With respect to the specific issues raised regarding formulary implementation, we would recommend the following:

- **Impact of Drug Switching**: Given that this new Part D program will affect the prescription patterns of millions of elderly individuals, including millions of low income Medicaid recipients, the potential for tens of thousands of drug switches to comply with new Part D drug formularies is possible, especially in the early months of 2006. This will create significant administrative burdens for pharmacists and beneficiaries, since almost all of these switches will likely require physician approval.
  There could be extensive pharmacist time and cost involved in explaining denials to patients, contacting physicians to switch drugs, and executing claims transactions back and forth before a particular drug is approved for dispensing by the plan.

  We are also concerned about the potential number of drug switches involved with a low-income Medicare beneficiary. For example, a beneficiary may be taking multiple drugs, some of which may be prescribed by different physicians, and some of them may have to be switched to accommodate the plan's formulary. It may not be advisable to switch all the drugs at once, especially for drugs that have narrow therapeutic ranges, or potential side effects. These switches should occur over time consistent with good patient care and sound medical practice, and not just to accommodate a plan's formulary.

  Pharmacists are not interested in engaging in independent therapeutic substitutions of drug products. As compared to generic substitution, which allows the pharmacist to dispense a therapeutically and pharmaceutically equivalent drug to the brand name drug prescribed (i.e., the same chemical entity), therapeutic substitution involves the switching of one drug to another drug with a different chemical entity. Pharmacists generally engage in therapeutic interchange, which allows for the substitution of a different drug product based on the physician's concurrence or approval. However, several states do recognize collaborative practice agreements between physicians and pharmacists that allow for the substitution of one drug product for another under an agreed upon physician-pharmacist protocol. We do not believe that Part D plans should be prohibited from using such agreements where they exist in certain states to allow for pharmacist substitution of certain drug products.

- **Generics Preferred**: Drug formularies should be structured so that a generic or innovator brand name drug is the preferred agent in as many classes as possible (where available) unless the physician has indicated that a specific brand is medically necessary. Plans may want to consider requirements for physician approval of certain brand name drugs in therapeutic classes where generic drugs are available.

- **Physician Obtains Prior Approval:** NACDS agrees that prior approval and step therapy programs can help plans reduce drug spending and improve overall quality of care. However, any prior approval program or step therapy program should require the physician to contact the plan and obtain approval.

- The plan's approval to dispense a particular drug should be communicated to the pharmacist through the online, real time claims adjudication system. The pharmacist should not be responsible for obtaining all the authorizations necessary from the plans to dispense a drug requiring "prior approval," or those drugs in a "step therapy" program.

- **Over the Counter Drugs:** The MMA allows plans to exclude over the counter medications from coverage (except smoking cessation products). However, it may be the case that plans will cover OTC medications in their formulary and attempt to have these "counted" as one of the two drugs that are required to be covered per each class or category. This is particularly likely in classes where there is a former prescription product that has been switched to OTC status.

  For example, there have been recent switches in the PPI class (i.e. omeprazole) and in the non-sedating antihistamine class (i.e. loratadine). Future potential switches are possible, such as lovastatin, which is a cholesterol-lowering drug.

  After these switches, many commercial managed care plans have stopped coverage for or limited coverage of (i.e., shifted to a higher tier copayment) prescription versions of these products. This has shifted the entire cost or most of the cost to the patient, even though these OTC drugs may not have the same indications as the prescription drug, nor be considered to be bioequivalent by the FDA's *Orange Book*. We urge CMS to determine whether plans are limiting availability of certain prescription medications in classes where equivalent or substitutable OTCs might be available.

- **Pharmacy and Therapeutics Committee:** Pharmacy and Therapeutics (P+T) Committees should be involved in the development of clinical programs for Part D plans, such as formulary development, prior authorization, medication management, and step therapy, but only if the majority of P&T committee members are free of conflict of interest. It makes no sense to vest more authority and control in a P&T Committee if there are significant conflicts of interest that compromise appropriate and cost effective drug use for that plan's beneficiaries. State Medicaid programs often use their Medicaid P&T Committees to, among other activities, develop formularies, preferred drug lists, prior authorization procedures, and monitor clinical programs, such as medication therapy management or disease management.

  Thus, using these Committees for these purposes makes sense, as long as the group consists of individuals whose goals are to assure the most appropriate, cost effective prescribing. Because cost management and clinical programs of these types are implemented at the pharmacy level, P&T Committees should include representatives of chain corporate offices since many of the procedures that might be put in place are likely to be implemented, in part, at the corporate chain level.

- **Off Label Usage:** Physicians who prescribe drugs for an off label use should indicate the diagnosis on the prescription or through the electronic prescription communication so the pharmacist knows that a drug is being used for such a use.

- The pharmacist cannot be placed in a position of "policing" off label use of prescription medications for the plan. The regulation indicates that prescribers are "encouraged" to "clearly document" and justify off label use in Part D enrollees "clinical records." We strongly urge that such information also be noted on the prescription provided to the pharmacist so the pharmacist can properly conduct drug utilization review.

- **Appeals Process:** It is the responsibility of the beneficiary and the physician to navigate the formulary appeals process. The pharmacist can provide the beneficiary with general information about the process but cannot and should not be placed in the middle of the process. The pharmacist should be told of the ultimate decision of the appeals process through the online real time claims adjudication system regarding the approval of (or disapproval of) coverage of certain drugs.

  Moreover, we are concerned with the complex appeals process that is put in place for beneficiaries and physicians to "appeal" a formulary decision. There are appeals processes both at the Part D plan level and the Medicare level. In addition, the length of time to make a decision on an appeal depends on many factors, including whether the beneficiary is paying or not paying for the drug on appeal.

  It is not clear how pharmacists will know the status of these appeals or how a decision on an appeal will be communicated. This status of these appeals must be communicated to the pharmacist through the real time electronic prescription processing system. Pharmacists cannot be placed in the middle of these determinations processes, but must be aware of the status of the appeals to help the beneficiary know the status of their prescription drug coverage.

  We believe that CMS should assure that plans develop an appeals process that is minimally burdensome to beneficiaries, physicians and pharmacists. CMS should require plans to document the process they will use, as well as involve pharmacy providers that are in their networks in the design and implementation of this process to assure that it is minimally burdensome on pharmacies and pharmacists.

  CMS may want to consider creating a standard dispensing procedure for a drug that is not on the formulary or is on appeal, especially if the pharmacist is unable to contact the physician. This might happen, for example, over a weekend when a beneficiary might have to fill a prescription for a necessary antibiotic or pain medication. For example, the Medicaid program requires the dispensing of a 72-hour supply of medication in an emergency situation. It will be very difficult for pharmacists and beneficiaries to know how to handle each plan's "emergency situations" procedures at network pharmacies regarding a physician's order for a non-formulary drug. There should be some standard procedure incorporated into the system.

  Moreover, pharmacies need to be paid for the dispensing of the emergency supply of the medication as well as the dispensing of the remaining quantity of the medication should the original prescription be approved under the appeals process or the physician prescribes another formulary drug.

Beneficiaries should pay the cost-sharing amount for that emergency supply of the drug, because it is not clear that the plan will ever approve the full prescription for the non-formulary drug. Pharmacists need to be sure that they are paid for the total cost of providing the prescription. We reiterate that pharmacists are able to waive the cost sharing for Part D drugs, but are not required to do so.Network pharmacists should not be expected to waive cost sharing requirements for the provision of emergency prescriptions.

- **Similar Formularies Between Retail and Mail Order:** CMS should assure that all formulary drugs are available to Medicare beneficiaries through both retail and mail pharmacies. Part D plans cannot structure formularies to only make certain drugs available through mail order rather than retail pharmacies.

  All covered outpatient drugs should be available to beneficiaries through retail pharmacies, as they are made available through mail order pharmacies. Also, consistent with congressional intent, plans cannot use differential cost sharing to steer beneficiaries to mail order pharmacies and create different cost sharing tiers for retail pharmacies versus mail order pharmacies.

- **Communication of Formulary Changes:** It is particularly important to communicate formulary changes to beneficiaries, pharmacists and physicians as soon as possible. Formulary changes are likely when new drugs come to market (or are removed from the market), generics are added, or new off label uses are defined. NACDS suggests that plans change formularies as infrequently as possible. This will minimize disruptions to beneficiary health care and limit operational issues for pharmacies. Pharmacists and patients often only become aware of formulary changes when a beneficiary comes in to fill and/or refill a prescription.

  We agree that a beneficiary should be able to obtain a prescription fill or refill for a formulary drug at the same cost share for 30 days after the plan formulary notifies enrollees about a change in the drug's status on the formulary. The formulary change should be communicated to the corporate chain headquarters of pharmacies so that any appropriate changes can be made in the chain-wide pharmacy system.

  The key is for the plan to communicate all information to the pharmacy in real time through the online claims adjudication system at the time the prescription is presented. Pharmacies need to have at least 30 days notice of any prepared formulary status changes. We believe that plans should use a standard formulary change form, and that CMS should develop standard policies and procedures for how these changes are communicated to beneficiaries, pharmacists, and physicians. Mass mailings should not be the only method by which these changes are communicated. Mail that is sent to pharmacies may not be opened in an expeditious manner, or may not be read by all pharmacists that are working in that pharmacy depending on their shift. The best way to communicate these changes to pharmacies is through the online claims adjudication system.

We also believe that this notice to beneficiaries regarding a formulary change should provide information to beneficiaries on how to appeal a formulary change, and serve as the legally-enforceable notice that a coverage change is being made. Beneficiaries may learn about these changes at the pharmacy counter if they do not read the communication or understand the communication, but it should not be the pharmacist's responsibility to provide a legally-enforceable document or communication at the point of service regarding appeals rights regarding the coverage of a covered Part D drug.

- **Payment Incentives to Pharmacies**: CMS should understand that many of the formulary management and drug utilization techniques described here are performed by pharmacists. As such, plans should indicate as part of their bid submission how they intend to compensate pharmacists for performing these valuable cost management and quality improvement functions.
  This compensation must paid be in addition to the product reimbursement and dispensing fees that have to be paid to the pharmacist. CMS envisions that pharmacies would be paid for these functions (i.e., formulary compliance and generic drug substitution) because they are described as part of "performance based measures" under the definition of "insurance risk". These professional intervention service payments should be consistent with the time needed to perform them and should be updated each year to account for increasing costs to the pharmacy operator.

Section 423.120 (c)- Use of Standard Technology (Standard Benefit Card)

NACDS agrees with the provision that indicates that CMS will base its card standards on the elements of the NCPDP "Pharmacy ID Card Standard", which have been developed and agreed upon by industry consensus. These are the elements that all payers require, at a minimum, to process a claim for pharmacy benefits. Additionally, these elements are required to properly route a pharmacy benefit claim to the correct entity for claims processing. We urge CMS to adopt NCPDP's "Pharmacy ID Card Standard" as the format for Medicare Part D benefit card. Any deviation from the NCPDP standard would cause unnecessary confusion for pharmacy providers which would lead to unnecessary delays in the delivery of medications and services to part D beneficiaries. CMS should approve any and all cards issued by plans to assure that they comply with the NCPDP standards.

A standard card for all pharmacy benefit payers would save pharmacies time and effort; all necessary claims reimbursement information would be provided, and it would be provided in a widely-accepted format that is easy to read. Dealing with the administrative burdens created by inconsistent and confusing prescription benefit cards creates unnecessary barriers to pharmacists providing care to their patients.

Section 423.124 – Special Rules for Access to Covered Part D Drugs at Out of Network Pharmacies

The proposed regulation requires that plans allow Medicare beneficiaries to obtain covered outpatient drugs at out of network pharmacies under certain conditions and establishes requirements for plans relating to how such drugs could be obtained at such pharmacies.

This assumes that these pharmacies are neither preferred pharmacies nor non-preferred pharmacies, and simply do not have a contract with the Part D plan to participate in that particular plan.

NACDS is concerned that the requirements specified in the rule's background regarding out of network pharmacies are impractical and inconsistent with current industry practice. Plans traditionally do not establish certain "out of network" pharmacies. While this proposed rule establishes "preferred" and "non-preferred" networks, it does not appear to be the intent of this rule to have the plans contract with select out of network pharmacies. Indeed, the very definition of out of network pharmacies in the rule indicates that the plan does not have a contract with a Part D plan. Therefore, any pharmacy not under contract in the network is an out of network pharmacy.

If a beneficiary has to use an out of network pharmacy to obtain covered outpatient drugs, then all the out of network pharmacy can do is fill the prescription for the beneficiary and charge the beneficiary the pharmacy's full usual and customary price for the medication. The pharmacy can provide the beneficiary with a receipt for the prescription, and the beneficiary will then have to reconcile with the plan any copayments, plan allowances, formulary status issues and application of the amount paid to the out of pocket maximum, after the prescription is filled. The very fact that the pharmacy is not in the plan's network means that the pharmacy cannot determine many important plan components that are necessary to fill the prescription if the pharmacy was in the network.

For example, out of network pharmacies cannot be in a position to determine that the prescription was or was not medically necessary, or if it is an emergency. We have no idea whether a beneficiary truly does not have access to a network pharmacy. A beneficiary filling a 90-day prescription for a needed blood pressure medication may be an emergency, but depending on the circumstances would not necessarily need a full 90-day supply from the pharmacy. A limited supply would probably suffice. However, the pharmacy would have to retain the original prescription (even if the beneficiary only wanted a limited supply) and the beneficiary would have to obtain another prescription from the physician or have the physician contact the regular network pharmacy that the beneficiary uses.

Plans and beneficiaries should not be allowed to seek any cash or payment recovery from the pharmacy subsequent to providing the prescription if the prescription was not urgently needed or the pharmacist filled the prescription for a quantity greater than allowed by the plan, or the drug was not on formulary. CMS may want to consider establishing a consistent emergency supply definition and consistent procedures from plan to plan. For example, Medicaid allows for the dispensing of a 72-hour supply of medication if prior authorization cannot be obtained within 24 hours. In some cases, the out of network pharmacy may be provide a short-term emergency supply, while in other cases it might be provide a longer-term supply.

Pharmacies that are not under contract to a plan cannot know a beneficiary's formulary status through the electronic claims processing system. That is because the pharmacy cannot access the important information necessary to adjudicate the claim real time because it does not have a contract with that pharmacy to access that information.

Therefore, pharmacies cannot determine the formulary status of a particular prescribed drug (i.e. tier, on formulary, etc.) unless the pharmacy has access to the online system.

The proposed regulation recognizes the impracticality of the pharmacy enforcing any formulary provision for a prescription filled at an out of network pharmacy in its section by waiving the public disclosure relating to pharmaceutical prices (e.g., lower cost generics) for these pharmacies. The explanation says that such a requirement is impractical because "by definition, out of network pharmacies are not under contract with a PDP sponsor or an MA organization, complying with such disclosure would be impracticable."

It is not fair to apply plan allowances from other Medicare Part D plans in which the pharmacy may be participating to prescriptions filled for out of network beneficiaries. Pharmacies accept certain reimbursement rates based on various factors, including plan design parameters, mix of generic and brand drug reimbursements, administrative issues relating to participating in plans, and other factors. Establishment of the total amount the plan will pay the beneficiary for an out of network prescription and any copays due from a beneficiary must be reconciled between the beneficiary and the plan after the prescription has been filled.

Finally, pharmacies do not set their "usual and customary" prices based on the potential that a Medicare beneficiary will seek to have a prescription filled at an out of network pharmacy. "Usual and customary prices" are set by the private marketplace consistent with the highly competitive nature of the retail pharmacy marketplace. Pharmacies do not differentiate these prices based on the type of cash-paying customers.

Beneficiaries should be told up front that they should only use out of network pharmacies in true emergencies. That is because out of network pharmacies will have a difficult time providing prescription services if they don't have information regarding the plan's allowance, or information necessary to perform drug utilization review (DUR). Pharmacies will not know if the person is even covered. Pharmacies will not know what the emergency access prescription limits are if they differ by plan, and the beneficiary should not be relied upon to tell them. Thus, uniform emergency access standards may have to be developed to reduce the confusion to the pharmacist and the beneficiary from inconsistent and conflicting out of network standards.

Plans also should not use the out of network requirements to force beneficiaries that live in another service area part of the year (i.e., snow birds) to use mail order. The proposed rule indicates that plans can "require the use of mail order pharmacies as appropriate for extended out of network travel." This could mean that beneficiaries that live in another location for part of the year could be forced to obtain their maintenance medications through the mail, even though the statute requires that beneficiaries be able to obtain such quantities from retail pharmacies. Plans must make adequate accommodations for enrollees to obtain (and pay for) such quantities from out of network retail pharmacies in the same manner that they make such quantities available through mail order pharmacies.

Section 423.128 – Dissemination of Plan Information

Content of Plan Description: As stated in a previous section, NACDS generally agrees with the proposed rules requirement regarding the type of information that beneficiaries have to receive both from CMS and individual Part D plans. However, we believe that it is important for beneficiaries to know the network status of all the pharmacies in the particular plans that they are considering so they can make an informed determination regarding which plan they may want to choose. The network status of pharmacies can be very confusing to beneficiaries under the scheme that CMS has constructed. Pharmacies can be considered preferred, non-preferred or out of network. Plans must specify the status of specific pharmacy locations, not just note whether a particular pharmacy chain is in the network.

In addition, beneficiaries should know the exact cost sharing amounts involved with using particular pharmacies in the network. Material should be carefully reviewed by CMS to assure that plan designs do not steer beneficiaries to mail order pharmacies.

Beneficiaries should also be told up front in both the CMS and plan educational materials that they have the option of using a retail pharmacy in the network to obtain a maintenance supply of their medication from a network or non-network pharmacy. Plan educational materials should be reviewed carefully by CMS to assure that plans do not say or imply that maintenance medication can only be obtained through mail order. This requirement should extend to CMS education materials as well as plan specific educational materials. Beneficiaries should also be told that appeals and grievances must be resolved through the plan, and that the pharmacist is not responsible for making decisions regarding formulary coverage.

Provision of Specific Information: We agree that Part D plans should maintain 7-day a week, 24 hour a day support centers for beneficiaries. A separate technical support center should also be maintained for pharmacies. Many pharmacies are now open 24 hours a day. Pharmacies that may need to contact a plan for information necessary to fill a prescription should have a separate support center and adequate phone lines for pharmacists to call at any time.

Claims Information: Section 423.128(e)(1)(5) of the proposed regulation require that Part D plans provide monthly summary statements to beneficiaries that include an explanation of their prescription drug benefits. It is suggested that, with regard to such statements "if technically feasible, a PDP sponsor or MA organization could also provide the notice of benefits at the point of sale…". This could imply that the pharmacist could provide such a statement.

The scope, nature and type of information envisioned being provided under this provision, however, would be far beyond what a pharmacy would have on file and would be technologically infeasible to do at this time. Pharmacies would have to purchase a separate printer to produce these forms, assuming their systems were even capable of receiving information from plans that would be used to provide this information. In addition, it would add another significant administrative task for pharmacies for millions of beneficiaries each year. This summary statement should be sent by the plan to the beneficiary by mail or be sent electronically to them if the beneficiary has that capability. This is not the pharmacy's responsibility.

Given the importance of beneficiaries knowing the plan's appeals and grievance process, we urge that plans include information on each month's statement regarding how this process works. This will help assure that beneficiaries, many of whom are likely to keep these statements, will have an easy reference on how the process works. We also suggest that this process be posted in a conspicuous position on the plan's website.

Section 423.132 - Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

This section requires that plans require that retail pharmacies that are dispensing a covered Part D drug inform a plan enrollee of any differential between the price of the drug and the price of the lowest-price generic drug available at that pharmacy, unless the particular Part D drug being purchased is the lowest price version of that drug available at that pharmacy.

In almost all cases, the pharmacist will be dispensing the only version of the product that is stocked in the pharmacy when a prescription is written for a multiple source drug. Therefore, in reality, this basically only requires the pharmacist to tell the patient the differential in cost if they are dispensing a higher cost version of a generic that they stock in the pharmacy rather than the lowest cost version that they stock. The use of the term "lowest" can imply that three or more versions of generics are available at a pharmacy. This is rarely the case. Most pharmacies only stock one supplier of each generic drug dosage form and strength, making that product the defacto "lowest" cost generic at that pharmacy. It would be unusual for a pharmacy to stock, no less dispense, a higher cost generic.

There may be cases where the product that the pharmacist is dispensing is an innovator multiple source drug whose price is equal to or less than the generic competitors. For example, the brand name versions of antibiotics are often priced equal to or lower than their generic competitors. The off patent brand name drugs are most accurately referred to as "innovator multiple source drugs." Thus, we urge that the regulation only require that the pharmacist inform the patient of the price difference if they are dispensing a higher cost version of a multiple source drug that is available at that pharmacy. In many cases, these off patent innovator brands – which are part of the multiple sources of supply – are less costly than their generic counterparts. Without making this technical correction, these drugs may not be considered by some plans to be "generics". This could trigger the requirement that the pharmacist inform the beneficiary that the drug they are dispensing is not the lowest cost "generic", but is the lowest cost version of that "multiple source drug" stocked at that pharmacy.

Retail pharmacies are required to provide this information at the point of sale. Mail order pharmacies are only required to inform Medicare beneficiaries at the time of delivery of the drug, after the prescription is filled. The Secretary can waive the requirements relating to the timing of the notice in circumstances specified by the Secretary. We believe that this should be interpreted and implemented so that the same requirements related to timing of the notice are placed on mail order pharmacy as are placed on retail pharmacy. Mail order pharmacies should be required to contact the Medicare beneficiary before the prescription is filled and delivered to the beneficiary's home to indicate the price of the generic being dispensed, unless it is the lowest cost generic dispensed by that mail order pharmacy.

Providing this information before the mail order prescription is dispensed is especially important since mail order pharmacies have lower generic dispensing rates than retail pharmacies, including for maintenance medications.

Section 423.153 Cost and Utilization Management, quality assurance, medication therapy management, and programs to control fraud, waste, and abuse Control and Quality Improvement Programs

Section 423.153(b) - Cost Effective Drug Utilization Management

NACDS supports programs that encourage the use of the most cost-effective medications. Pharmacists can be critical to making these programs work, since they are the health professionals that are interacting directly with the beneficiary and the physician regarding their prescription.

One such item proposed in the regulation is establishing differential dispensing fee for generic drugs or multiple source drugs. We believe that such a differential, combined with a reduction or elimination in cost sharing for generics, could help increase the use of generics. This position should not be interpreted as our supporting higher generic dispensing fees and lower brand name drug dispensing fees, but rather, an additional bonus payment for pharmacist to increase generic substitution and dispensing rates. Pharmacies have fixed costs to dispense prescriptions whether brand or generic. In fact, because of the higher carrying costs for more expensive brands, it costs pharmacies more to stock and dispense a brand name drug.

However, encouraging the use of generics also requires that plans use reasonable programs to reimburse pharmacists for generic drug products. CMS should assure that plans are not using aggressive Maximum Allowable Cost (MAC) programs to reimburse pharmacists for generics. While these programs are commonly used in third party programs, they should be developed so that there are appropriate incentives to dispense these drugs. Also, these MAC lists should be regularly updated to keep pace with rapidly-changing generic drug pricing and market conditions. CMS should actively monitor whether plans are using different generic reimbursement mechanisms for their retail pharmacies versus their mail order facilities. That is, plans often reimburse themselves more for the same quantity of generic dispensed through their own mail order facilities than they do retail pharmacies.

We also believe that the legislative history of the law precludes plans from using differential cost sharing to encourage beneficiaries to use mail order as compared to retail pharmacies. Evidence suggests that encouraging individuals to use mail order really offers little if no savings, and actually encourages wastage of higher-priced brand name drugs. While plans can use different cost sharing to encourage the use of preferred pharmacies versus non-preferred pharmacies, the legislative history described above makes clear that Congress did not intend plans to steer beneficiaries to mail order. Evidence suggests that “conflicts of interest” exist when plans own and operate their own mail order pharmacies. This conflict ultimately results in higher costs to beneficiaries and ultimately to Medicare.

Section 423.153(b) - Quality Assurance Programs

The preamble to the regulation engages in an extensive discussion about quality assurance programs that plans should have in place. The discussion asks whether OBRA-90 standards adopted for the delivery of pharmacy services for Medicaid beneficiaries should be considered the industry standard that should be applied to the Medicare population. Medicaid consists of a program of prospective utilization review (ProDUR), retrospective review (RetroDUR), and educational interventions for prescribers and physicians.

In terms of ProDUR, almost all pharmacists have systems in place to help assure the quality of prescription drugs dispensed before the prescription is provided. This includes special software programs that detect potential medication related problems such as over utilization and under utilization of prescription drugs, therapeutic duplications, and inappropriate drug use. Included in these ProDUR standards is an OBRA-90 mandated requirement that pharmacists offer to counsel Medicaid beneficiaries on their prescription use.

These requirements have been adopted by almost all Boards of Pharmacy as part of their practice acts, and have become the standard for the practice of pharmacy. We believe that requirements relating to counseling Medicare beneficiaries on their prescription medications should be consistent with the state's pharmacy practice act. All states address the issue of how pharmacists are to offer to counsel individuals on their prescription use. State practice acts specify whether the offer to counsel must be made on refills as well as new prescriptions, who is to make the offer, and method of documentation. We do not believe that Federal law should create a new standard for pharmacy practice, which has traditionally and appropriately been regulated by state boards of pharmacy.

Likewise, quality assurance programs for pharmacies are required by many states. State practice acts and regulations specify the legal protections afforded the programs, the types of policies and procedures required, and the level of flexibility the pharmacies have in developing their own quality assurance programs. NACDS is supportive of quality assurance programs and we believe that focusing on lessons learned from quality assurance programs will benefit both the beneficiary and pharmacy practice. We suggest, however, that rather than requiring Part D plans to develop their own quality assurance program that providers would have to utilize (which may conflict with a program they are currently using for all their patients), they should have systems and measures in place to ensure providers have a quality assurance program, and comply with the program.

It is noted in the preamble that, in the future, quality reporting may be required that includes error rates which would be used for enrollees to compare and choose individual plans. We feel strongly that this would be counter productive to an effective quality assurance program. The Institute of Medicine (IOM) Report *To Err is Human: Building a Safer Health System* released in 1999 recognized that for any quality improvement program to be effective, those who report errors must feel safe to report in a <u>confidential</u>, non-punitive environment with all of the necessary legal protections. We urge that Medicare have a more in depth discussion with stakeholders about a potential medication error reduction and reporting program.

While we are clearly supportive of programs that would reduce such errors, we need to be sure about what constitutes such an error, and how such errors would be reported to plans and how they would be reported to beneficiaries.

The use of bar codes on prescription products can help improve the quality of pharmacy dispensing and overall pharmacy operations. Bar codes can help identify potential medication related issues before the product is dispensed, such as whether the wrong drug or wrong dose is being dispensed, potential drug interactions or therapeutic duplications, or other issues.

In its final bar code rule issued in February 2004, FDA will require that all human prescription drug products include the National Drug Code (NDC) number of the pharmaceutical product in a linear bar code. Most products have to meet this requirement by February 2006. Many hospitals and retail pharmacies are incorporating this technology into their practices for various patient safety and operational reasons. Because of the cost involved in acquiring and installing this technology, the final regulation should not require plans to require pharmacies to have such technology in place in their pharmacies.

Most plans have policies regarding early refill of medication. Such policies should be implemented through the online real-time claims adjudication system in which the plan would indicate that a refill has been obtained too early. Beneficiaries should be fully informed of their policy and pharmacists should be able to obtain this information through the online system.

Section 423.153(d) - Medication Therapy Management (MTM)

Section 423.153(d) requires Part D plans to include programs of medication therapy management (MTM) in their plan offerings. NACDS supports the inclusion of MTM services in the Part D plans, but we are concerned with CMS's interpretation of the law through the proposed rule. Our comments relating to specific components of the proposed rule are detailed below.

Unlike DUR programs, which tend to be focused on prescription drug issues relating to "populations", we believe that MTM programs are supposed to be focused on improving medication use in specific individuals. We believe that MTM programs should be structured with the clear goal of improving quality, reducing overall health care costs and demonstrating improved health care and quality outcomes for specific beneficiaries by optimizing their use of prescription medications. Community retail pharmacists are extremely well qualified to provide MTM services and community pharmacies are increasingly moving toward developing these types of programs. The inclusion of MTM services under Medicare Part D will accelerate the development of this capability.

Medicare enrollees are more likely than other population groups to have multiple chronic illnesses that require treatment from multiple physicians. According to CMS data, 20 percent of Medicare beneficiaries have five or more chronic conditions. The average Medicare beneficiary sees seven different physicians and fills upwards of 20 prescriptions per year. Problems relating to care fragmentation and insufficient provider communication often lead to avoidable complications for Medicare beneficiaries.

Medication therapy management represents a positive step in ensuring that Medicare beneficiaries are placed on optimal drug therapy regimens and experience better health outcomes.

Program Structure and Incentives: Part D plans are required to provide MTM services. We support the inclusion of MTM on both the managed care and fee-for-service side of the Medicare program. However, we would point out that financial incentives for the two types of plans are likely to be different as they relate to MTM programs. MA-PDs are at risk for all of the health care utilization of their enrollees (including pharmacy, hospital, and physician services). PDPs, on the other hand, will only be placed at risk for prescription drug expenditures. This may give these plans a financial disincentive to promote comprehensive MTM programs.

Based on experience from other disease management programs for the chronically ill, for example in state Medicaid programs, MTM services are likely to increase drug utilization while decreasing the utilization of hospital and emergency room services. For MA-PDs which are at risk for each of these service types, higher costs on the prescription drug side could be seen as an investment in lower health care utilization overall. However, for PDPs, MTM may represent only an added administrative expense that actually decreases their ability to manage their risk.

CMS should be aware of these conflicting incentives and should ensure that the MTM programs that are offered to beneficiaries, both on the managed care and the fee-for-service side, are as comprehensive as they need to be in order to optimize medication therapy. This is especially true since, at least historically, sicker beneficiaries with higher numbers of chronic conditions have often chosen to remain in the fee-for-service program. While this trend may shift in the future, we still remain somewhat concerned about how PDPs serving the fee-for-service side of the program might choose to structure their MTM programs.

Under Part D, PDPs can seek accreditation from a national accreditation organization, and part of that process will include a review of the plans' MTM programs. While we are aware that CMS would prefer to allow fairly broad flexibility to the private plans in determining the structure of these programs, we would encourage CMS to specify in the final rule some of the specific requirements for meeting accreditation standards, including the primary use of community pharmacists in performing MTM services. Plans should also be required to demonstrate that they are offering a specific package of MTM services and indicate how they will pay providers, including pharmacists, for these services.

MTM Program Development: As mentioned above, CMS has expressed a clear preference to allow the private sector prescription drug plans to design and develop their own MTM programs and allow competition in the private market help determine the structure of these programs. The proposed rule also indicates that there is likely to be a broad range of services, ranging from simple to complex, that will be offered to enrollees, as well as a range of providers who may supply MTM services. We believe it is essential to give community pharmacists and physicians a significant role in the design of these programs. Both the Medicare law and the proposed rule specify that pharmacists and physicians will be given a role in helping to design Part D plans' MTM programs.

We support this provision and would emphasize the importance of including practicing *community* pharmacy providers, rather than those that are employed only by the private plans, in assisting with this effort. We also believe that executives from chain corporate headquarters (i.e., pharmacy practice, pharmacy operations), should be involved in the design and implementation of these programs since the programs will have to be integrated into the existing workflow of the pharmacy and the pharmacist. We believe that involving Pharmacy and Therapeutics (P+T) committees (whose members are free of conflicts of interest) in helping to structure these programs could help assure that they are suited to meet the needs of Medicare beneficiaries.

MTM Services: We agree with CMS' conclusion in the proposed rule that the MTM services offered to beneficiaries should vary depending on the needs of the individual. Some cases are more complex than others, and there will be varying need for medication therapy management services. We also agree that enrollees should not be charged copays for the services offered through MTMs. Imposition of copays could likely discourage the use of MTM services.

We do believe, however, that Part D plans should be required to offer a basic package of services which may be provided to beneficiary at the pharmacist's discretion (or within a certain approved protocol) and billed by the pharmacy to the plan.
Unlike the case with the "standard drug benefit" defined under the statute (which may be an actuarially-equivalent offering), we are concerned that there will be significant variability among plans, even within the same region, regarding the nature and scope of MTM services that might be provided.

Given that these services remain undefined in the minds of many beneficiaries, it will be important to define a basic package of services that beneficiaries that are eligible and enrolled in these programs might expect from the plan. While the competitive marketplace might be able to decide this, it is unlikely that a Medicare beneficiary will be able to distinguish among the types of services that might be offered by a plan.

Pharmacy providers recently gathered to discuss what services should be included under the rubric of medication therapy management. These providers generated a consensus document that provides a comprehensive list of services (see Appendix 2). We believe that private plans offering MTM programs under Medicare Part D should draw from the core set of MTM services included in that consensus document.

For example, we believe that Medicare beneficiaries newly-enrolled in the MTM program should be provided an initial face-to-face consultation by the pharmacy provider in the community retail pharmacy setting to assess their medication therapy management needs. This activity, which would be of appropriate length to achieve its objective, would involve an assessment of the prescription and non-prescription medications being taken by the Medicare beneficiary (medication history review). The pharmacist should have available information on all the medications that the beneficiary is taking, including those that might have been provided by mail order pharmacies. The pharmacist would also assess the ability of the Medicare beneficiary to coordinate the appropriate use of their medications.

Next, the pharmacist would develop a treatment plan that would include:

- Avoiding adverse drug reactions and duplicate therapy with other prescription and non-prescription medications by recommending to the physician that the beneficiary terminate or change certain therapies;
- Helping the beneficiary remember to take all the current prescription and non-prescription medications, and interacting with the beneficiary's physician to discuss modifying various treatment options, including use of generic drugs and long-acting (one/day) dosage forms, if needed;
- Developing interventions to help beneficiaries take their medication appropriately, such as:
    - Special medication treatment cards or reminders;
    - Special packaging, such as blister cards which include the beneficiary's daily medication dosages;
    - Written refill reminders or telephone calls to the beneficiary to determine if they have taken their medications.

The MTM program should allow beneficiaries to have at least monthly consultations with the pharmacy provider to provide continuity of care, positive reinforcement, and an assessment of the interventions used.

The purpose of these consultations is to assess the impact of the MTM program on optimizing therapeutic outcomes, and to reduce the risk of adverse events in the beneficiary. This will also allow the pharmacist to assess the educational activities and interventions being provided to the beneficiary under the MTM program, and to make appropriate modifications. After these basic services are provided, then a higher level of services can be provided for individuals that have more complex conditions or require a different level of services. Thus, we would support a "step" approach to MTM services in the final regulation that would specify how plans would have to implement these programs.

Defining MTM Eligibility Criteria: Beneficiaries eligible for MTM services could be identified either by the plan itself or the beneficiary's pharmacy provider. We agree with the proposed rule that states that MTM services should be targeted to specific beneficiaries rather than population groups. Under MMA, eligibility for MTM services is to be based on three criteria.

The Medicare enrollee must (1) have multiple chronic illnesses; (2) be taking multiple covered Part D drugs; and (3) have high estimated annual drug costs. The law specifically provides examples of five disease states that would likely trigger the inclusion of a Medicare beneficiary in an MTM program. These include diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. In determining potential candidates for MTM services, plans should obviously focus on individuals that have two or more of these comorbidities.

CMS has indicated that it would prefer to have the private drug plans set their own eligibility criteria to the greatest extent possible, rather than establishing federal guidelines. However, CMS has asked for comment on further defining these criteria. We believe that determination of the need for these services cannot be solely based on objective criteria; there are also subjective criteria that need to be considered.

For example, we believe that patients that have two or more chronic medical conditions (e.g., diabetes, CHF, hypertension), taking two or more prescription medications (e.g., antihypertensives, antidiabetic medications, cholesterol-lowering medications) should be identified as potential candidates for MTM. Some of these individuals may have the capability of managing their drug therapy, and may not be in need of MTM services. We do not necessarily believe, however, that a patient taking a medication for chronic glaucoma as well as chronic medication for a toenail fungal infection would necessarily meet the criteria.

We also believe that the beneficiary's full range of drug therapies should be considered, not just covered Part D drugs, when considering eligibility for the MTM program. For example, a beneficiary may be taking several non-covered Part D drugs, such as benzodiazepines or barbiturates, and some Part B drugs, such as immunosuppressives or oral cancer drugs. To ignore the other drugs the beneficiary might be taking when determining eligibility for MTM could exclude certain beneficiaries from the program who would clearly benefit from MTM services.

We believe that criteria should require plans, working with the pharmacist, to assess the need for MTM for plan enrollees that are taking two or more drugs for two or more chronic conditions. We also suggest that, instead of setting a specific targeted expenditure threshold to identify beneficiaries that are candidates for MTM, that the plans analyze beneficiaries in certain top percentile ranges of drug spending for the plan (i.e., top 10 %, top 20%).

In general, the highest drug spenders will likely be taking the most drugs, making them the most likely candidates for MTM. Using a percentage amount, rather than a specific dollar amount, would reduce the influence of regional variation in drug prices and drug use patterns in determining which individuals should be candidates for MTM. We also believe that plans should consider that some beneficiaries could be taking multiple medications, all or many of which are generic, potentially disqualifying them from the spending threshold, even though they may need MTM. Moreover, if an individual's drug spending falls below a threshold (or percentage), it should not be assumed that they can be eliminated them from the program. That is because the services being provided through the MTM program may be the only reason that they are taking their medications appropriately and reducing the need for other medications.

We believe that pharmacists can play a role in identifying which patients should be receiving MTM services. Input from pharmacists could be gathered at either the program development stage, or over time as pharmacists encounter Medicare beneficiaries that are likely candidates for MTM services. Given that MTM is still fairly new, there will be a learning curve over time regarding which Medicare beneficiaries should be receiving MTM services.

Plans might want to develop a system to assure that pharmacists can contact plans to encourage enrollment of certain Medicare beneficiaries in these MTM programs, such as through a "prior approval" process before the pharmacist could provide these MTM services. CMS should structure the program so that the expertise of community pharmacists is taken into account as this experience is gained. If a pharmacist's recommendation is not taken regarding enrollment of the beneficiary in a MTM program, the pharmacist should receive a written response from the plan describing the reasons why that beneficiary was not accepted into the program.

We believe that once beneficiaries are enrolled in the MTM program, whether such enrollment is initiated by the plan or through a joint agreement between the plan and the pharmacy, the beneficiary should receive a more complete description from the plan about the nature and scope of the MTM services that should be provided. While we believe that an explanation of these services should be included in the marketing and plan description materials that are provided to beneficiaries before and after enrollment, a more complete description of the program should be provided to the beneficiary upon MTM enrollment.

This would include the purpose of the program (i.e., improving their health); the services that the beneficiary should expect under the program (i.e. initial consultation with the pharmacist, periodic meetings with the pharmacist to review progress); the fact that the beneficiary can obtain their MTM services from any pharmacy in the network, preferred or non-preferred; and, that there are no copayments for the services. We encourage CMS to develop and test a model form that plans would have to distribute to beneficiaries enrolled in MTM programs.

Eligible Providers under MTM: More than 85 percent of all outpatient prescriptions are dispensed in community retail pharmacy settings, and we believe that MTM services should be provided primarily in these settings. Pharmacists working in these settings are often the only health professionals that know the beneficiary is taking multiple medications, often times from multiple physicians, or is having trouble managing the task of taking medications appropriately.

Pharmacists are highly-trained health care professionals and are experts in managing the medication needs of patients, including Medicare beneficiaries. Pharmacists are trained in pharmacology, therapeutics, disease management and clinical assessment, and have either five or six years of professional training. Some have post-graduate training in community pharmacy residencies. State boards of pharmacy license pharmacists. As such, these professionals are appropriately trained and qualified to provide MTM services. For all practical purposes, the "scope of practice" for a health professional as legally defined in their state practice act should determine the extent to which they are eligible to participate as providers in this program. Health professionals that are not trained as experts in medication therapy management or do not have this activity as part of their scope of practice should be precluded from providing services under this program.

In the proposed rule, CMS writes that MMA "specifically states that a pharmacist may furnish MTM services. While we believe that pharmacists will be the primary providers of these services, MTM services could also include other qualified health care professionals as providers of services." We agree that pharmacists should be the primary provider of these services and that there may be cases where it is appropriate for other qualified health care professionals to perform MTM services. The type of provider most appropriate to provide these services should be based on the complexity of the patient's condition. Because MTM will be directed to patients who, by definition, have multiple chronic illnesses and are taking multiple different drugs, the vast majority of MTM participants will be complex cases. Given this degree of complexity, we believe that community pharmacists are uniquely qualified to perform the majority of medication therapy management services that will be needed.

We would also emphasize the importance of having face-to-face patient encounters, rather than relying on phone-based services. The proposed rule makes reference to programs that rely on "impersonal telephone services" and we agree that developing and maintaining on-going beneficiary-provider relationships is key to the success of the MTM program. Many pharmacies have established or are establishing special consultation areas in their pharmacy departments where they can provide these MTM services. This will help provide a comfortable and professional environment in pharmacies to provide these important face-to-face services.

Finally, given that there is no cost sharing for these services, beneficiaries should be able to obtain their MTM services from any pharmacy in the network. That is, a beneficiary may obtain their drugs from one network pharmacy (for example, they might go to a preferred pharmacy for their covered Part D drugs because there is lower cost sharing), but go to a more local pharmacy for their MTM services. We do not necessarily believe that this is the best model for the delivery of pharmacy care and would prefer integration of the delivery of these services. However, because of the way that CMS has proposed to create preferred and non-preferred pharmacies, there will likely be cases where beneficiaries will obtain drugs and MTM services from different pharmacies.

Provider Payments Under MTM: Both the MMA legislation and the proposed rule indicate that Part D should take into account the time and resources required to offer MTM services in determining payment rates for those services. We would add that since these costs increase over time, payment rates should be updated frequently to reflect price changes.
We also support CMS' conclusion that payment for MTM services should be separate from the payment of a dispensing fee. Payment should be made to the pharmacy or chain pharmacy corporation, not the pharmacist, unless the pharmacist is the proprietor and owner of the pharmacy.

Because MTM is a relatively new service, pharmacies will need some time to gather experience and information about resource utilization in providing these services. A number of pharmacy chains would prefer to be reimbursed on an hourly basis (or fraction thereof), rather than a "per member per month" (PMPM) basis, at least initially. The hourly rate will allow provider payments to vary along with the complexity of the services offered. Once more experience is gained with the program, pharmacies may be more likely to offer a PMPM rate.

In addition, pharmacy providers support the development of a standardized billing process for MTM services. Billing for these services should occur through the same online, real time electronic process that is used to provide prescription services. We encourage CMS to include in the final rule a provision that would incorporate this standardized billing process.

NACDS is a pharmacy association member of the Pharmacist Services Technical Advisory Coalition (PSTAC) that has created specific CPT billing codes for MTM services that will be reviewed by the American Medical Association (AMA) for inclusion in its Current Procedural Terminology (CPT) book. These codes could be used by pharmacies to bill for MTM services because they take into account the "time and resources" expended by pharmacists to provide MTM services. NACDS is interested in learning what codes CMS will require for the billing of pharmacy professional services.

NACDS is also interested in learning if CMS will require submission of MTM payment claims, including the appropriate CPT codes, in the HIPAA 837 batch Health Care Claim or if it plans to allow community pharmacies to submit payment claims like it does to virtually all other third party payors, in the real-time HIPAA 5.1 Pharmacy Payment Claim Standard.

We support CMS's requirement that Part D plans disclose to CMS the fees paid to pharmacists or others, including an explanation of those fees attributable to MTM services. These terms should be included in the standard contract that CMS suggests should be developed to anchor the negotiations betweens plans and pharmacies. However, we have some concerns about CMS' preliminary decision that it will not adjudicate any specific disputes between Part D plans and pharmacists or other providers regarding the specific fees due for MTM services. We believe that CMS should provide some mechanism by which such disputes can be resolved.

MTM Outcomes Assessment: Pharmacies can provide information to the Part D plans that will help assess outcomes from MTM programs. However, the program should contain provisions for the Part D plans to provide relevant information to pharmacies about the impact of MTM services on clinical outcomes for the beneficiary. To the extent possible, the impact of the MTM program should be assessed against changes or improvements in clinical outcomes, economic impact, and quality of life improvements for the beneficiary. Assessment of cost outcomes should reflect total health care spending, including spending under Medicare Parts A and B, and not just drug spending alone.

Coordinating MTM and CCI: As CMS indicates in the proposed rule, there may be some overlap between the Chronic Care Improvement (CCI) program and MTM program. CMS' goal is to avoid duplication in the delivery of MTM services, which will likely be a component of the CCI program. The overlap is mitigated by the fact that CCI only applies to about 300,000 fee-for-service Medicare enrollees, and applies to only a limited number of conditions, primarily congestive heart failure and complex diabetes. The CCI program will begin sooner than the MTM program, and the CCI program is likely to arrange for the delivery of covered Part D medications to CCI enrollees. This makes sense given that medications are critical to the treatment of the CCI program targeted conditions.

If the CCI program is in fact providing medications as part of its program, then one question that will have to be answered is what happens to beneficiaries when Part D becomes available in 2006. If CCI enrollees are not receiving medications through the CCI program, then they will likely enroll in Part D when it becomes available. CMS should be able to share with Part D plans those individuals enrolled in the CCI program so they can identify individuals enrolled in both programs. Part D plans should work with the CCI contractors to determine the extent to which their CCI programs are already providing the MTM services that would be offered by that Part D plan. We believe that pharmacists should be kept informed when a Medicare beneficiary is also receiving services through the CCI program. This will assist pharmacists in providing an appropriate level of services for their patients.

Model MTM Programs: In the proposed rule, CMS requested information on current MTM best practices. As mentioned above, MTM is a new area that is constantly evolving. One pharmacy-based program that provides MTM services for the chronically ill is in Ashville, North Carolina. The program provides community-based pharmaceutical care services for patients with diabetes enrolled in self-insured employer health plans. A study published in the *Journal of the American Pharmaceutical Association* in March/April 2003 found that patients receiving those services showed significant improvement in A1c values and lipid levels, as well as a decrease in direct medical costs of $1,200 per enrollee on average.[4]

The provision of a community retail pharmacy-based medication therapy management program for select Medicare beneficiaries, as required under the new Medicare Part D drug benefit, will enhance the use of medications in this population, reduce the chance for adverse reactions, and improve overall health and quality of life. Community-based pharmacy providers have a key role in identifying individual beneficiaries who are candidates for this program and developing specific interventions that will help them manage their medications. Pharmacists are also in a key position to assess the impact of these beneficiary interventions and make necessary modifications.

Section 423.153(e) – Program to Control Fraud and Abuse

Section 423.153(e) would require plans to implement programs to control fraud and abuse. NACDS strongly supports this requirement. It is important for CMS to provide more details regarding the necessary components of an acceptable fraud and abuse program. Otherwise, any fraud and abuse program, no matter how lax, would appear to satisfy this requirement.
In particular, CMS should strictly limit the potential for fraud and abuse surrounding drug substitution programs, commonly referred to as "switch programs." CMS specifically requests comments on fraud and abuse issues surrounding switch programs. *(See* 69 Fed. Reg. at 46670).

It is often entirely appropriate for a pharmacist to recommend that a patient take an alternative medication instead of the prescribed medication. For example, switching from a brand name drug to a generic drug may save the patient and the plan money. Similarly, switching from one drug product to another therapeutically equivalent product may reduce adverse reactions or provide other advantages (e.g., increased ease of use in switching from a pill to a liquid, or from a daily pill to a weekly pill). For these reasons, switch programs should not be eliminated. But the potential for fraud and abuse associated with switch programs does make it important for CMS to limit switch programs operated by the PBMs that subcontract with plans. PBM switch programs have raised many fraud and abuse concerns, and have resulted in a great deal of litigation.

One of the largest investigations into PBM switch programs led the Attorneys General of twenty states and the federal government to file a complaint against Medco Health Solutions, Inc. ("Medco"), the nation's largest PBM, for alleged violations of various consumer protection and unfair trade practice statutes. The complaint claimed that Medco had a "conflicted interest"

[4] Cranor, Carole, Barry Bunting and Dale Christensen. "The Asheveille Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program." Journal of the American Pharmaceutical Association Vol. 43, No. 2 March/April 2003: 173-184.

because its drug switching programs were improperly influenced by its desire to receive rebates from drug manufacturers, not by a desire to save clients money. According to the complaint, Medco failed to pass on savings to patients or their health care plans, and failed to disclose to prescribers or patients that the proposed drug switches would increase rebate payments from drug manufacturers to Medco. Medco's drug switches also allegedly resulted in increased costs to health plans and patients, including additional costs for follow-up doctor visits and tests.

The complaint against Medco was settled in a Consent Order on April 26, 2004. NACDS recommends that CMS require plans to implement fraud and abuse programs that are consistent with the Medco Consent Order. The Consent Order carves out four specific instances in which Medco may not make drug switch solicitations to physicians and prescribers in cases where:

- The cost of the proposed drug exceeds that of the current drug;
- The current drug has generic equivalents, but the proposed drug does not have generic equivalents (except in situations in which the proposed drug is cheaper than all generic equivalents of the initially prescribed drug);
- The patent for the current drug expires within six months, or the proposed drug switch would have the effect of avoiding competition from future generic equivalents; and
- Within the past two years, a patient has either already switched a drug in the same therapeutic class in response to Medco's solicitations, or subsequently reversed such a switch.

Medco must disclose certain information to prescribers when it requests a drug switch. For example, Medco must disclose:

- The annual minimum or actual cost savings of the proposed drug switch, as well as the effect of the proposed drug switch on patients' co-payments;
- Whether and under what circumstances the patient's health plan will continue to cover the current drug;
- Whether Medco receives any payments from manufacturers for promoting drug switches; and
- Any material differences in side effects between the initial and the proposed drugs.

The Order expressly allows patients to reject the proposed drug switches by Medco. If the patient declines the proposed drug switch, the Order requires Medco to honor such requests and provide the initially prescribed drug. If switching drugs causes the patient to incur additional medical costs (e.g., costs associated with additional medical tests or physician visits), the Consent Order requires Medco to reimburse those costs.

The Consent Order also requires Medco to disclose important information to health plans, such as information regarding rebates received from drug manufacturers. Finally, the Consent Order requires Medco to adopt the code of ethics of the American Pharmacists Association. NACDS recommends that the requirements of the Medco Consent Order should be incorporated into CMS' guidance regarding what constitutes an adequate fraud and abuse program. We encourage CMS to provide specific guidance for plans and their PBMs, in order to avoid future fraud and abuse problems.

CMS also requests comments on the possibility that "plans could develop and utilize methods such as data analysis, record audit of PBMs, pharmacies, physicians, and other providers, ... and methods used to consider and resolve disputes related to pharmacies, physicians', and other provider's dissatisfaction to ensure the integrity of all entities (government, beneficiary, PDP sponsor, PBMs, pharmacies, physicians, and other providers)." (See 69 Fed. Reg. at 46670). We certainly agree that plan sponsors must guard against fraud, abuse and waste. However, we are concerned that audits of pharmacies may be misused to deny reimbursement that is properly due to pharmacies. Experience shows that PBMs sometimes abuse the audit process by conducting invalid "extrapolation" audits, and by hiring "bounty hunters" to deny valid pharmacy reimbursement claims.

"Extrapolation" audits involve auditing a sample of reimbursement claims and then extrapolating from that the results of the audit to deny reimbursement claims that were not in the sample. For example, a PBM may audit 100 of the claims submitted by a pharmacy for dispensing drug, allege that 5 of these claims are somehow improper, and then extrapolate from that audit to deny reimbursement for five percent of the tens of thousands of drugs dispensed by that pharmacy. PBMs have been known to abuse extrapolation audits by using samples that are too small, and by cherry picking particular types of claims to be included in the sample and then extrapolating the results to all of a pharmacy's claims. Therefore, we do not believe that extrapolation is an appropriate method for plans or their PBMs to use to audit pharmacies.

At the very least, CMS should require plans and their PBMs to avoid extrapolation audits based on samples that are too small or otherwise unrepresentative of all the reimbursement claims. In describing it's own procedures for audits of plans, CMS wrote that "the program audit process would require at least a statistically valid random sample of all Part D drug claims." (Id. at 46687). If plans and PBMs are allowed to conduct extrapolation audits of pharmacies, these same standards should apply. "Bounty hunters" are independent auditors that plans and their PBMs pay based on the number of pharmacy reimbursement claims they reject.
These bounty hunters have an obvious conflict of interest, because they are not paid based on an objective analysis of reimbursement claims, they are paid based on denial of reimbursement claims. We ask CMS to warn plans and their PBMs against using bounty hunters to audit claims.

In general, we ask CMS to discourage plans and PBMs from abusing the audit process. In discussing its own audits of plans, CMS noted that "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." (Id. at 46686). That same standard should be applied to plans' oversight of pharmacies.

Section 423.159 - Electronic Prescription Programs

NACDS supports electronic prescribing because of the efficiencies it provides and its significant potential to improve patient health and reduce medication errors. Indeed, NACDS partnered with the National Community Pharmacists Association (NCPA) to create SureScripts, an electronic prescription gateway for pharmacies.

To date, SureScripts has signed contracts to provide electronic prescribing services to more than 75 percent of the community pharmacies in the U.S.

CMS Should Move Forward with NCPDP SCRIPT: Currently, of community pharmacies that have electronic prescription connectivity with prescribers, the vast majority uses the NCPDP SCRIPT standard. We know of no competing standard, and we are not aware of any serious flaws in this standard. We believe that there is adequate industry experience with this standard for CMS to move forward with notice and comment on using NCPDP SCRIPT as a foundation standard for communication between prescribers and community pharmacies for new prescriptions, prescription renewals, cancellations and changes. However, we agree with NCVHS' recommendation that CMS conduct pilot tests of NCPDP SCRIPT with respect to fill status notification. Fill status notification is a feature of SCRIPT that has not been used much in the industry.

Spurring Prescriber Adoption of Electronic Prescribing: With respect to CMS' request for additional steps to spur adoption of electronic prescribing, NACDS believes that the proposed differential payments are a very appropriate incentive to increase the number of prescribers who engage in electronic prescribing. Unfortunately, most prescribers have been slow to adopt this technology. It has been difficult to convince them of the benefits of investing time and money in changing their prescribing processes. Because of this challenge, NACDS believes that the differential payments, at the MA organization's discretion, should take into consideration the cost to the prescriber of implementing an electronic prescribing program. The cost consideration should include both actual technology costs and costs that may be more difficult to quantify, such as training and temporary workflow disruption.

Coordination between NCPDP Pharmacy ID Card and X12 270/271: From a practical point of view, we urge CMS to move forward on NCVHS' recommendation of supporting NCPDP's efforts to create a guidance document to map the information on the NCPDP Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271.[5] One barrier to electronic prescribing is that prescribers have limited access to a patient's pharmacy benefit information. The NCPDP Pharmacy ID Card Standard provides information on a patient's pharmacy benefit. ASC X12N 270/271 is the HIPAA-named standard for prescribers to perform eligibility and benefits verification. Coordination between these two standards would better facilitate prescriber communication with payors about a patient's eligibility for pharmacy benefits and formulary information.

Recognize and Foster Pharmacist's Vital Role in E-prescribing: In this age of managed care and reduced reimbursements, harried prescribers are searching for efficiencies. Many have realized that pharmacists are able allies ready to assist. Any electronic prescribing technology should not reverse the trend of prescribers' relying more upon pharmacists. Since pharmacists are medication experts, pharmacist collaboration with prescribers reduces the likelihood of medical errors and adverse drug reactions. Reducing medical errors and adverse drug reactions are not only laudable goals, but also they are goals of the MMA.

[5] Letter from John Lumpkin, Chairman, NCVHS, to Tommy G. Thompson, Secretary, Department of Health and Human Services (September 2, 2004), p. 7-8.

We believe it is only logical that electronic prescribing programs and pilots recognize the value of prescriber-pharmacist collaboration, encourage such collaboration, and do not create standards or procedures that would disrupt such collaboration. Prescribers will be less likely to adopt an electronic prescription system that requires them to perform pharmacists' traditional duties, such as drug utilization review and checking for medication-related concerns.

We agree with NCVHS' assessment that the deployment of electronic prescribing may involve workflow or policy issues that are outside the scope of standards but are important related issues.[6] One such workflow issue concerns the flow of patient medication and medical histories among prescribers, pharmacies and payors. In its recommendations, NCVHS states that "HHS should actively participate in support of rapid development of an NCPDP standard for medication history message for communication from a payor/PBM to a prescriber, using the RxHub protocol as a basis."[7] We have concerns with NCVHS' recommendation on this point. To allow the pharmacist to assist the prescriber in drug product selection, any patient medical and prescription history from payors/PBMs should be available to the pharmacist also. Pharmacists have information that patients provide specifically during patient counseling, such as potential allergies, sensitivities, and other adverse reactions.

Only pharmacies have patient records for items that the patient has paid for out-of-pocket, such as prescriptions not covered by a payor, and a vast array of nonprescription items including herbal and nutritional supplements. A more complete patient medication history can be achieved by combining the records of the payor/PBM with that of the pharmacist. The pharmacist should assist the prescriber in drug product selection, at the prescriber's request, based upon information available from the payor, and provided by the prescriber to the pharmacist at the prescriber's discretion. This can be accomplished if payor information related to patient medical and medication history is made available to the pharmacist.

Incentives to Pharmacists and Pharmacies: Similar to the grants authorized for prescribers, CMS should spur more widespread adoption of electronic prescribing by providing financial incentives to pharmacists and pharmacies. Community pharmacists have been the early adopters of electronic prescribing technology. Not only have they had to pay for software modifications necessary to engage in electronic prescribing, but also they are the only entities that are required to pay an electronic prescribing transaction fee.

Protection from Commercial Messaging: While we fully support the further adoption and expansion of electronic prescribing, we are concerned about the inherent potential for abuse that exists with this new technology. NCVHS has also expressed concern to HHS about this. Specifically, NCVHS has stated to HHS that electronic prescribing messages should be free from commercial bias.[8] We believe that CMS must incorporate additional standards in regulation to prevent commercial entities from exercising undue influence on prescribers' choices of medications and patients' choices of pharmacies.

[6] Ibid. at 5.
[7] Ibid. at 9.
[8] Ibid. at 14.

We recommend that CMS adopt a broad definition of commercial messaging to include any non-clinical messaging from any outside entity that would influence a prescriber's choice of medication or a patient's choice of pharmacy. For the sake of patient care, the professional, autonomous relationship between health care providers (prescribers, pharmacists) and patients must be preserved. CMS must prohibit commercial messaging at the point of prescribing. Only such prohibition could prevent outside parties from unduly influencing a prescriber's choice of medication or patient's choice of pharmacy.

Moreover, the prohibition on commercial messaging must include messaging that might occur prior to or subsequent to the actual medication selection by the prescriber. There should not be pre-emptive messaging that seeks to influence a prescriber's choice because of a prescriber's indication that he or she is interested in a particular type of drug or class of drugs. Similarly, there should not be messaging that seeks to make the prescriber's choice difficult to finalize or to otherwise change a choice already made.

Another way that outside entities may seek to unduly influence the prescribing process is by affecting the way information is presented to the prescriber. CMS should require that formulary information and pharmacy information be communicated in a single, neutral consolidated list. All medication information should be equally legible and readable; the same should apply to pharmacy choices. Prescribers should not be forced to click through numerous screens to access non-preferred or non-formulary medications, or to access traditional retail pharmacies. Electronic prescribing offers much promise to health care providers and patients to improve the delivery of medication and medical care. However, we must be sure that regulation of electronic prescribing is carefully crafted to take full advantage of the benefits of electronic prescribing and that it is not used solely to benefit of commercial interests.

Section 423.162 - Quality Improvement Organizations

QIO Activities Under Medicare Part D: Section 423.162 of the proposed rule under MMA would expand the work of Medicare Quality Improvement Organizations (QIOs) to include Parts C and D. QIOs have a long history of advancing care quality under Parts A and B of the program, and we support their involvement in providing quality assurance to Medicare drug beneficiaries under Part D.

Under the draft 8th Scope of Work, QIOs will be directed to offer quality improvement assistance to Medicare Advantage Drug Plans (MA-PDs), Prescription Drug Plan (PDP) sponsors, and medical providers (including physician practices and pharmacies). Quality improvement initiatives will center on improving disease-specific treatment (i.e., therapeutic monitoring), reducing adverse drug interactions, increasing generic use, addressing problems with polypharmacy, and improving medication therapy management (MTM) programs. These are all areas where opportunities for quality improvement will exist for Medicare beneficiaries.

Interaction with Other Quality Improvement Initiatives: To some extent, the quality improvement work of the QIOs under Part D is likely to overlap with other activities initiated in the Medicare reform law relating to Part D plan requirements.

These initiatives include drug use review (DUR) programs that will likely be established by plans, other internal quality assurance programs that might be established by pharmacy providers, and the required MTM programs.

Drug use review programs generally include a program of prospective drug use review (ProDUR), retrospective drug use review (RetroDUR), and educational interventions for physicians and pharmacists. These activities can be designed as population-based measures, or for individual patients. However, they are designed specifically to identify and correct some of the very issues tasked to the QIOs, such as reducing adverse reactions, therapeutic duplications, and polypharmacy, as well as increasing the cost effective use of drugs.

Each Part D plan will be required to have in place a MTM program that, in addition to increasing enrollee knowledge about, and adherence to, medication regimens, will be aimed at reducing adverse drug events and decreasing over-utilization and under-utilization of recommended drug therapies. These programs will be directed to beneficiaries with multiple chronic illnesses, whereas the activities of the QIOs will be directed to all beneficiaries, but to some extent the work of the QIOs will likely mirror that of existing MTM programs.

We believe that the QIOs can serve an important function in assessing the MTM programs initiated by the drug plans and making recommendations for improvement. Comprehensive MTM programs, while potentially increasing drug spending among Medicare beneficiaries, will lower overall Medicare spending by reducing hospitalizations and emergency room use. We are particularly concerned, however, that the final regulation will not provide sufficient specificity to plans in how to develop and conduct their MTM programs. We believe that there is potential for wide variability in the nature and scope of services that might be offered by plans; a potential that each plan will have a different set of criteria regarding Medicare beneficiary eligibility for MTM services; and the potential that plans will restrict the ability of beneficiaries to use their local community pharmacy provider for these MTM services. QIOs can help plans assess their MTM programs and modify them if necessary to assure that these programs are truly meeting the needs of Medicare beneficiaries.

PDP sponsors serving the fee-for-service population may have a financial incentive to initiate more modest MTM programs, perhaps relying less on face-to-face interactions with pharmacists and more on impersonal phone conversations with nurses who have limited expertise regarding prescription medications. We believe the QIOs can help in providing oversight and assuring that the MTM programs offered by plan sponsors are robust.

MMA will also launch the Voluntary Chronic Care Improvement Program (CCIP), which will focus on improving care processes for chronically ill enrollees in the Medicare fee-for-service program. During its 3-year pilot phase, CCIP will be limited to enrollees with one of three chronic illnesses and a total of 150,000 to 300,000 beneficiaries. However, given that this population includes many beneficiaries that are high-utilizers of health care services, a number of these enrollees may also be targeted by the QIO. QIOs can help assure appropriate coordination of activities between MTM programs and CCI programs.

CMS indicated in the proposed rule for Part D that it intends to issue guidance on how QIOs can coordinate their activities with the other quality related initiatives. We would advise CMS to be aware of these potential overlaps and to clarify the relationships between these various quality improvement programs in the QIO Scope of Work.

Interactions with Multiple QIOs: A number of chain pharmacies in the United States serve broad regions of the country and many operate in multiple states. Many of these companies have already instituted quality improvement initiatives at the corporate level, and have implemented them system-wide. However, because each QIO will be serving only one state, these chains are likely to interact with multiple QIOs, each with different requirements in their quality improvement standards. This could pose a significant administrative and operational challenge for chain pharmacies and their quality assurance programs. The same challenge exists for PDP plans, since they are likely to be serving regions that consist of multiple states.

We encourage CMS to consider this issue as it proceeds forward with more clearly defining the relationship between pharmacies, plans, and QIOs. Given that most quality assurance programs are developed at the corporate level, whether for chains of 4,000 stores or 4 stores, it is important for QIOs to interact with chain corporate personnel when providing feedback. Moreover, given that these chains operate in multiple states, it is important to foster greater standardization among the QIOs that will be serving the Part D populations. Rather than having each QIO interact with each pharmacy chain that operates in the state, an alternative approach would be to designate one or two QIOs with certain expertise in prescription drug quality improvement areas to work with pharmacies on quality-related initiatives.

QIO Data Review: In the proposed rule under Part D, CMS indicates that QIOs will be given access to pharmacy claims data resulting from transactions between pharmacies and the private drug plans. These data are to include a number of specific elements, including NDC, dose, days supply, ingredient cost, dispensing fee, pharmacy identifiers, and prescriber identifiers. CMS says that, "potentially" the information will be aggregated before it is distributed to QIOs.

We support the role of the QIO in reviewing these data and identifying areas where quality improvements can be made. We also support CMS' suggestion that it will aggregate the data prior to its being released. It will be important to identify trends in treatment patterns that are not meeting recommended standards of care and we welcome the opportunity to identify some of those improvement areas, both for the prescribers and the pharmacies. The rule states that CMS has been consulting with pharmacy benefit managers, managed care organizations, programs that have monitored drug utilization, and others who have utilized pharmacy claims data. We recommend that CMS also consult with pharmacy chain representatives to receive their views regarding the use of these data.

Issues Regarding Confidentiality: We support CMS' assertion that any information collected by the QIOs would be subject to confidentiality requirements in Part 480 of the regulations.

It specifies that "each QIO must instruct its officers and employees and health care institutions participating in QIO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of QIO information." We also ask for clarification that the confidentiality provisions of 42 USCA Section 1320 c-9 would apply as well.

CMS has indicated that for the purposes of these confidentiality requirements, Part D plans will fall within the definition of health care facilities. The rule does not specify how pharmacies under contract with these private plan sponsors will be regarded. We recommend that CMS incorporate into the final Part D rules language specifying that pharmacy providers under contract with Part D plans are also entitled to the same confidentiality provisions including the disclosure prohibitions of 42 USCA Section 1320c-9. In order to ensure that service improvements are made through the QIO process, pharmacies should be shielded from potential legal actions resulting from possible information disclosure. In addition, pharmacies should receive assurances that any information disclosures that they make to the QIOs do not violate patient privacy rules contained under the Health Insurance Portability and Accountability Act of 1996.

Section 423.165 – Compliance Deemed on the Basis of Accreditation

NACDS is concerned about the ability of Part D PDP plans to circumvent several of the access and quality assurance requirements in the program by seeking accreditation for its plans from an outside accredited entity. The actual proposed regulation, as well as the background, does not provide a good description of how such programs would operate, or the identity of the accrediting entities.

Moreover, it is not clear (but could be assumed) that plans would not be required to obtain this accreditation to be able to contract as a Part D plan. It appears that the accreditation is voluntary. We strongly urge that CMS engage stakeholders in a more deliberate and detailed process of how such a process should work, and more fully delineate the criteria that would be used to "accredit" the accrediting organizations. We are concerned that this deeming process may diminish important beneficiary protections – such as access to pharmacies, and assuring a level playing field between mail order and retail pharmacy – that are key to establishing an effective prescription drug program for Medicare beneficiaries.

Subpart F - Submission of Bids and Monthly Beneficiary Premium - Determining Actuarial Valuation

Sections 423.251-293 describes the process by which CMS will review bids from Part D plans to determine whether they meet necessary standards to provide qualified prescription drug coverage. In reviewing the bids, NACDS asks that CMS pay particular attention to reviewing the following sections of the plan's bid:

Pharmacy Networks: The plan should submit complete information to indicate that all the pharmacies in its network are currently under contract with the PDP and the pharmacy has positively indicated that it intends to participate in the Part D plan's network. CMS should not rely on plan attestations, but should review actual signed contracts from pharmacies to indicate that a pharmacy has agreed to participate in a plan's network.

To prevent discrimination against Medicare beneficiaries in fairly choosing a pharmacy provider, we believe that CMS should only approve those pharmacy networks whose *preferred* networks meet the TRICARE access standards in each state in each region that the plan operates. That is, CMS should give preference to plan designs that include more preferred pharmacies in their networks. This is, in our view, the intent of the MMA for how plans should structure their pharmacy networks.

CMS should examine the number of pharmacies in the plan's preferred network in relation to the number of total pharmacies in the network, and then determine the resulting net beneficiary access to preferred pharmacies by applying the TRICARE access standards. For example, if beneficiaries in certain urban areas in the region are within 3 miles of a network pharmacy (because of the ability to average the 2 mile urban standard across all urban areas), but the average distance to a preferred pharmacy is really 5 or 6 miles, this would appear to be discriminatory against many Medicare beneficiaries in an area who would not have realistic access to the lower cost sharing of preferred pharmacies. Using this approach, plans could designate pharmacies for non-preferred status in certain areas of the region where there is high maintenance medication use to encourage the use of mail order. This would be discriminatory against beneficiaries.

CMS should require plans estimate the total number of Medicare beneficiaries that will be served by preferred pharmacies and the total prescriptions they expect to be dispensed by preferred pharmacies in the network. There are real concerns that too few preferred pharmacies will be in a network, but because these networks have lower cost sharing, that these pharmacies will have to fill a disproportionate share of prescriptions for Medicare beneficiaries in that plan's region. In addition to the frustration of traveling longer distances, some beneficiaries might have longer waits to obtain their prescriptions because pharmacies may have excess volume. Combined, these factors help to encourage beneficiaries to use alternative prescription sources, such as mail, which we believe is inconsistent with the intent of Congress and the spirit of the TRICARE standards.

Cost Sharing: CMS should examine the extent of the differences that exist in cost sharing between preferred pharmacies and non-preferred pharmacies. Any significant difference in cost sharing would be discriminatory against those beneficiaries who do not live within a reasonable driving or traveling distance of these preferred pharmacies. Moreover, CMS should require plans to submit information on the cost sharing amounts that would apply to all beneficiaries in the plan if a "preferred" vs. "non preferrerd" scheme was not used. In other words, the ability of a few beneficiaries to obtain reduced cost sharing could increase the cost sharing for a larger percentage of beneficiaries than if the cost sharing had been uniform across all the pharmacies in the TRICARE network.

Mail Order Issues: CMS should also review plan bids to ensure that plans are not charging differential cost sharing to encourage beneficiaries to use mail order over retail pharmacy providers. CMS should also ensure that plans are not creating different tiers of formulary coverage so that certain drugs are only available through mail order rather than retail pharmacies, and that plans are not using artificial limits on the amount scope and duration of drugs that might be obtained through a retail pharmacy rather than a mail order pharmacy. NACDS also suggests that CMS not approve any plan bid that would allow the plan to administer both the retail network and the mail order program in the same region.

Section 423.401 - Organizational Compliance with State Law and Preemption by Federal Law

Proposed section 423.440(a) would implement sections 1860D-12(g) and 1856(b)(3) of the Social Security Act, which provide that the Medicare Part D rules will preempt "any state law or regulation" with respect to PDPs, except for "state licensing laws or state laws relating to plan solvency." NACDS supports CMS' conclusion that Executive Order 13132 on Federalism requires CMS "to construe preemption statutes narrowly." (See 69 Fed. Reg. at 46696). Unfortunately, that policy of narrow construction is not reflected in the proposed rule.

CMS should state in the final rule that it does not intend to "occupy the field" by preempting all state health care standards that apply to plans. Instead, CMS should clarify that a state law or regulation will be preempted only to the extent it directly conflicts with a specific provision of the Medicare Part D rules. A state standard should not be preempted if it is possible for a PDP sponsor to comply with both the state standard and the Medicare Part D rules.

At the very least, the Medicare Part D rules should not preempt state laws and regulations to the extent that the state standards apply to the non-Medicare operations of plan sponsors and their business partners, such as PBMs. In other words, if a plan sponsor offers both a Medicare plan and a private plan, CMS should clarify that state standards (e.g., any willing provider laws) should continue to apply to the private plan even if those state standards are preempted by the Medicare Part D rules with respect to the Medicare plan. Congress was careful to limit preemption only to Medicare PDP plans that operate under Part D, not to all operations of plan sponsors.[9]

In particular, CMS should expressly state that the Medicare Part D rules will not preempt state pharmacy practice acts. The regulation of pharmacy practice traditionally is under the jurisdiction of state law. In enacting the Medicare Part D drug benefit, Congress never expressed an intention to preempt state standards regarding the practice of pharmacy. Preemption of state pharmacy practice acts would be contrary to a narrow interpretation of the preemption authority enacted by Congress.

[9] Section 1856(b)(3) of the Social Security Act, as amended by section 232(a) of the MMA, provides that "the standards established under this part" preempt state law "with respect to MA plans which are offered by MA organizations under this part." Section 1860D-12(g) of the Social Security Act provides that section 1856(b)(3) "shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C."

Section 423.452-464 - Coordination Under Part D Plans with Other Prescription Drug Coverage

Overview: NACDS has focused its comments in this section on the two major tasks that we believe CMS must accomplish to reach its self-defined goals of maximizing the efficiency and effectiveness of a Coordination of Benefits (COB) system that can provide information to pharmacies in real time regarding a beneficiary's "true out of pocket costs," also know as TrOOP. CMS has indicated that it wants to have this system in place by January 1, 2006. The two major tasks that we believe CMS must accomplish are:

- Creating an online real time COB–TrOOP system that expands CMS' Option 2 by including community retail pharmacies in its single point of contact system, thereby considerably increasing the efficiency and effectiveness of CMS' Option 2. NACDS proposes that CMS implement the Single Point Of Contact System (SPOCS) as described below; and,
- Streamlining current COB policies and procedures so they can be accommodated in the new COB–TrOOP system. NACDS comments on these policies under the appropriate preamble subsections below.

NACDS proposes a Single Point of Contact System (SPOCS) for COB and TrOOP. This SPOCS proposal has two major advantages over CMS' proposed Option 2. (See 69 CFR 46706). Those advantages are that both providers and Medicare beneficiaries also have the advantages of a single point of contact system, not only payers. This increase in functionality maximizes the efficiency and effectiveness of a COB–TrOOP real time system.

We offer this SPOCS proposal to assist CMS in its efforts to establish, before July 1, 2005, procedures and requirements that will promote the effective COB between a Part D plan, a State Pharmaceutical Assistance Programs (SPAPs), Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage CMS may specify at in the future. In addition, SPOCS can be operational by the MMA deadline of January 1, 2006. Most importantly, Medicare beneficiaries will find SPOCS to be the easiest system to understand and the most convenient system to obtain their prescription medication and supply services.

Proposed Single Point of Contact System for Medicare Part D COB and TrOOP Calculations:

Overview of the Proposed COB–TrOOP Process

- Medicare beneficiary presents Medicare standard benefit prescription card and prescription(s) at the pharmacy;
- Pharmacy submits all Medicare beneficiary's prescription claims (e.g., SPAP, Medicaid, group health plan, FEHBP, TRICARE) to the "SPOCS";
- SPOCS has all of the Medicare beneficiary's insurance eligibility information and the correct billing order in its electronic files;

- SPOCS, after receiving a prescription medication or supply payment claim from the pharmacy, identifies the Medicare beneficiary in its electronic file and sends the payment claim to that Medicare beneficiary's primary payer. The primary payer responds back to the SPOCS with the necessary COB and TrOOP information and the SPOCS repeats the process with the Medicare beneficiary's secondary payer, etc. until all of the responsible payers are billed;
- SPOCS sends the claim with a "separate response payment segment" for each payer back to the pharmacy so the pharmacy knows what each payer has paid and who to expect payment from;
- SPOCS receives the final TrOOP calculation for that claim and sends this information to the appropriate parties.

Advantages of Suggested Process:

- Medicare beneficiary only needs to present Medicare card at the pharmacy. No other insurance cards are necessary because of the single point of contact with the SPOCS;
- Medicare beneficiary's claims will go through the SPOCS and can be accessed for Medicare eligibility determination, TrOOP management, physician-billed Part B claims updates, claims reversal communications, and inquires by appropriate parties about the TrOOP;
- CMS will only need to work with the SPOCS for eligibility and TROOP management;
- Pharmacy knows where to send ALL of the Medicare beneficiary's prescription claims reducing dispensing time so that the Medicare beneficiary obtains prescription medications and supplies more quickly than she/he otherwise would if the pharmacy was required to make eligibility inquires or to try to determine the correct billing order of the Medicare beneficiary's payers;
- A prescription ID card is not required to be sent to Medicare beneficiary. The Medicare beneficiary's standard prescription benefit card is all that is necessary. SPOCS will be able to manage all[10] payment claims real-time, including Medicare Complementary Cross Over Claims;
- SPOCS is an independent entity that acts as a switch for real–time COB and TrOOP information that does not have a potential conflict of interest managing patient identifiable health care information and pharmacies' confidential payment rates;
- Separate response payment segments from the SPOCS will eliminate the current confusion in those cases when the DMERCs do not let the pharmacy know the secondary payer information on Medicare Complimentary Billings;
- Each payer is responsible for its own payments, which are reflected in the SPOCS's separate response payment segments back to the pharmacy.

[10] A discussion regarding the relationship between this SPOCS system and the Medicare Part B claims process system is discussed later in this section.

SPOCS' System Requirements:

- Claims processing at PBMs must have a separate and enforced Bin Number for all Medicare claims processing at their site to assure that claims go through the SPOCS with the proper routing;
- All Medicare beneficiaries' billing information and billing order must be on file at SPOCS and continually updated;
- Must have separate "response payment segments" for each payer billed through the SPOCS;
- To process COB claims, the processors would need to follow one of the NCPDP COB billing standards. The processor would elect to process the payment information by electing to use the 5.1 COB segment and accepting the "Other Payer Amount Paid", or, not use the 5.1 COB segments but use the 5.1 pricing segment and accept the "Copay Billing" which would be populated with the gross amount due;
- SPOCS treats all pharmacy claims and information as proprietary and confidential;
- Pharmacy maintains ownership of submitted claims data to dissuade the unauthorized uses and further disclosures of patient identifiable health care information as prohibited by the HIPAA privacy regulations;
- Pharmacies and payers would need to make appropriate software changes that would allow them to interact with SPOCS as the central point of contact for Medicare billed claims, receive multiple payment response segments, and receive TrOOP accumulator information. These changes for the Medicare beneficiaries' claims would allow the SPOCS system to identify the eligible Medicare beneficiary, bill their claims to responsible payers in the proper billing order, send the information back to the pharmacy in an identifiable payment reconciliation format, and communicate the TrOOP back to the appropriate parties. The system should also allow for easy update of physician billed Part B claims;
- Medicare Part B pharmacy claims must process on-line, real time through SPOCS. This is required to allow for proper and accurate TrOOP calculation for the Medicare beneficiary. It is necessary to know the Medicare Part B paid amount (which by today's use of paper claims can takes weeks to obtain) to do any wrap around or additional COB billings and obtain a real-time calculation of Medicare beneficiary's TrOOP;
- Medicare Part B claims processing requirements would need slight modifications to make them as streamlined as pharmacy commercial payment claims and Part B would need to move to NCPDP 5.1 online, real time claims management;
- COB claims submission process would need to be accomplished within the industry standard claims submission time-out window of approximately 12 seconds;
- It is preferable that all Medicare Prescription Plans use the Medicare beneficiary's Medicare ID number (or one ID number designated by CMS) as the Medicare beneficiary's ID number for all the various prescription programs the Medicare beneficiary may be enrolled. If not, SPOCS would need to maintain the alternate ID billing numbers for the Medicare beneficiary to cross reference and COB bill;
- Work towards using common claim identifier values for physicians (NPI) and for drugs (NDC numbers).

*Summary***:** This proposed COB–TrOOP single point of contact system is the most effective and efficient system that can be designed. Although the SPOCS utilizes current industry capabilities, CMS must recognize that there would be significant programming requirements by pharmacy to make the SPOCS work. However, of the preamble alternatives set out by CMS, the SPOCS model is clearly the best because it: is easy and convenient for the Medicare beneficiary; does not require additional insurance program ID cards; facilitates pharmacies' correct billing of COB plans in the proper order; provides a central entity to collect, manage, and resolve TrOOP questions, for Medicare beneficiaries, CMS, claims processors, and pharmacies. The result would be a simpler process, less people hours to manage the process, better service to all, and satisfied Medicare beneficiaries; provides online real time TrOOP calculation; increases the efficiency of pharmacy claims reconciliation; and, maintains the confidentiality of Medicare beneficiaries' personally identifiable health care information.

The Medicare program should fund the development and implementation of CMS' COB system because it receives the largest amount of financial savings as a result of its use. In addition to the savings the Federal government will accrue from the use of the COB e–highway, this e–highway will be part of the National Health Information Infrastructure (NHII), which CMS is promoting.

Community pharmacies should not be charged a "user fee" or any other charge for using CMS' COB system. Because community pharmacies will expend substantial resources, both financial and human, to connect to this federal COB e-highway, it is not reasonable to expect them to pay to use that highway. For this reason, user fees must not be charged, nor allowed to be charged, to community pharmacies for using the federal COB e-highway.

The Federal government should fund both the increased claims transaction fees and the fees for re–routing post adjudication claims, both of that frequently occur if CMS does not implement SPOCS. If community pharmacies are not allowed to share information real time with the single point of contact as the router to and from the multiple payers, the number of pharmacy transactions will increase substantially, causing administrative costs to rise significantly. An even larger increase in administrative costs will occur when pharmacies are required to re–direct post adjudication claims for COB and TrOOP because that information was not updated when the claim arrived at the pharmacy.

By not implementing SPOCS, CMS will be shifting huge administrative costs to pharmacies and will also increase the time of dispensing while pharmacists wait for the necessary COB and TrOOP information to correctly bill the Medicare beneficiary. More importantly, Medicare beneficiaries' wait time will be unnecessarily increased as a result of a much less efficient and effective COB–TrOOP system proposed by CMS.

Coordination with State Pharmaceutical Assistance Programs (SPAPs): At 69 CFR 46701-2, the proposed regulation discusses the coordination between Medicare Part D and SPAPs. This coordination must be efficient and effective because SPAPs payments will count toward TrOOP expenditures for Part D enrollees (whereas Medicaid and Pharmacy Plus 1115 waiver programs do not). Medicare pays first and the SPAPs are the secondary payers. SPAPs could pay the Part D premiums on behalf of enrollees and/or develop a claim–specific wrap–around benefit, which would complicate the necessary coordination between Medicare Part D and SPAPs.

Part D enrollees' TrOOP is required to be calculated by payers. After paying a claim and updating the TrOOP, the payer should then send that updated TrOOP real time to the single point of contact's database, where that single point of contact could include it as part of the claim response back to the pharmacy where the Part D enrollee is waiting. NACDS SPOCS proposal allows this real time sharing of information that will meet Part D enrollees' expectations that their TrOOP will be correct and delivered real time to their pharmacy.

In those situations where SPAPs create a wrap around benefit, the SPAP information would be included in the SPOCS' database so that when a pharmacy submits a Part D enrollee's claim to the SPOCS, it would know to first route that claim for payment to the Part D plan as the primary payer. The Part D plan would then send a claim response back to the SPOCS including the updated TrOOP, which would then send the remaining claim to the SPAP as the secondary payer. The SPAP would then send a claim response back to the SPOCS including the updated TrOOP, which would be sent by the SPOCS to the pharmacy on a claims response indicating what each payer has paid along with the updated TrOOP. The SPOCS would then send an information-only claim to the primary payer to update the TrOOP so their system would be able to accurately calculate subsequent claims against the TrOOP. Real time information feedback loops will be essential in determining an accurate TrOOP.

SPOCS would actually routes claims, unlike the COB system described on page 46702 of the prepared regulation, which merely passes information to the pharmacy so the pharmacy will know where to submit both the initial claim and the resulting secondary claim. The SPOCS is much more efficient than the system described by CMS in the preamble.

The Part D enrollment card is not the most efficient way for pharmacies to obtain necessary COB information. NACDS' proposed SPOCS only requires the Part D enrollee to present his or her standard prescription drug benefit card. No other cards are necessary so the costs for those other cards are thereby eliminated. This card provides sufficient information for the pharmacy to submit the payment claim to the SPOCS for routing to the appropriate payers in the proper billing order.

Coordination with Other Prescription Drug Coverage: At 69 CFR 46702, NACDS is offering CMS its SPOCS proposal because its use will allow Part D enrollees to receive their prescription medications and/or supply services more quickly**.** SPOCS will provide the most efficient and most effective coordination between Medicare Part D and other plans providing prescription drug coverage, including: (1) Medicaid programs (including a state plan operated under a waiver under section 1115 of the Act); (2) group health plans; (3) FEHBP; (4) Military Coverage (including TRICARE); and (5) other prescription drug coverage that CMS may specify.

Although NACDS understands that there is a relatively limited applicability of COB between Part D plans and state Medicaid programs, the SPOCS would still need to provide the updated TrOOP real time to pharmacies so that Part D enrollees waiting at those pharmacies would know how much they are required to pay for their prescription medications and/or supply services.

Coordination of Benefits (COB): In regard to the discussion at 69 CFR 46702-4, NACDS' SPOCS could manage all of the information described in the following paragraph. SPOCS would use this information when a pharmacy submits a Part D enrollee's real time claim to the SPOCS for the SPOCS to route to the appropriate payers in the correct billing order.

NACDS understands from the preamble:

- The MMA requires that CMS, by July 1, 2005, establish requirements for COB between Part D and the SPAPs;
- Elements that are to be coordinated must include: Enrollment file sharing; claims processing and payment; payment of premiums for both basic and supplemental drug benefits; third-party reimbursement of out-of-pocket costs; application of the protection against high out-of-pocket expenditures (by tracking TrOOP and the annual out-of-pocket threshold); and other administrative processes and requirements that CMS may specify;
- Enrollment file sharing might include information such as beneficiary name, date of birth, health insurance claim number, sex, name and address of benefit administrator, insured's identification number, electronic transaction routing information (RxBin, RxPCN, RxGRP), group number, patient relationship, and coverage effective dates; and
- Claims processing information might include collecting information similar in nature to that currently contained in a Medicare provider Remittance Advice statement. Information must be sufficient to successfully link with enrollment files and in order to allow Part D plans to make a correct determination of TrOOP expenditures on the part of beneficiaries.

NACDS' SPOCS proposal would provide a solution to CMS' technical communications concerns and assure that CMS' stated goals would be accomplished. CMS correctly stated in the preamble that the COB at the pharmacy point of sale is a technical communications challenge and that this challenge must be overcome if CMS is to attain its stated goal:

> *"… the goal is that the beneficiary pays the correct coinsurance or co-payment at the point of sale and that the pharmacy is subsequently reimbursed the correct amount from the other source or sources." [See 69 CFR 46702]*

CMS also realizes the need for a "reliable feedback loop," which is an essential component of the NACDS SPOCS solution that is the real time organized system that CMS has described:

> *"coordination of benefits for beneficiaries enrolled in Part D plans must include a reliable feedback loop of paid claims data from the employer, union or other insurer back to the Part D plan for purposes of tracking TrOOP. Additionally, given the real-time claims environment for pharmacy benefits, the feedback would ideally be in real-time so that beneficiary liability (if any) can be known at the point of sale, the correct insurer pays the correct share of the total drug cost, and the TrOOP calculation can be updated as quickly and accurately as possible. This suggests the need for an organized system to share, update, and push data back and forth between pharmacy benefit managers and pharmacies…." [See 69 CFR 46702] [Emphasis added.]*

Medicare Part B must be managed by SPOCS to maximize the efficiency of COB and TrOOP calculation. Pharmacy-dispensed drugs covered by Part B include medical equipment and supplies including durable medical equipment (DME), certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and oral anti-cancer drugs, and such other items as the Secretary may determine.

NACDS understands that community pharmacies will not be paid by Part D in those situations when "payment is available" for an individual who could have been enrolled under Part A and/or Part B. NACDS also understands that there are a number of complex plan design situations that determine whether or not "payment is available" under either Part A and/or Part B, including the fact that Part B coverage varies depending on the region of the country the individual resides.

NACDS' SPOCS proposal would eliminate the need for 50,000 pharmacy computer system to be modified to incorporate the intricacies of Medicare's Part A, Part B, and Part D payment policies and benefit designs. CMS' statement in the preamble clearly supports a system such as the NACDS' SPOCS proposal:

> *"We would wish to ensure that Part D coverage coordination works seamlessly for beneficiaries with Parts A and B of Medicare, and that beneficiaries do not lose Medicare coverage otherwise available to them due to unforeseen difficulties encountered in the coordination process. This is a critical consideration for effective and efficient coordination between the original Medicare program and the new coverage provided under Part D." [See 69 CFR 46703] [Emphasis added.]*

Certainly, CMS would have to agree that the chances for "unforeseen difficulties encountered in the coordination process" would be much more likely if Part D enrollees were required to go to community pharmacies for Medicare payment and benefit information rather than one single source. Seamless COB between Part A, Part B, and Part D has benefits for providers, beneficiaries, and for Medicare as the payer. Described below are four examples that demonstrate problems that could occur if SPOCS is not implemented:

- *Example One:* Beneficiaries with Part B and Part D potentially will have prescription products coverage in both Part B and Part D. The Part B coverage is typically targeted toward treatment for specific diseases or disease states (e.g., immunosuppressants, anticancer and antiemetic, inhalation therapy as well as blood glucose monitoring such as diabetes testing equipment and supplies). A number of these products are treatment options for multiple disease states and only a small number of these disease states may qualify in Part B exclusively. A good example is methotrexate. This drug has a common use in treating some forms of cancer therefore qualifying for Part B coverage and also for arthritic conditions, which is not covered in Part B but is in Part D. If proper coordination of coverage does not exist, coverage in two distinct Parts of Medicare could be costly to the provider, Medicare, and the beneficiary.

- *Example Two*: The provider could be negatively impacted by incurring additional administrative costs. Medicare Part B has significantly more and different documentation requirements than Part D. If a provider prepares the documentation for a Part B claim,

submits the claim to Part B, only to have the claim denied, then all that time spent in obtaining the documentation was wasted and added significant costs to the process. Additionally, if a provider submits a claim initially to Part D, which is rejected because it is covered in Part B, the provider must then spend substantial time pursuing the required Part B supporting documentation. After spending considerable time pursuing these required supporting documents, the provider may not receive full payment because of not complying with the timely filing requirements of Medicare.

- *Example Three:* Improper coordination of co-insurance and deductible requirements between Part B and Part D can have a negative impact on the beneficiary. A claim submitted to the wrong Part can cause the beneficiary to pay a deductible or co-insurance amount beyond their actual requirement. Though providers will promptly refund the overpayment, the beneficiary potentially could be ill-prepared to pay out of pocket for these funds. Additionally, customer co-insurance obligations associated with claims submitted to the wrong Medicare program can potentially skew the customers TrOOP and create situations where a refund is due to the beneficiary, again creating an out of pocket situation many seniors cannot afford.

- *Example Four:* Medicare could be negatively impacted because of the potential for duplicate payments. Without coordination between Part B and Part D, Medicare could potentially pay for a service in Part B, and then duplicate that payment in Part D. This duplication could occur through clerical billing errors.

Just as importantly, NACDS' SPOCS proposal would allow CMS to meet the Part D enrollees' expectations of knowing what they owe when they pick up their prescriptions at the pharmacy. To meet these expectations, the SPOCS will provide the necessary billing information real time so that Part D enrollees' TrOOPs can be accurately applied and updated by payers before being communicated by the SPOCS pharmacy. Meeting Part D enrollees' expectations will be key for a successful implementation of the Part D program in January 2006. CMS' following preamble example of the Part B and Part D double coverage illustrates how complex it would be for community pharmacies to determine whether or not they will be paid by Part D without the implementation of SPOCS:

> *"This means, for example, that if a form of administration of a drug is covered under Part B in a region when injected incident to a physician office visit, that drug administered in that manner in that setting cannot meet the definition of a covered Part D drug. However, that same drug can be covered under Part D when picked up at a retail pharmacy to be self-administered by the patient." [See 69 CFR 46702–03]*

CMS provides another coverage problem also illustrating how difficult it would be for community pharmacies, without the implementation of SPOCS, to determine whether or not they will be paid by Part B:

> *"…under local medical review policies, a drug that might be covered under Part B for an individual in one area of the country may not be covered under Part B in another area of the country. Thus, what is covered "under Part B for that individual" may be different in different geographic regions." [See 69 CFR 46703]*

Medicare's payment policies and plan designs must become more streamlined when it moves to real time information interchange that is the essential component of an efficient and effective COB–TrOOP system. The MMA has given Medicare the opportunity to create a real time COB–TrOOP system that reflects the purpose of HIPAA's Administrative Simplification requirements that were enacted in 1996:

> *"to improve the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."*

The private sector has already taken advantage of the standards that have been adopted by HHS. However, they are still waiting for some to be adopted (e.g., unique payer identifiers) and for the NPI regulation to be modified to require that all prescribers obtain an NPI, not only those that submit electronic payment claims on their own behalves.

In general, real time payment transactions will force Medicare to review and revise its outdated paper administrative programs. Medicare administrative procedures are often too complex for both beneficiaries and providers. Moving to a real time information system will force the streamlining of the Medicare paper and batch claim process. Today's processing of Medicare Part B claims incorporates policies and procedures that are vastly different from the norm of processing private third party prescription claims. Consequently, Medicare Part B's requirements result in increased pharmacy workflow and increased patient wait times, which is the antithesis of HIPAA's promised "Administrative Simplification." These administratively burdensome Medicare Part B policies include**:**

- Medicare will not cover a DMEPOS item if the community pharmacy has a verbal order at the time that the payment claim is submitted. If the pharmacy does not have a detailed written order for an item prior to submitting a payment claim, that claim will be denied as not medically necessary. Pharmacists have traditionally been allowed by state laws to take verbal orders from prescribers and reduce them to writing as legally valid prescriptions. These transcribed orders are recognized as valid prescription orders for payment claims made to all non-Medicare third party payers, including state Medicaid programs. The few exceptions to this recognition include prescriptions for Schedule II controlled substances and DAW 1 prescriptions for some state Medicaid programs, both of which are currently not factors in Medicare pharmacy claims. Not recognizing a prescriber's order taken and transcribed by a pharmacist as valid for Medicare claim submission is contrary to current industry practice that exists for the care and convenience of patients. This Medicare policy results in additional labor cost for community pharmacies and the needless delay in service for Medicare beneficiaries.

- Medicare policy prohibits community pharmacies from entering medical necessity information (e.g., an ICD-9 diagnosis code, narrative description of the patient's condition, abilities, limitations, etc.) on the prescriber's order when the prescriber has omitted that information. This Medicare policy, like many others, is totally inconsistent with the policies of other third party payers.

Rather than allowing community pharmacies to simply add the missing information to written prescriber's orders like other third party payers, Medicare requires pharmacies to obtain a new written order from the prescriber. This Medicare policy is not administrative simplification.

- Medicare policy has recently been interpreted by a Regional DMERC to require community pharmacies to obtain a new detailed written order, personally signed and dated by the prescriber, when the prescriber has written the words take "as directed" on the original order. This Medicare policy, like many Medicare policies, is totally inconsistent with the policies of other third party payers, which allow pharmacists to clarify the "as directed" instructions on the original order. This Medicare policy is not administrative simplification.
- In general, Medicare's certificate of medical necessity (CMN) must be streamlined to reflect the changes provided by the online real time prescription billing process used by the private sector and state Medicaid programs. The same drugs covered by Medicare Part B (e.g., immunosuppressive and oral anti-cancer agents) are prescribed, billed online real time, and dispensed daily to patients covered by numerous private prescription drug benefit plans, including state Medicaid programs. The prescription drug's NDC number, quantity, and days supply provide payers with all the knowledge they need to adjudicate claims real time.

- For initial fills under Part B of immunosuppressive drugs, Medicare requires community pharmacies to provide the ICD-9 diagnosis code, the name of the organ transplanted, the date of discharge along with data about where and when the transplant occurred. This information is known by the prescriber. While pharmacy recognizes that the billing from these entities may <u>not</u> yet have occurred, it is unreasonable to expect pharmacies to track down this data in order to provide patients with medication necessary for their discharge and quality of care. Additionally, all of the existing HIPAA unique identifiers (Medicare Supplier Number as the Provider ID should suffice to identify who is providing the dispensing; UPIN for the prescriber should suffice to identify the prescriber thus negating the need for further prescriber information; NDC for the drug, etc.) should be used to increase the speed of payment claim transaction rather than forcing busy pharmacies to input identifiers in text data, which is much more time consuming.
- If prescribers are mandated to provide the ICD-9 diagnosis and date of discharge on initial prescription orders, these values can be input and transmitted on the claim, but there should only be the <u>minimum</u> additional data requirements in order to receive payment for dispensing the immunosuppressive drug.
- Medicare should process these claims as commercial health plans currently do by having the payer update the patient's file via a prior authorization for the drug for those patients who are eligible. The claim will process for eligible patients who have had the drug prior authorized. This suggestion is consistent with commercial programs and the system supports this process.

NACDS' SPOCS proposal would be more efficient and more effective than the automatic cross–over procedures that CMS is considering, according to the preamble, for drugs potentially covered by Part B that are dispensed by a pharmacy that is a Medicare supplier. According to the preamble, CMS is considering requiring that:

- The pharmacy submit the claim to the appropriate Part B carrier; and
- If it denies the claim, the carrier would submit the claim automatically to the PDP (or its claims processing agent) through which the beneficiary has Part D coverage. This assumes that the beneficiary receives Part D through a PDP. For beneficiaries enrolled in MA-PD plans, coordination of benefits will generally occur internally within the MA organization.

CMS should not be considering expanding the automatic voluntary complementary cross over billing system to provide the COB for Part D because it is not working well today. Medicare Part B has a complementary cross over billing system operating today with Medicaid for dual eligible-individuals and also between Medicare and Medicare supplemental insurers. The complementary cross over paper claim billing system is not working well today for the following reasons:

- Community pharmacies do not always know which insurers, with the exception of the state Medicaid programs, are participating in the complementary cross over billing system;
- One of our chain members requested from the DMERCS a list of complementary cross over payers and to date, only one DEMERC could supply that list;
- Community pharmacies waste time trying to determine who the cross over payer is so that claims can be reconciled;
- The cross over/secondary payer does not always respond to these paper cross over claims in those cases when they deny payment;
- Community pharmacies waste time watching for unpaid or short paid claims and then go back to Medicare to determine who to contact to resolve the payment issues;
- Community pharmacies work load is high for the reasons mentioned above even for the relatively small number of the current cross over claims, but this work load can be expected to become unduly burdensome if this cross over billing program is expanded in 2006; and
- The increase in cross over claims in 2006 will slow the processing of these claims and updating the TrOOP, which to be accurate must involve a real time processing system like SPOCS.

NACDS SPOCS proposal would eliminate all current Medicare cross over billing system problems because it is a real time system that will assure that secondary payers will be billed in the proper order. The real time SPOCS will eliminate the time lag for payment, the needless administrative time spent "looking for payment"; and will assure an accurate determination of the TrOOP. Medicare beneficiaries will also benefit from SPOCS because it will help assure that they receive the benefits due from their secondary payers.

Medicare Part D as Secondary Payer (MSP) to Another Payer: Medicare currently pays as a secondary payer when payment has been made or can reasonably be expected to be made by another party such as workers compensation, automobile insurance, a liability insurance policy, or another health insurance policy (for example, when a beneficiary's spouse has primary insurance through their employment). Although NACDS assumes that most instances of COB under Part D will occur when Medicare is the primary payer, NACDS' SPOCS proposal would still need to be implemented to bill the appropriate payer as the primary payer. The necessary information to do this would be included in the SPOCS' data base and would be used by the pharmacy as the single point of contact to submit Part D enrollees' real time pharmacy claims.

Tracking True Out-Of-Pocket (TrOOP) Costs: As discussed in 69 CFR 46705 NACDS understands from the preamble that CMS is considering the following options for operationalizing the data exchange related to the Part D coordination of benefits system and TrOOP accounting:

- *Option* 1: The PDPs and MA–PD plans would be solely responsible for tracking TrOOP costs. Data collected by a PDP or MA-PD plan would be annotated to the Medicare Beneficiary Database and be available to pharmacies for the purposes of proper billing.
- *Option* 2: CMS would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary and secondary. CMS could use existing fee-for-service coordination of benefits processes to implement many of the processes needed to implement these provisions. Information concerning primary and secondary plans would be shared with and PDPs and MA-PD plans, as well as annotated in the Medicare common working file/Medicare Beneficiary Database to enhance pharmacy billing and beneficiary customer service.

NACDS prefers CMS' Option 2, but Option 2 does not go as far as it must to really maximize the efficiency and effectiveness of COB and the calculation and tracking of TrOOP. NACDS' SPOCS proposal extends Option 2 to also include community pharmacies in its single point of contact system, not only the primary and secondary payers. SPOCS would thereby increase the efficiency and effectiveness of CMS' Option 2 considerably. NACDS proposes SPOCS, in response to CMS' request for comment on these options and input on the best means to ensure an efficient and effective coordination of benefits related to the Part D Medicare program.

NACDS SPOCS proposal would eliminate the need for CMS to spend the time and money building the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 as described in the preamble. Rather than having 50,000 pharmacies querying this eligibility system, the NACDS SPOCS Proposal would build this information into the SPOCS' database and make the SPOCS responsible to route pharmacies' claims to the correct payers in the correct billing order. The CMS eligibility query system would be far less efficient. CMS is even concerned about the eligibility system they propose:

> *"We are concerned that with the significant expansion of health care options available to beneficiaries that providing information to pharmacies about Medicare and other coverage is essential to facilitate proper claims processing. We are requesting comments concerning the development of this system."*

CMS' suggested use of the X12 270/271 Eligibility Query and Response (See 69 CFR 46706) to determine eligibility before submitting the payment claim is not working now in Medicare Part B pilots with chain pharmacies and more importantly would be totally unnecessary if CMS implemented the SPOCS. Many problems currently exist with the proposed Part D 270/271 Eligibility Query and Response in the current Medicare Part B's Beta Tests with several of NACDS' chain pharmacy members:

- The X12 270/271 is not used by community pharmacy because eligibility is already built into the real time HIPAA NCPDP 5.1 transaction standard. That standard will process about 3.5 billion prescriptions online real time for prescription medications and supplies;
- The 270/271 eligibility queries and response transactions have not been able to be made to work in the real time community pharmacy environment. Most testing has been batch testing, and the average response time does not approach the real time rate of less than 10 seconds;
- Not being able to perform real time transactions increases administrative waiting time for the response information that is necessary before the prescriptions can be filled;
- Increased administrative time requires Medicare beneficiaries to wait longer for their prescription drugs and supplies;
- Dispensing prescription medications and supplies is a very high volume business that makes real time information essential;
- Requiring Medicare beneficiaries to wait longer for their prescriptions than other patients whose payers use a real time eligibility response creates a lower level of service for Medicare beneficiaries;
- These transaction standards have not been incorporated into the vast majority of community pharmacy practice software;
- Developing the software to incorporate the X12 270/271 eligibility standards and to implement those new standards into the 50,000 community retail pharmacies would be very costly and time consuming;
- There is virtually no experience with the X12 270/271 eligibility standards within community pharmacy. The DMERCs are in the testing phases only, which is going very slowly; and,
- Even if the concept to use the X12 270/271 is proven, the DMERCs would still need to go into production with clearinghouses and community pharmacies, an expense of both time and money.

Even if the X12 270/271 Eligibility Query and Response transactions were proven in the future to be able to share eligibility information real time, their use would still not be as efficient or as effective as NACDS' SPOCS proposal. Eligibility information would be contained in the SPOCS' data base so that pharmacies would not have to spend the money to develop and implement the 270/271 Eligibility Query and Response transaction standards. And, even more important than these cost savings, is the savings of administrative time that would otherwise be spent performing the required eligibility queries and waiting to receive responses. SPOCS would reduce the Part D enrollees' privacy concerns because the proposal would reduce the amount of patient identifiable health care information shared between different plans as contemplated by CMS in the preamble:

"… beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA compliant beneficiary "release" or authorization. For instance, if we were to clearly require that all Part D plans coordinate benefits and that all Part D enrollees provide consent for release of third-party data on their Part D enrollment forms, the Part D plans would have the authority to implement inter-plan reporting mechanisms in order to coordinate benefits…."

SPOCS can be implemented by January 1, 2006, so its implementation would remove CMS' concern that "temporary or phased-in approaches that may be necessary or advisable given the short timeframe between publication of the final rule and program implementation." NACDS does not support a temporary or phased–in COB system because its proposed SPOCS can be implemented by January 1, 2006, and therefore avoid the extra time and money CMS would need to spend to develop a temporary or phased in COB system. SPOCS can also solve CMS' concern that cancelled/reversed prescriptions could disrupt the calculation of the initial deductible and TrOOP because they could throw off the correct sequencing of those calculations. CMS expresses its concern about the sequencing of payment claims:

"Another complicating factor in the sequencing of claims is cancelled prescriptions. Generally, a claim is adjudicated when a prescription is filled. If the prescription is not picked up, and is eventually cancelled, the claim needs to be cancelled. If, in the meantime, other claims have been adjudicated, the sequencing is thrown off by the cancelled prescription, potentially disrupting the calculation of the initial deductible and TrOOP, and making coordinating benefits and tracking TrOOP costs more difficult." [See 69 CFR 46707]

By using the SPOCS system, CMS would have a solution to the "claims cancellation/reversal" problem. Since SPOCS is real time, any reversed payment claim would immediately be sent by the community pharmacy to the SPOCS' data base for the SPOCS to route to the appropriate Part D Plan. A reversed claim would follow the same routing path as an initial claim in the SPOCS' scenario and the appropriate parties would receive the adjustment payment request just as they would receive the final TrOOP calculation for a paid claim. Subsequently processed claims would be appropriately priced. CMS states in the preamble that it prefers a real time system like SPOCS, but does not believe it could be operational by January 1, 2006. NACDS believes SPOCS can meet that operational deadline:

"Ideally, we would prefer that the system actually coordinate the adjudication of claims and provide real-time claims processing across multiple insurers, but we do not believe that such a complex and unique system could be operational by January 1, 2006." [See 69 CFR 46707]

NACDS does not agree with CMS that the majority of employers, group health plans and other third party payers would participate in a voluntary system because they would receive a clean claim:

"We anticipate that the majority of employers, group health plans and other third-party payment arrangements would participate in a voluntary system since they would receive a clean claim from the pharmacy that has already been adjudicated by the Part D plan.

In return for the clean claim, we would request that third-party payers provide information back to the coordination of benefits system regarding how much they paid on the claim for purposes of calculating the TrOOP under Part D…." [See 69 CFR 46707]

Today, the Medicare complementary cross over process is voluntary and not all employers or managed care organizations participate. However, the TrOOP can only be accurately calculated for each Medicare eligible if all employers, managed care organizations, and all other payers are required to participate in the system. If all payers are not required to participate, how could a system be developed for those non-participating payers and who would develop and pay for such a system.

NACDS' response to CMS' request for "comment and relevant information (if any exists from current market practices) on how these situations should be resolved under Part D at the point of sale…" is again that the COB–TrOOP system must be real time and like the NACDS proposed SPOCS, include community pharmacies as well as payers. NACDS knows that the private sector is ready for real time information sharing because that is how more than 3 bilion prescription claims are paid for each year. NACDS also believes that Medicare can meet the January 1, 2006 deadline if it moves quickly to real time information sharing, and streamlines its policies and requirements so they can be accommodated in a real time electronic environment.

Interaction of Part D with State Pharmaceutical Assistance Programs: NACDS has strongly supported the establishment of state pharmaceutical assistance programs, (SPAPs) and believe they have been a significant source of meaningful prescription drug coverage for older Americans in many states. With the advent of Part D, we believe that many of these programs will have to be substantially modified from their existing structure. We expect that states may approach restructuring their programs differently. Some may subsidize the purchase of a standard Part D plan or a supplemental Part D plan for beneficiaries, while others may wrap around a standard Part D prescription drug plan. We strongly support the provision of the law and proposed regulation that allows PDP plans to issue one single card to Medicare beneficiaries that are enrolled in a PDP that is supplemented by a SPAP. This will create simplicity for the Medicare beneficiary and administrative simplicity for the pharmacy.

We would support CMS allowing existing state pharmaceutical assistance programs that meet the actuarial equivalence tests for Part D prescription drug coverage to qualify as a PDP. These states could receive subsidies from Medicare for that portion of the prescription drug coverage that they provide that is equivalent to that year's Part D standard benefit package. This approach will allow hundreds of thousands of Medicare beneficiaries that currently have good prescription drug coverage through their state programs to retain this coverage and benefit structure without disruption in quality of care.

There are several states that offer more generous prescription drug coverage than would be offered under a standard Part D prescription drug benefit program. These beneficiaries should be able to retain their coverage just as other retirees with private sector prescription drug coverage will be able to retain their coverage, if it is actuarially-equivalent.

Medicare beneficiaries in these state programs have become stabilized on certain medications that they have obtained through certain retail pharmacies of their choice. Many of these programs have no mail order programs, and in the programs that have voluntary mail order, the overwhelming majority of beneficiaries have opted to obtain their medications through their local pharmacy rather than through mail order. Moving them to a Part D plan could be significantly disruptive to these beneficiaries because they will have to potentially switch to the drugs on the Part D plan's formulary rather than being able to continue to take their current medications. They may also have to give up using their local pharmacy, or have to obtain their prescriptions through the mail. By qualifying SPAPs as PDPs, CMS would assure that beneficiaries that are comfortable with their long-standing SPAP can continue to use that program.

Under an approach by which a state would supplement or wrap around an existing Part D program, we would support the ability of states to pay for drugs not on the Part D plan's formulary, as well as to designate as "preferred" pharmacies those pharmacies that may be designated as non-preferred by the plan. That is, if a SPAP wants to use its own state funds to supplement the pharmacy network developed by the PDP plan by increasing reimbursement to all pharmacies to the SPAP rate, or designating all current SPAP network pharmacies as "preferred," then the SPAP should be allowed to do this. This is what many SPAPs did in implementing the Medicare-approved discount card in their state. To assure access to pharmacies that beneficiaries had been using for years, some of the SPAPs increased the pharmacy reimbursement rates provided under the plan to the existing SPAP pharmacy reimbursement rates. This should be allowed for SPAPs that either purchase a standard or supplemental policy, or wrap around an existing Part D plan.

NACDS also encourages states to use some of the $125 million in funding that they can apply for over the two-year period beginning in 2005 to develop outreach programs to pharmacists regarding the changes in their SPAP program's design. Pharmacists interact with Medicare beneficiaries daily, including those that are enrolled in SPAPs. Using some of these funds to work with the national and state pharmacy associations to develop educational programs for pharmacists would be a wise investment. Pharmacists can be very helpful to the state in helping beneficiaries understand the changes, given that many beneficiaries are likely to be concerned about how the changes affect their ability to obtain prescription drug coverage.

II. Subpart K - Proposed Application Procedures and Contracts with PDP Sponsors

Section 423.502-423.516 requires a PDP to have procedures and policies to ensure a prompt response to detected offenses and to develop plans of corrective action. It requires PDP sponsors to conduct inquiries in a timely, reasonable fashion, if they learn from any source, of evidence of misconduct relating to payment or delivery of prescription drugs items or services under the contract.

If, after "reasonable inquiry", the PDP sponsor determines that such misconduct may violate civil, criminal or administrative law, it must report the existence of such misconduct to the appropriate government agency within 60 days or to the HHS Inspector General if the misconduct relates to any of the numerous laws and statutes that are enforced by the HHS Inspector General.

NACDS has several concerns with this section. For example, there is no determinant of "reasonable." Hence, PDP sponsors, in order to be compliant with the rules, will respond to any misconduct reports eagerly, conduct a hurried inquiry, and forward findings to the appropriate government agencies. These agencies, presumably, will then conduct their own investigation.

There is no discussion of due process, nor of a process to allow the accused to rebut or appeal allegations before they get to government agencies. There is a concern that PDP sponsors, in their rush to pursue inquiries in order to comply with the rule, may arrive at conclusions that may be inaccurate, biased, and even not factual. While one understands the desire to detect misconduct, safeguards must be in place to assure that entities are not improperly accused of misconduct due to over zealous auditors, or whistle blowers. Since this section proscribes a method of what steps to follow if an allegation is made, it should also contain proscriptive methods for guaranteeing due process, as well as an appeals process for any entity that is alleged to have engaged in misconduct.

Section §423.505(b)(9)(i) of the proposed regulation requires the PDP to provide to CMS information that CMS determines is necessary for carrying out the payment provisions in Subpart G. Any information relating to claims, patients, prescriptions, or prescribers will originate at the pharmacy. If CMS determines that information that is not part of the existing data elements captured by pharmacies and as spelled out in NCPDP standards is needed, pharmacies will be subjected to unfair burdens in attempting to capture and report this information. The final rule should identify the necessary data to be submitted by pharmacies or make some statement that CMS will not require pharmacies to provide data that is not part of the NCPDP standards.

Section §423.505(e)(2) section spells out the documents that the Comptroller may review, which includes "…books, records… or *information as the Secretary may deem necessary to enforce contract."* Information that the *Secretary deems necessary* that occurs subsequent to the capture and reporting of the information mentioned in the section will be extremely difficult or impossible for pharmacies to obtain. Here, again, the rule should limit itself to requiring only that information which is spelled out in the rule and is included in the NCPDP standards.

Section §423.505(l)(3) requires contractors or subcontractors (presumed to include pharmacies) to have a CEO, CFO, or a person who is delegated by and reports directly to such executive, certify that based on the individual's best knowledge, information and belief that the claim data it submits are accurate, complete, and truthful and that the claims data will be used for the purpose of obtaining Federal reimbursement.

Pharmacy claims are submitted electronically on line at point of sale. Pharmacies submit millions of claims daily. There is no reasonable way every claim could be certified, nor is there a way of batching claims with an accompanying certification. Perhaps the easiest way of obtaining a certification is by including such a phrase in the participating pharmacy contract. In Section §423.504(b)(4)(G)(5) the agency requests comments on whether a provision should be included in the rules requiring PDP sponsors to have standard contracts with reasonable and relevant terms and conditions of participation. Any willing provider could access the contract with these standard provisions and participate as a network pharmacy.

Subpart M – Grievances, Coverage Determinations and Appeals

Sections 423.560-638 relates to grievances, coverage determinations and appeals. The new Medicare Part D prescription drug program will introduce a system of grievances and appeals for Medicare beneficiaries regarding their prescription drug coverage that are generally unfamiliar to pharmacy providers and pharmacists. As we note above in comments made in the formulary section, pharmacists cannot be put in the middle of implementing the coverage appeals and grievance process. Pharmacists can only provide medications that are part of the Part D plan's formulary, or drugs that are not on the formulary (or in a different tier of cost sharing) if they are approved by the plan.

We are concerned that the inability of the pharmacist to dispense the prescription presented to the pharmacist as written could be designated as a "coverage determination" decision that triggers a set of legal and procedural obligations regarding the ability of that beneficiary to obtain the prescription. Pharmacists do not want to deny dispensing prescriptions as written to Medicare beneficiaries or any beneficiary for that matter. However, as is the case with private commercial third party programs, the pharmacist can only dispense products that are on formulary, unless a formulary exception is granted. If the pharmacist cannot fill the prescription, it is likely because the plan does not cover the drug on the formulary. The pharmacist will usually contact the physician to seek approval to switch to an acceptable formulary drug. In some cases, the pharmacist will not fill the prescription because a potential medication-related problem has been identified and the pharmacist wants to contact the physician before filling the prescription.

We are unclear regarding the role of the pharmacist in informing beneficiaries of their rights of re-determination regarding an initial coverage determination. If the plan denies the prescription, then all the pharmacist can do is provide the prescription back to the beneficiary if the beneficiary's physician will not authorize the pharmacist to change the drug to a formulary drug. There are some concerns that the pharmacy will have to submit the claim to the plan anyway, and then give the beneficiary a notice regarding their right to appeal.

These rights should be clearly spelled out for the beneficiary in all the pre-enrollment educational materials, and post-enrollment educational and benefit design materials provided by the plan. The pharmacist cannot be put in the middle of a "legal" process here regarding coverage determinations that might have a material impact on the ability of a beneficiary to ultimately obtain a medication.

Moreover, if there are multiple plans in a region, and given that chain pharmacies usually operate in multiple states, it will be difficult for the pharmacist to determine the correct notice to provide to the beneficiary. If a prescription drug is denied, the pharmacist should give the prescription back to the beneficiary, and the plan should be responsible for sending a notice to the beneficiary that they have the right to appeal.

Executing this process at the pharmacy is further complicated by the fact that many beneficiaries may speak other languages, or may have to receive the information in other formats (i.e. Braille) to be understandable to them. Many may have problems understanding issues relating to appeals, which can take the pharmacist away from performing pharmacy-related activities, such as filling prescriptions, counseling patients, and performing medication management; prescriptions may be denied for any variety of reasons, meaning the pharmacist would have to document the exact reason on a form and provide it to the beneficiary; the process might require the pharmacist to document a clinical or scientific basis for denial in order for the beneficiary to use the appeals process appropriately; or other information. All this information should come from the plan after the pharmacist determines at the point of service that the prescription cannot be filled and provides it back to the patient. The plan will know that the prescription claim is not able to be filled because it will have provided a notice back to the pharmacist indicating so. This should trigger the plan sending a letter to the beneficiary.

If the pharmacist cannot contact the physician to obtain approval to switch from a non formulary drug to a formulary drug, and the beneficiary agrees to the switch if the physician does, then some standard procedure should be put in place to allow the pharmacist to dispense an emergency supply of the prescription medication as written until the physician can be contacted. The plan should pay the pharmacist for this non-formulary prescription and the beneficiary should be charged the formulary cost sharing amount for this drug.

Should the physician later determine that the formulary drug would be acceptable, then the pharmacist should create a new prescription and dispense the formulary drug to the beneficiary. If the physician wants the non-formulary drug, then the physician or the beneficiary must file a separate written document to initiate the coverage determination process. The pharmacist cannot be in the position to provide written documentation regarding a coverage determination in a busy pharmacy filling potentially hundreds of prescriptions each day. Such a process would be compounded by the potential for many Medicare beneficiaries to be using that same pharmacy, all attempting to appeal coverage determinations at the same time. It is important to note that a pharmacist refusal to fill a prescription may be based on clinical grounds, but may also be based on the fact that the plan will not pay for the prescription (or the quantity requested) because of formulary structure or plan design. These components are often out of the control of the pharmacy provider.

Based on our understanding of the process, the PDP will have up to 14 days to make a determination on a coverage request, even if an expedited request has been filed. This coverage request could occur, for example, if a plan is changing formulary drugs, or if the physician wants to switch the beneficiary to a drug that is on a different formulary tier or not on the formulary at all.

In the former case, given that plans have to maintain formulary status of drugs for 30 days after a notice of change, it would seem likely that a beneficiary could resolve the coverage appeal by the 30 day lapse. It is not clear what would happen in the other case, where the physician wants to switch to another non-formulary drug (or different tier drug). Would the beneficiary continue on the formulary medication until the switch is approved? What if the beneficiary would continue to experience adverse effects from the formulary medication that they are taking, and should be switched to the non-formulary medication.

We believe that all these decisions must be communicated to pharmacies through the real time claims adjudication system, and/or that a standard acceptable procedure should be in place to require plans to pay for an emergency supply of a non-formulary or higher-tier medication until the appeals process can be resolved. We are genuinely concerned that the number of appeals that are possible as this new program phases in – especially among the dual eligibles – can create significant patient care issues for beneficiaries and administrative and patient care issues for pharmacists.

III. Subpart O - Intermediate Sanctions

Sections 423.750 through 423.760 relate to the imposition of intermediate sanctions against PDP sponsors that violate Medicare Part D standards. NACDS supports these sanctions. Without intermediate sanctions, the only penalty available in many situations would be termination of the PDP sponsor's Medicare contract, which would result in major inconvenience and disruption for beneficiaries enrolled in the PDP sponsor's plan.

CMS requests comments on "whether closing enrollment should be used in any situation or should we generally rely on civil monetary penalties as a sanction for PDPs." NACDS believes that freezing a PDP sponsor's enrollment activities should be one of the intermediate sanctions available to CMS. We understand the concern that freezing enrollment reduces beneficiary choices, and therefore we agree that enrollment freezes should be used sparingly, especially in regions where there are only two PDP sponsors. However, freezing enrollment should remain a potential sanction in order to deter violations of the rules by PDP sponsors. Freezing enrollment is a particularly appropriate sanction when a PDP sponsor violates Medicare enrollment rules. For example, proposed section 423.752 lists "cherry picking" of enrollees and other enrollment violations as bases for imposition of intermediate sanctions. In those situations, freezing enrollment is an appropriate sanction. Otherwise, without an enrollment freeze, the PDP sponsor could continue to enroll beneficiaries pursuant to policies that violate Medicare enrollment standards.

IV. Subpart P – Premiums and Cost Sharing Subsidies for Low Income Individuals

The new Medicare Part D program will shift almost all dually-eligible Medicare beneficiaries (i.e. those also eligible for Medicaid) to the new Part D plans to obtain their prescription drug coverage. Unlike the case with Medicare beneficiaries that are not subsidy eligible, plans are prohibited from creating different deductible or cost sharing requirements other than those established by law for Medicare beneficiaries below 150 percent of poverty.

That is, $1 generic/$3 brand in 2006 for those up to 135 percent of poverty; $2 generics/$5 brands in 2006 for those up to 150 percent of poverty. Thus, plans are prohibited from creating actuarially equivalent benefit plans for these individuals.

Because there cannot be differential cost sharing or "actuarially equivalent" plans for dual eligibles, any pharmacy (in network or out of network) that wants to provide prescription services for these individuals should be able to do so, as long as they meet the other terms and conditions of the contract. Allowing dual eligible Medicare beneficiaries to obtain their prescription drugs from any pharmacy in the network will help assure appropriate pharmacy care for these individuals, many of whom do not have the means to travel long distances to "in network" retail pharmacies to obtain their prescription medications and pharmacy services.

Plans should be discouraged from using mail order pharmacies for these low-income populations, and should be prohibited (as they are for non dual eligibles) from varying the cost sharing amounts for these individuals to encourage the use of mail order pharmacy over retail pharmacy. There also should be no additional payment required from these individuals to obtain the same benefits (same quantity of medication) from retail pharmacy as through mail. This could possible make it prohibitive for these beneficiaries to obtain their medications from retail pharmacies, which is inconsistent with Congressional intent not to steer beneficiaries to mail order.

Waiver of Copays for Low Income Beneficiaries: Neither the proposed rule nor the preamble discusses implementation of an important part of the MMA regarding the conditions under which pharmacists can waive cost sharing for Medicare beneficiaries in Part D plans. The law allows the waiver or reduction by pharmacies of any cost sharing under the program under 1860D-42(e). This waiver is included in the section of the Medicare law that prohibits providers from offering inducements to beneficiaries to encourage them to obtain a service or product from the provider.

Under this provision, a pharmacy can waive the copayments if three conditions are met: (i) the waiver is not offered as any part of advertisement or solicitation; (ii) the pharmacy does not routinely waive coinsurance or deductible amounts; and, (iii) the pharmacy waives the coinsurance or deductible after determining that the individual is in financial need or fails to collect the coinsurance or deductible amounts after making reasonable collection efforts.

For low income subsidy eligible individuals, the pharmacy only has to meet one condition: the waiver cannot be offered as any part of advertisement or solicitation. We believe that this issue should be addressed in the final regulation, if nothing more than to restate the law, so that pharmacies will have reaffirmed for them that they can waive cost sharing amounts under certain conditions. We are concerned that without this restatement of the law in the final regulation that it could make it more difficult for pharmacies to waive copayments if they so choose.

V. Subpart Q - Guaranteeing Access to a Choice of Coverage (Fallback Plans)

Sections 423.851 through 423.875 establish requirements relating to fallback plans in PDP regions where two choices of plans are not available to Medicare beneficiaries. NACDS supports the establishment of a fall back option for Medicare beneficiaries in regions (or areas of regions) where two choices for prescription drug coverage do not exist. We support the regulation's requirements that CMS be prohibited from contracting with a national fallback plan. This will allow more regional or local entities that have expertise in pharmacy benefits administration to be able to win contracts as a fallback plan.

NACDS believes that the final rule should make clear that fallback entities have to comply with all the other access and quality standards that risk-bearing PDPs as well as MA-PD plans have to comply with. These include requirements relating to pharmacy access standards, a level playing field between retail pharmacy and mail order, electronic prescribing, out of network pharmacies, standard benefit card, medication therapy management, and others. The need for fallback plans to comply with these requirements should be explicitly stated in the final regulation.

CMS requests comments on how CMS should assess the performance of fallback plans, such as identifying the measures to determine whether fallback plans are containing costs, assuring quality, administering the benefit program efficiently, and providing customer service. We provide comments on potential performance measures for each of these areas.

Containing Costs: Fallback plans, like risk-bearing PDPs, should develop programs and drug formularies that help encourage the use of generics. These programs would include differential generic dispensing fees, as well as cost sharing to encourage generic use. Fallback plans, like risk-bearing plans, should also demonstrate that the majority of the discounts that they obtain on prescription prices are derived from drug manufacturers, not retail pharmacies, and passed through to the Medicare beneficiary in the form or lower prices or premiums. Failure to pass along all discounts from pharmacies and manufacturers would be a direct violation of the Federal Anti-Kickback Statute in a non-risk-bearing entity. The fallback plan must be reimbursed only the administrative fees and performance incentives, not reap profit from the reduced price of the pharmacy products/services.

While CMS has expressed interest in using a value like Average Sales Price (ASP) or Average Wholesale Price (AWP) to measure cost performance of these fallback plans, these references would measure the average price for each drug, for each plan, for designated time periods. It does not measure a plan's efforts or effectiveness in controlling costs but merely reports the price negotiated for a drug. Moreover, there are various AWPs for brand name drugs. (i.e., repackaged drugs that are commonly used in mail order have higher AWPs, but greater discounts, making it appear that the plan is offering the payer a better deal at mail order than retail).

A more valuable measure that takes into account not only the price and discounts a plan negotiates, but also measures a plan's cost control efforts to minimize costs is the per member per month (PMPM) cost. PMPM aggregates all of a plan's measures to reduce the cost of providing prescription services to enrollees.

This includes price discounts, the use of generics, step therapy, monitoring utilization, conducting drug utilization review, and the discontinuance of prescriptions identified as unnecessary or that duplicate therapy. Like risk-bearing plans, these fallback plans should also provide bonus payments to pharmacies for performing cost management functions, such as formulary management and step therapy protocols.

Quality Performance Measures: Measures of a plan's quality efforts to avoid drug interactions and over utilization should be based, not on the number of warnings it discovers and sends to pharmacists, but on how often these warnings actually result in a therapy or utilization change. Almost all pharmacies have these types of electronic quality assurance and improvement programs incorporated into their prescription processing systems, so most pharmacies will be able to perform these functions. Plans (or their administrators) use electronic system edits to alert pharmacists to a whole host of situations that could affect a patient's therapy. Pharmacists follow up these alerts with prescribers and patients and review the alert information and the patients' therapy.

Most of these alerts are determined to be inaccurate or non applicable and thus do not result in any therapy or utilization modifications, but do take up considerable time of pharmacists and prescribers. Plans should not be rewarded for generating large numbers of frivolous alerts that are not germane to a patient's treatment, just to inflate the plan's reported frequency of intervention alerts. The fallback plan should be able to provide information to pharmacists about prescriptions that a beneficiary may have filled at other pharmacies so that pharmacists can make an informed clinical judgment about the appropriateness of the new prescription, and work with the physician to make any modifications if necessary.

Fallback plans should also be evaluated on the extent to which they develop and offer meaningful medication therapy management services to beneficiaries, and include pharmacists in their development and execution. Plans should also pay pharmacists for these services, consistent with the time and resources invested by pharmacists in these programs.

Benefit Administration: Any fallback plan should have to have a state of the art, contemporary infrastructure to support the processing and adjudication of prescription drug claims billed by pharmacies. These include being able to adjudicate claims using the online real-time NCPDP prescription processing standard, provide periodic reports and updates to pharmacies on prescription claims billed and paid, and pay pharmacists promptly, preferably by electronic funds transfer.

These plans also should maintain a call center for beneficiaries and pharmacies, as do risk-bearing Part D plans. The call center should be measured by how quickly it answers beneficiaries and pharmacists calls, and how frequently it provides the correct answers. NACDS believes that, should plans be able to access payments from CMS by "debiting" an account established for them, then payments to pharmacies should be turned around as quickly as the fallback plans collect payments from CMS. Plans should not be allowed to earn money on the payments due pharmacy providers.

NACDS believes that these fall back plans, while not risk-bearing entities, must meet certain minimum standards for being successful at operating prescription drug insurance program. For example, CMS should establish some standards for operational longevity in the marketplace (i.e. operated for 3 years in the marketplace), ability to process prescription drug claims (i.e. has experience processing 3 million prescription claims or more), and adequate financial solvency and capital requirements. These plans should be well established in the market to avoid the possibility that they will not be able to meet the operational and financial demands of being a fallback plan. This would create significant access issues for beneficiaries since there would likely be no other Part D plans available in that particular area.

Finally, CMS should hold a public solicitation conference regarding more specific components of and expectations of fallback plans so that interested parties can provide input on the structure of this component of these programs.

Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

This part of regulation describes the procedures by which subsidy eligible individuals will become aware of how they apply for these subsidies, and the responsibilities of the various state and Federal agencies to enroll these individuals in the new Part D program.

The transfer of dual eligibles from the Medicaid program to the Medicare program will be an enormous undertaking. All interested and affected parties need to be involved in assuring a smooth transition. The proposed regulation indicates that states must make available low-income subsidy application forms no later than July 2, 2005. We believe that retail pharmacies can help identify those individuals that are eligible for low-income subsidies and provide them with any applications that they might need. Millions of Medicaid recipients will be affected by this transition from Medicaid and Medicare and we believe that pharmacies can help provide information to Medicaid recipients about what they need to do to retain their drug coverage after January 1, 2006. We encourage CMS, states, and Part D plans to work with pharmacy providers regarding outreach to subsidy-eligible Medicare beneficiaries.

NACDS is particularly concerned about the impact of this Part D drug benefit on dual eligible beneficiaries who have traditionally received their drug coverage through the state Medicaid program. The Medicaid program in each state has traditionally offered a relatively uniform drug benefit, has not required mail order for maintenance medications, has allowed freedom of choice of pharmacy, and has not subjected beneficiaries to strict formularies. Requiring beneficiaries to make these complex choices among Part D drug plans in their region may result in many not making a choice of drug plans during the early stages of the open enrollment period.

Many of these dual eligible enrollees will likely have to be automatically enrolled in the early part of 2006, but we are concerned that many dual eligibles will find themselves without prescription drug coverage on January 1, 2006. This can create serious health implications for Medicare dual eligible beneficiaries, and CMS should allow these dual eligible beneficiaries to have a transition period of no less than six months into 2006 to allow for a transition to this new drug benefit.

We would urge that automatic enrollment of these individuals begin no later than December 1, 2005 so that we can be certain that these individuals will have drug coverage on January 1, 2006. We also urge CMS to include pharmacies in any educational efforts that may be started next spring to reach these dual eligible individuals so they can both obtain the subsidies for which they might be eligible, as well as get enrolled in a Part D prescription drug program.

States should continue to receive FMAP during this transition period to assure that pharmacy service to this critical population is not disrupted. NACDS is also seriously concerned about the potential disruptions in care that may result in 2006 by transitioning these low-income individuals to drugs that they may have been receiving from their Medicaid program to drugs that are on their new PDP or MA-PD plan's formulary. This could involve hundreds of thousands of calls to physicians to obtain authority to switch drugs, further justifying some type of special transition period for dual eligible Medicare beneficiaries who are transitioning from the Medicaid program.

As an alternative, CMS should consider requiring Part D plans to pay for a continuation of a dual eligible's existing drug therapy through the first six months of 2006 or until the individual can select a plan that is appropriate for them in terms of the drugs covered on the formulary. This extended time will also allow for the pharmacist to work with the physician to execute any formulary switches that are necessary, and exhaust any appeals process that might be initiated. This will also allow for a gradual switching of medications in the most logical clinical order if the dual eligible has to be switched from several existing drug therapies to several new drug therapies.

We agree with CMS assertion on 69 CFR 46793 regarding the ability of low-income individuals to obtain their prescription drugs in larger quantities from retail pharmacies (either preferred or non-preferred) as they do from mail order. The economic analysis indicates that "there is likely to be no effect on mail order use by beneficiaries who qualify for the low-income subsidy because nominal cost sharing exists regardless of where the beneficiary purchases the prescriptions…". Thus, these individuals should pay the same cost sharing whether they obtain their medications from preferred or non-preferred pharmacy providers.

We are concerned that the benzodiazepine category of drugs may be excluded by Part D plans. The MMA law and regulation consider these drugs to be "excludable". Many Medicare beneficiaries likely take these medications, because they are safe, cost effective medications to treat such conditions as insomnia and anxiety. It is not clear what physicians might substitute for these drugs. The only way that beneficiaries can obtain these medications are if they pay for them or if they purchase (or are offered through an employer or state-based program) a supplemental Part D plan or wrap around that covers these drugs. We interpret the regulation at 69 CFR 423.906(C) as allowing state Medicaid programs to pay for these excludable medications, such as benzodiazepines, and collect Federal matching funds to help defray the cost.

IV. Collection of Information Requirements

The information collection requirements regarding notice of formulary change seems to only envision that physicians, pharmacists and beneficiaries are notified by mass mailing. We believe that plans should be required to notify chain corporate headquarters of these changes too, and that they develop a system to send these changes electronically to minimize the amount of paper that is sent to pharmacies.

V. Regulatory Impact Statement

The regulatory impact statement appears to overstate the degree of certainty about the revenue impact on retail pharmacies, and fails to conclude that under some scenarios retail pharmacies may lose revenue. It should be emphasized that the estimated impact of the program is subject to a great degree of uncertainty and that the net impact on pharmacy could potentially be negative.

NACDS wants to provide our perspectives on some of the economic assumptions made by CMS in the regulatory impact statement accompanying the proposed regulation. CMS estimates that the net effect on pharmacy revenues resulting from the new MMA prescription drug benefit program will be an increase in the range of 0.6 percent to 1.9 percent. This estimate is based on CMS anticipating an increase in new prescription drug revenues coming into pharmacies from this program *minus* lost revenues from a potential increased use of mail order prescriptions, an increase in pharmacy discounts (i.e. shift of Medicare beneficiaries revenues from cash to third party rates or shift from current third party rates to lower third party rates) and the shift of Medicaid dual eligibles from Medicaid (where the analysis assumes that pharmacy reimbursement rates are better in Medicaid than they will be under the new Medicare prescription drug program.) The analysis estimates a positive revenue increase from the medication therapy management (MTM) program required to be provided by plans to select beneficiaries.

It is difficult to make a general statement regarding the economic impact of this program on retail pharmacy, as CMS does in its analysis. That is because each pharmacy provider has a different model regarding the overall contribution of prescription sales to total sales. Independent and small, medium and large traditional chain pharmacies have a different economic model than do other outlets with pharmacies such as mass merchandise pharmacies and supermarket pharmacies. The former pharmacy types generate the overwhelming majority of their business from prescription sales. The latter types generate a smaller percentage of their sales from prescriptions, even though prescription sales are an important component of their overall business model.

Therefore, the extent to which a pharmacy operation is affected by the MMA will depend upon the extent to which its business model depends primarily on prescription sales. For example, a pharmacy with a significant amount of prescription business generated by Medicare beneficiaries as well as dual eligible Medicare beneficiaries will be disproportionately affected compared to a pharmacy that does not do a significant amount of this business.

The impact will also differ depending on the network status of the pharmacies. Two different pharmacies with a similar amount of business will be affected disproportionately depending on whether the pharmacy is a preferred or non-preferred pharmacy.

We would like to expect that the impact of this law will be positive for all pharmacies, especially independent and small chain pharmacies. At 69 CFR 46795, CMS indicates that "We believe that the program's effect on small pharmacies specifically will be positive. We expect that small pharmacies will participate in the networks of Medicare Part D plans and consequently will share in the positive revenue impacts." The analysis specifically references the broad "any willing pharmacy provision" as evidence that there will be broad pharmacy networks.

First, an "any willing provider" provision really exists only in name. Although any pharmacy in theory can participate in the program, there are multiple provisions that limit the effectiveness of this provision. For example, plans can create smaller pharmacy networks (which we believe is inconsistent with the statute), and allow these networks to charge lower cost sharing than most of the other pharmacies in the network. This will disadvantage pharmacies that are not in the smaller network and likely shift beneficiaries to these limited number of pharmacies at best, or possibly shift them to mail order.

In addition, under certain circumstances Part D plans can "meet" the pharmacy network access requirements if, for example, the MA-PD plan owns or operates its own pharmacy and has a network that is equivalent to the access required under the TRICARE access standards. Part D plans can also seek accreditation from a Medicare-approved accrediting organization that would allow them to potentially circumvent the TRICARE standards. The exact accrediting program has not been detailed, so the impact on pharmacy participation in networks is unknown. Therefore, the analysis gives more importance and attaches more economic importance to the any willing pharmacy provision in the law and regulation than is likely to be the case in reality.

Given the significant lack of specificity provided by CMS in the regulation regarding the medication therapy management program, it is difficult to estimate the economic impact on pharmacy. In theory, these programs would help generate revenues for pharmacy providers, but the lack of programmatic specifics in the proposed regulation could allow for significant variance among plan's MTM programs. While many plans might use retail-based pharmacists, it is not clear how many beneficiaries will qualify for MTM not whether plans will pay pharmacists adequate for these services.

The regulation also overstates the amount of revenues that pharmacies currently receive from Medicaid. State Medicaid programs often appear to be a more generous payer than most commercial third party prescription programs. However, a business operation does not measure the profitability of a particular book of business through its reimbursement rate, but by the net revenues it receives from that book of business. The economic analysis fails to consider that almost 20 percent of all Medicaid prescriptions are paid at the pharmacy's usual and customary rate, not at the EAC rate for brands or generic rate. Moreover, there are higher costs of doing business in Medicaid that do not exist in private programs (i.e., coordination of benefit costs; longer payment cycles; higher rate of claims rejects due to more frequent eligibility changes).

In addition, many Medicaid recipients cannot pay their copays, but the pharmacy cannot be reimbursed by the state. Thus, the economic analysis overstates the current Medicaid revenues to pharmacies, meaning that the transfer to Medicare Part D of the dual eligibles could have a greater economic analysis on pharmacies than is estimated.

We are also concerned that the economic analysis also assumes that Part D plans might pay pharmacies a dispensing fee of $1.96 for brand name drugs and $2.11 for generic drug. This is a difference of 15 cents per prescription, and will not likely create a sufficient incentive for pharmacies to dispense generic drugs. As we have noted in our discussion in these comments, a pharmacy's average cost to dispense a prescription is about $7.50-$8.00, depending on geographic location.

We urge CMS to be sure that plans propose to pay and actually do pay pharmacies adequate dispensing fees consistent with the preamble to the regulation, which discusses the components of a dispensing fee. These components include overhead costs and should include a reasonable profit.

As is often the case with single issue rulemaking, CMS fails to also consider the combined impact on pharmacy economics and revenue from this proposed rule, as well as the reduction in potential pharmacy revenue resulting from changes made in Medicare Part B and reduction in pharmacy sales resulting from the new competitive bidding program for DME which begins in 2007. Medicare Part B will start reimbursing pharmacies for a select few Part B covered drugs at average sales price (ASP) rather than an AWP-based reimbursement. This could lower pharmacy revenues for these drugs significantly, and certainly possibly below their costs of acquisition.

In 2007, CMS will create a limited award competitive bidding program for some high-volume items sold in pharmacies, such diabetic testing strips and lancets. This could preclude pharmacies from being able to supply these items and services if they are not among the few successful winning bidders that are likely. (Obviously, some pharmacies may win a contract to supply DME products to Medicare beneficiaries, increasing the revenues of that particular pharmacy or chain of pharmacies.) Taken together, these changes could have a modest impact on a significant number of pharmacies and a substantial impact on a smaller but measurable number of pharmacy providers. CMS must assess these changes collectively, given that the MMA made several significant policy changes that will affect pharmacy providers.

NACDS asks that CMS contact us to provide more information about the issues raised in this document. The structure of the Part D program will have a significant impact on community retail pharmacy and our ability to serve Medicare beneficiaries. We look forward to working with CMS, Part D plans, Medicare beneficiaries and other affected parties to develop the highest quality, most cost effective benefit possible. Thank you for the opportunity to comment.

NACDS
NATIONAL ASSOCIATION OF CHAIN DRUG STORES

IssueBrief

Elements of a Pharmacy Dispensing Fee

This brief describes the importance of paying an adequate pharmacy dispensing fee and the components that comprise the cost to dispense. This brief outlines many components that go into the provision of pharmacy services, and which should be considered when developing accurate pharmacy supplying fees.[1]

Elements of Pharmacy Service Costs	
I. Staffing	
	Salaries (pharmacists, technicians, managers, cashiers, etc.) Licensure and/or continuing education for pharmacists, technicians
II. Store operations and overhead	
	Rent or mortgage Cleaning, repairs and security Utilities (heat, light, telephones) Computer systems, software and maintenance Marketing and advertising Accounting, legal and professional fees Insurance, taxes and licenses Interest paid on pharmacy-related debt Depreciation Complying with federal and state regulations (e.g., HIPAA) Corporate overhead (central management, etc.)
III. Preparing and dispensing prescriptions	
	Prescription dispensing materials (packages, labels, pill counters, etc.) Compounding the Rx (if necessary) Special packaging (unit dose, blister packs, bingo cards) Special supplies (syringes, inhalers)
IV. Assuring appropriate use of medication	
	Drug use review Consumer/patient counseling Consulting with prescribers Disease management Education and training
V. Reasonable profit	

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[1] The survey instrument from a South Carolina Medicaid dispensing fee study and a listing of included elements of a pharmacy dispensing fee from Myers and Stauffer's California dispensing fee study are included with this memo as background material.

Staffing: Staffing is listed as the first item in Figure 1 because it is probably the most important factor in determining an accurate pharmacy supplying fee. Labor costs include total salaries, payroll taxes and benefits. Prior studies that estimated dispensing costs typically allocated these costs based on employees' time spent in the prescription department. Owner compensation, particularly in the case of pharmacist owners, may require special modifications to account for differences unrelated to the normal compensation for a typical employee or employee pharmacist. Corporate overhead must be considered in any cost of dispensing calculation.

Pharmacy staffing costs are particularly important in California. California has one of the highest average salaries in the nation for pharmacists, an estimated $91,170 as of May 2003. The national average pharmacists' salary for the same period was $78,620. California also has a very low technician-to-pharmacist ratio, 1:1 for the first pharmacist and 2:1 for additional pharmacists. Many states allow ratios of 3:1 or higher. Given that the average technician salary in California was just over $32,000 in May 2003, this low technician ratio leads to higher costs for California's pharmacies. In fact, Myers and Stauffer's June 2002 study of Medi-Cal Pharmacy Reimbursement highlights higher pharmacist salaries as the primary reason why California has a higher cost of dispensing than other states that they have observed.

Overhead & Other Dispensing Costs: Overhead and other dispensing costs are important factors that can be difficult to quantify, particularly by outside observers. In its June 2002 study, Myers and Stauffer considered the following costs to be entirely prescription-related:[2]

- Prescription department fees
- Prescription delivery expense
- Prescription computer expense
- Prescription containers and labels
- Continuing professional education for a pharmacist

Overhead costs that Myers and Stauffer did not allocate as prescription expenses include income taxes (because they are based on profit), bad debts, advertising and contributions. South Carolina appears to allocate all taxes based on the prescription department's sales ratio, and also includes prescription department advertising under the cost of dispensing.

Most other overhead costs were partially allocated as prescription costs by both Myers and Stauffer and South Carolina. Some overhead costs were allocated as a percentage of floor space, such as real estate taxes, rent, janitorial service, and utilities.

Repairs and depreciation were allocated based on floor space by Myers and Stauffer, but sales ratio by South Carolina. Other overhead costs were allocated based on sales ratio by both studies, including: personal property and other taxes, insurance, interest, accounting and legal fees, telephone and supplies, dues and publications.

[2] NACDS prepared an analysis of the Myers and Stauffer study that indicated key shortcomings of and exclusions from their dispensing fee estimates. This document is available from NACDS.

CMS-4068-P-1037

Submitter : Mr. William Schiffbauer **Date & Time:** 10/04/2004 06:10:48

Organization : Schiffbauer Law Office

Category : Attorney/Law Firm

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

I am attaching comments that relate to proposed changes to Part 403 and other requirements for Medigap insurance policies and issuers. Thank you for your consideration.

CMS-4068-P-1037-Attach-1.doc

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October 1, 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 Modernization Act Proposed Rule Part 403

To Whom It May Concern:

I am writing to comment on the proposed rules of August 3, 2004, that would amend 42 CFR 403.205. The agency proposes to amend the federal regulatory definition of a "Medicare Supplemental Policy" to include a stand-alone "limited health benefit policy or plan." For the reasons discussed below, the agency should make no changes to the current definition of a "Medicare supplemental policy" at 42 CFR 403.205 except to conform to the MMA changes regarding what is not a "Medicare supplemental policy".

General Comments

The statute explicitly requires only two changes to the definition of a Medicare supplemental policy in current federal regulations. These changes relate to what is not a Medicare supplemental policy, rather than what is a Medicare supplemental policy. The first is to add "a prescription drug plan under Part D" as a type of coverage not included in the definition of a Medicare supplemental policy. The second is to replace the term Medicare+Choice with Medicare Advantage.

Amendments to §403.205 (Medicare supplemental policy) should be limited to these two changes.

The other changes to the definition proposed by the Agency are not authorized by the MMA. Certain changes will have negative consequences for beneficiaries. Of greatest concern is the proposal to include "stand-alone" limited health benefit plans in the definition of Medicare supplemental policy. CMS does not have statutory authority to advance this proposal; that the proposal does not accomplish Congressional objectives set forth in the MMA; and that the proposal, in fact, runs counter to expressed Congressional intent regarding the scope of section 1882.

Except for the two changes noted above, none of the provisions of the proposed rule relating to the definition of a "Medicare supplemental policy" are required as the result of any statutory changes by the Congress. Therefore, absent statutory change by the Congress, the current regulation at 42 C.F.R. 403.205 should remain unchanged.

Specific Comments on the Proposed Definition of Medicare Supplemental Policy

Inclusion of a rider attached to an individual or group policy.

In general, the proposed amendments addressing the treatment of "riders" appear to be driven by CMS' concern to halt prescription drug benefit add-ons that might distract beneficiaries from choosing Medicare Part D. Otherwise, there is no statutory basis for expanding the federal definition of "Medicare supplemental policy" to include "riders". This is already addressed as a matter of state law. The proposed rule also appears to treat all riders as riders for "benefits"; however, riders may also address non-benefit contract terms and conditions.

Because benefits for Medicare supplemental policies are standardized by "plan type" the only "rider" permitted with respect to benefits would be through the approval of "new or innovative benefits". Importantly, the NAIC Model Regulation provides that, after December 31, 2005, the "new or innovative benefit" shall not include an outpatient prescription drug benefit. See NAIC Model Regulation, § 9.G (September 8, 2004). Therefore, it would appear that the NAIC Model Regulation already addresses the agency's concerns about any "rider" to a Medicare supplemental policy providing prescription drug benefits.

The proposed language is ambiguous and raises several issues. Is it intended to mean a rider attached to an individual or group *Medigap* policy? To specify that a rider to a Medigap policy is also a Medigap policy poses compliance difficulties with respect to standardized benefits, rating and loss ratio standards, disclosure and other Medigap requirements. This is because the rider would appear to be required to meet all of the requirements of a Medicare supplemental policy even though the policy to which the rider is attached already meets these requirements.

Alternatively, if it is intended to mean any rider attached to any individual or group insurance policy or benefit plan, this clause could draw a broad array of insurance products into the definition – and regulatory requirements – of Medigap. The purpose of such a provision is unclear. There have been no instances in the marketplace of companies trying to offer "unregulated" Medigap benefits by providing them through a rider to a different health insurance policy or health benefit plan. Absent such problems, there is no need to regulate such arrangements as Medigap policies. This proposal also raises many of the same issues as the proposal to include stand-alone limited benefit plans.

A rider becomes an integral part of the policy.

As noted above, the NAIC Model Regulation prohibits "new and innovative" benefits from including prescription drug coverage, and riders providing benefits to the standardized plan types

may only be approved under the "new and innovative" benefits authority provided to state regulators under section 1882(p)(4)(B) of the Social Security Act.

Although this proposal is generally consistent with state law and regulations, this broad provision is unrelated to, and not authorized by the MMA. Adding the provision as new "federal law" could raise many questions about its interaction with current state standards for riders. In state law, riders are often considered as part of the policy for specific purposes, but not necessarily across the board with respect to all requirements. Also, riders may be used not only for "new or innovative" benefits, but may also address changes to the contract that are unrelated to benefits.

Inclusion of certain stand-alone limited health benefit plans.

The Medicare Modernization Act did not amend the current statutory definition of a "Medicare supplemental policy" to include a stand-alone "limited health benefit policy or plan". As a result, the Congress did not authorize this amendment to the current regulation. The Medicare Modernization Act made no statutory change to the definition of what "is" a Medicare Supplemental policy, only what "is not" a Medicare Supplemental policy. Accordingly, there is no legal basis in the MMA or current law to including "stand-alone" limited health benefit policies in the definition of a Medicare supplemental policy.

The Congress did not amend the current definition of a Medicare supplemental policy of the Social Security Act at section 1882(g) to make this regulatory change.

CMS initially proposed this change to the definition during the NAIC's Senior Issues Task Force (SITF) consideration of changes to the "Model Regulation to Implement The NAIC Medicare Supplement Insurance Minimum Standards Model Act". The NAIC and its Statutory Working Group concluded that there was no statutory authority or need to make the proposed change to the definition.

CMS' intent appears to be that certain types of stand alone insurance that provide prescription drug benefits should somehow be regulated. The MMA did not enact such a provision. A stand-alone limited health benefit plan cannot be regulated as a Medicare supplement policy because of the standardization of Medigap benefit plan types. Limited health benefit plans do not provide the type of benefits that are included in the standardized Medigap plan types.

Medigap policies may not provide prescription drug benefits after January 1, 2006, and benefit riders to these standardized plans (only authorized as "new or innovative benefits") may not include prescription drug benefits. Therefore any concerns about Medigap plans or benefit riders providing drug benefits have already been addressed.

In addition, the proposed rule's conditions that these limited health benefit plans must "supplement" Medicare and be "sold primarily" to Medicare beneficiaries is vague and ambiguous and will create compliance uncertainty and undue administrative burdens. What does the phrase "to supplement" mean? Providing any benefit that Medicare does not provide? Because the types of items and services that Medicare covers is comprehensive, the phrase could

be read to include almost any type of health insurance benefits offered to Medicare beneficiaries. What does “sold primarily” to Medicare beneficiaries mean? Does one Medicare beneficiary’s purchase meet this test, or must it be a certain percent of total sales? What would be that percentage standard? How would CMS implement this standard?

If prescription drug only plans are intended to be regulated, then the term “stand-alone limited health benefit plan” is overly broad, undefined, and at odds with similar terms used in various NAIC Model regulations. CMS would reach far beyond policies/riders containing prescription drug benefits. The proposed definition could be interpreted to apply to “any” limited benefit policy purchased by a Medicare eligible individual. This would establish unauthorized federal regulatory requirements over types of insurance policies that the states clearly regulate.

Section 1882(f) of the Social Security Act explicitly directed the Department to consider whether there is a need for (federal) standards for health insurance policies, other than Medicare supplements, sold to Medicare beneficiaries. The study specifically addressed hospital indemnity insurance, nursing home indemnity insurance, specified disease insurance, and long-term care insurance, and health insurance policies "other than" Medicare supplemental policies. Congress saw a distinction between Medicare supplemental insurance and these other limited health benefit plans in 1980 when it originally established federal standards for Medicare supplemental insurance.

Now CMS would circumvent the "only Medigap" nature of the statute by redefining it to include a "limited health benefit policy or plan".

On March 9, 1987, the Secretary of the Department of Health and Human Services submitted to Congress a study mandated by PL 96-265, the Social Security Disability Amendments of 1980, entitled “Study of Health Insurance Designed to Supplement Medicare and Other Limited Benefit Health Insurance Sold to Medicare Beneficiaries.” Based on the study, the Secretary concluded that federal standards for health insurance policies other than Medicare supplements sold to Medicare beneficiaries were not needed. Instead the Secretary concluded:

> In considering the need for standards for health insurance policies, <u>other than Medicare supplements</u>, sold to Medicare beneficiaries, we recommended that States be encouraged to adopt appropriate minimum benefit standards for private health insurance sold to Medicare beneficiaries.[1]

Consistent with this 1987 recommendation, the states do regulate limited benefit policies, under provisions that differ significantly from the federal-state Medigap regulatory framework. The NAIC Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act currently sets forth standards for “Limited Benefit Insurance

[1] Letter from Otis R. Bowen, Secretary, U.S. Department of Health and Human Services, to the Honorable George Bush, President of the Senate, March 9, 1987.

Coverage." Congress has not altered the provisions of section 1882 regarding the regulation of "limited health benefit plans" nor has the Congress requested that CMS update findings that State regulation of limited benefit plans is inadequate, or that federal minimum standards are now needed for some reason. The NAIC has separately published Model Individual Accident and Health Insurance Regulations and Disclosures that include standards for any "limited health benefit plan".

Federal law distinguishes "other" supplemental insurance from "Medicare supplemental policies". See Social Security Act section 1882(d)(3)(A)(vi). The states currently do not regulate such policies as "Medicare supplemental policies". In addition, the NAIC Model Regulation for Medicare Supplement Policies includes disclosure forms for limited health benefit plans that state prominently "This is Not Medicare Supplement Insurance". See NAIC Model, Appendix C.

The current federal minimum standards for Medigap, incorporate the NAIC Model Regulation provisions, and demonstrate that limited health benefit policies held by Medicare beneficiaries are not Medicare Supplement insurance.

The NAIC Model Regulation, in section 20, has explicit marketing standards related to marketing Medigap policies to beneficiaries who have other (non-Medigap) insurance coverage. Appendix C of the "Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act," dated September 8, 2004, contains seven disclosure notices which must be provided with all types of health insurance policies that duplicate Medicare. In bold lettering at the top of each disclosure notice is the phrase "This is not Medicare Supplement Insurance." The seven types of policies identified are:

1. Benefits for accidental injury only
2. Benefits for specified limited services.
3. Reimbursement for expenses incurred for specified diseases or other specified impairments.
4. Payment of fixed dollar amounts for specified diseases or other specified impairments.
5. Indemnity policies and other policies that pay a fixed dollar amount per day (excluding long-term care policies).
6. Policies that provide benefits upon both an expense-incurred and fixed indemnity basis.
7. Policies not specifically identified above.

The Agency has provided no statutory basis for expanding the definition of a Medicare supplemental policy to include the broader concept of any stand-alone limited health benefit policies, *regardless* of whether they contain prescription drug benefits. As previously noted, Medigap policy benefits are standardized and any benefit "riders" must be approved as a "new or innovative" benefit. Such "new or innovative" benefits may not include prescription drug benefits.

Congress was specific in providing that Medicare Supplemental policies (as currently defined in federal law and regulation) would be prohibited from offering prescription drug benefits after

January 1, 2006. Congress could have expressly addressed stand-alone prescription drug policies in connection with Medicare supplemental policies, or even separate and apart as individual insurance other than Medicare Part D "qualified" coverage, but did not restrict or prohibit the sale or issuance of any private, stand-alone prescription drug insurance policy. The Part D standards simply establish the rules for "qualified" Medicare Part D policies and carriers.

There would be numerous unintended consequences of imposing Medigap standards on limited health benefits policies. States would not automatically "excuse" these policies from current state insurance requirements for limited benefit policies, so such policies would be subject to both sets of regulations. In many respects it would be impossible simultaneously to meet current state requirements and all federal-state Medigap standards for standardized benefit packages, minimum loss ratios, premium refunds, guaranteed renewability, disclosure, marketing, etc.

Types of coverage excluded from the definition.

Apart from updating terminology to refer to Medicare Advantage (rather than Medicare+Choice) plans, and excluding Part D coverage as a "Medicare supplemental policy", it is not clear why CMS is proposing to change any of the language in the current federal regulation on the current types of coverage excluded from the definition.

CMS proposes to eliminate specific current law provisions relating to a policy or plan of a profession, trade, or occupational association. However, the agency relied on express legislative history in 1982 in drafting current language regarding types of coverage excluded from the definition. See 42 C.F.R. 403.205(d)(4) and (5) (current law). See H.Rept. No. 944, 96th Cong., 2d Sess. at 77 (conference report to accompany the Social Security Disability Amendments of 1980); see also 46 Fed. Reg. at 6299 (January 21, 1981), and 47 Fed. Reg. at 32392 and 32394 (July 26, 1982).

The MMA provides no statutory basis for making changes to this language. Congress did not request CMS to disregard the 1980 committee report directives that were the basis of these regulatory provisions in 1982. Therefore CMS is not authorized by any change of Congressional directive to make this change to the current regulation.

Standards for Medigap Disclosure Notice

Notice to Medigap Rx Policyholders.

In addition, it is recommend that the agency retain the version of the "notice" required by section 104 of the MMA for Medigap carriers that was transmitted to CMS by the NAIC in a letter to Dr. Mark B. McClellan, dated May 20, 2004. The NAIC approved version of the "notice" represents a consensus among state regulators, consumer advocates, senior representatives, and the insurance industry, and that consensus is deserving of deference and maintenance on this matter. That version of the "notice" meets all of the statutory requirements of the MMA and does not require Medigap carriers to make unfounded statements about the "value" of coverage, or to promote competing business arrangements such as Medicare Advantage plans.

The statement in the CMS proposed notice that "The coverage options that will be available to you under Part D beginning January 1, 2006 will provide greater value than your current coverage," could be false and at best misleading, depending on a Medigap Rx policyholder's circumstances. The policyholder may have other coverage, in addition to their "non-equivalent" Medigap Rx policy, and the sum total of their coverage may have greater actuarial value than the Part D benefit.

Such statements as CMS proposes may raise issues of "suitability" and violations of the Unfair Trade Practices under state law.

The phrase "will provide greater value" on its face is a subjective statement that conveys a value judgment on the part of the insurer. Although the phrase may be intended to refer to the actuarial value of the Part D drug benefit in comparison to the Medigap prescription drug benefit, seniors will not easily follow this logic and may misinterpret this statement. This statement is inappropriate for inclusion in this disclosure notice. Medigap issuers do not counsel their policyholders.

The notice provides phone numbers for the state insurance counseling program and the Medicare hotline. Both the state counseling program and the Medicare hotline have trained professionals who provide seniors with information about their individual health insurance choices that assist them in making choices.

The phrase "will provide greater value" also, by federal fiat, would convey a negative message to the policyholder about their current coverage.

Finally, of note, the CMS notice requires Medigap carriers to advise policyholders that competing coverage options, such as Medicare Advantage products, should be considered. This is, at best, an impermissible anticompetitive mandate that a federal agency is unauthorized to require. Should Medicare Advantage plans be required to counsel beneficiaries that they may not be available the next year, and so applicants should consider original Medicare and various Medigap policy options?

* * * * *

I appreciate the opportunity to offer comments on these proposals and thank you very much for consideration of these comments.

Sincerely,

William G. Schiffbauer. Esq.

CMS-4068-P-1038

Submitter : Helen Spencer **Date & Time:** 10/04/2004 06:10:30

Organization : Helen Spencer

Category : Attorney/Law Firm

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 or,
2. The submitter did not follow through when attaching the document, or submitted only one file or,
3. The document was protected file and would not allow for CMS to attach the ile 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 : Mr. Paul Reinhart **Date & Time:** 10/04/2004 06:10:47

Organization : Michigan Medicaid

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Michigan Medicaid is submitting its comments on the proposed rule to implement the new Medicare Prescription Drug Benefit (CMS-4068-P). Our comments are focused on the following: I) Background and II) Provisions of the Proposed Rule. The following highlights key issues for Michigan Medicaid:

Subpart B - Eligibility, and Enrollment
- CMS should be responsible for the ?random? auto assignment at the end of an individual?s initial enrollment period.
- States must be allowed to coordinate the enrollment of qualified Part D individuals before the initial enrollment period, including executing the application on the individual?s behalf as long as the individual is provided an opportunity to decline this assistance or ?opt-out? of any available PDP. This process would prevent gaps in coverage under the process proposed by CMS.
- Full benefit dual eligibles should not be required to pay late enrollment penalties or a monthly premium amount above the low-income subsidy benchmark.

Subpart C - Benefits and Beneficiary Protections
- CMS must further clarify the definition of covered Part D drugs, particularly in the coordination between Part D and Part B drug coverages.
- The definition of long-term care should include assisted living facilities, county medical facilities, home and community based waiver programs, hospice, hospital long-term care facilities, ICF/MRs and PACE organizations.

Subpart M - Grievances, Coverage Determination, and Appeals
- The Medicare processes for grievances, coverage determinations, and appeals are more complex and appear less responsive than Medicaid?s processes.
- The PDP formularies must ensure continuity of therapeutic regimen for the full benefit dual eligible transitioning from Medicaid to Medicare pharmacy benefit.

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals
- SSA should determine the eligibility for the low-income subsidy.
- The Part D regulations should include Medicaid cost-sharing provisions addressing full benefit dual eligible?s inability to pay the cost-sharing requirements.

Subpart S - Special Rules for States (Phased-Down State Contributions)
Various critical comments are provided on the base year ?per capita expenditure?, the growth factors for the base year, manufacturer rebate factor and other adjustments.

Issues 1-10

BACKGROUND

See attachment

BENEFITS AND BENEFICIARY PROTECTIONS

See attachment (Subpart C)

ELIGIBILITY, ELECTION, AND ENROLLMENT

See attachment (Subpart B)

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

See attachment (Subpart M)

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

See attachment (Subpart P)

SPECIAL RULES FOR STATES

See attachment (Subpart S)

CMS-4068-P-1039-Attach-1.doc

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Michigan Medicaid Comments

Proposed Regulations for Medicare Prescription Drug Benefit (CMS-4068-P)

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I. Background

1. Separate Subpart for Duals Recommended – Requirements for full benefit dual individuals should be consolidated into one subpart of the regulations. This would add clarity and would avoid confusion regarding the provisions applicable for the full benefit duals.

2. *Duplicate Information* – Regulations at §423.650 through §423.669 are listed twice in the proposed rules.

3. Manual Guidance Instead of Promulgating Regulation – In the preamble to the proposed regulations, CMS often specifies that additional guidance will be provided in its policy manuals. Michigan Medicaid would like to be provided opportunities to comment on the "Drafts" of the related policies and procedures.

4. Second Review Process Recommended – Given the significant impact of the comments, Michigan Medicaid recommends that once CMS addresses related issues another review process of the revised regulations should be initiated.

5. *Technical Advisory Groups* – Michigan Medicaid would like to be involved with CMS technical advisory groups related to Part D, including the Transition Subgroup and Financial Subgroup.

II. Provisions of the Proposed Rule

Subpart B. Eligibility, Election and Enrollment

This subsection describes eligibility for enrollment in the Part D benefit, enrollment periods, disenrollment, and application of the late enrollment penalty, approval of marketing materials and enrollment forms, and the meaning and documentation of creditable coverage.

§423.34 Enrollment process, §423.36 Enrollment periods, and §423.38 Effective dates

1. Enrollment requirement for full benefit dual eligibles – Federal Medicaid matching funds will no longer be available after January 1, 2006 for Part D covered drugs, when Medicaid pharmacy coverage ends. Michigan Medicaid believes that auto-enrollment will be essential to transition full benefit duals from Medicaid prescription drug coverage to Medicare. The proposed regulation stipulates that duals, who fail to enroll during the their initial enrollment period, will be automatically enrolled. The full benefit duals' transition from Medicaid pharmacy coverage to Medicare is summarized at Table 1. The enrollment schedule and procedures for full benefit duals will be problematic and will likely cause coverage gaps, as described below.

Table 1
Full Benefit Duals: Enrollment Schedule into Part D for 2005 -2006

11-15-2004	Initial enrollment starts. Full benefit duals have the option to enroll directly with a PDP or with a MA-PD (if enrolled in the Medicare Advantage plan). CMS envisions the full benefit duals initiating enrollment with paper forms.
01-01-2006	Part D begins. Medicaid no longer provides pharmacy coverages to full benefit duals.
05-15-2006	Initial enrollment ends. Full benefit duals who failed to enroll with a PDP or MA-PDP will be auto-enrolled into a Medicare pharmacy plan. If there is more than one plan, plan assignment will be random to those plans that are below the low-income subsidy benchmark.
06-1-2006	Because Part D is effective the first day of the month after enrollment is made, June 2006 would be the soonest Part D effective date for auto-enrollment duals.

2. Coverage Gaps Likely – The proposed process will likely cause pharmacy coverage gaps. The new Medicare prescription drug benefits may be confusing for beneficiaries. The Medicaid population may not understand the need to enroll in Part D. If enrollment is based on *paper forms*, it will be slow and inefficient – especially given the 6 to 7 million full benefit duals across the nation. Michigan qualified for a two-year grant of $600,000 annually for outreach and education; however, this amount may not be sufficient given our State's nearly 200,000 duals. Delays in Part D enrollment will cause gaps in prescription coverage for the full benefit duals. These gaps may result in increased hospitalizations, emergency room visits, physician office visits, etc. Also, enrollment delays will cause significant administrative costs for States, who will undoubtedly have to respond to inquiries from beneficiaries and pharmacies. Auto-enrollment for the duals must begin November 2005 and be completed by December 31, 2005 to prevent prescription drug coverage gaps.

3. Why Random Assignment of Plans in Full Benefit Duals in Auto-Enrollment? Part B fee-for-service mandates enrollment with one carrier within each region. The need for random plan assignment of the full benefit duals is questionable. Our preference is that a State's duals be enrolled with one plan, which provides a formulary closely resembling the State's Medicaid coverages. States need to avoid problems with duals switching medications by allowing sufficient time for prescribers to switch to a Part D covered drug or obtain prior authorization for critical non-covered medications. This parallels the process used for State Pharmaceutical Assistance Programs (SPAPs) and the Medicare Discount Card Transitional Assistance program.

4. Who Should Perform Auto-Enrollment with Random Plan Assignment? CMS requested comments on whether the federal government or the States should have responsibility for administering the "random" automatic enrollment process for the full benefit duals who do *not* otherwise enroll in a PDP or MA-PD plan during their initial enrollment period. In the preamble to the proposed regulations, CMS recommends that States be responsible for this new function because States have access to Medicaid eligibility data and have experience with random assignments through their Medicaid programs. Michigan Medicaid recommends that **CMS perform the *random* auto-enrollment after the initial enrollment period** for the full benefit duals.

If States are required to perform this *random* auto-enrollment for the full benefit duals:

- States should be reimbursed 100% for their administrative costs, instead of the 50% proposed in the regulations. Part D is a federal program and States are already funding their share through the Phased-Down State Contribution.
- A State should be allowed to coordinate enrollment with a preferred PDP with a formulary that closely matches the State's.

5. State Enrollment Coordination Prior to the End of the Initial Enrollment Period - Regardless of whether CMS or the States coordinate the *random* auto-enrollment process, States should have the ability to coordinate enrollment for qualifying Part D individuals *before the end of the initial enrollment period*. Michigan Medicaid recommends 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. This would prevent the gaps in pharmacy coverage mentioned previously.

6. QMBs and SLMBs - The proposed regulations stipulate that QMBs and SLMBs automatically are eligible for the Part D full low-income subsidy. However, no auto-enrollment process is specified for them. States should have the ability to perform auto-enrollment for this population as well as the Medicaid full benefit duals. (See # 5, State Enrollment Coordination Prior to the End of Initial Enrollment Period)

7. CMS Should Define State Data Requirements for Auto-Enrollment – CMS and States should define and develop data requirements and automation processes for auto-enrollment for the full benefit duals.

8. Special Enrollment Periods – Regulation at §423.36(c)(4) stipulate that full benefit duals are allowed to enroll in a PDP or disenroll from a PDP and enroll in another at any time. CMS should coordinate this process for full benefit duals and establish processes that will allow PDPs to distinguish full benefit dual from other beneficiaries.

9. Central Enrollment Broker – Michigan Medicaid recommends that CMS provide centralized enrollment services for Part D, e.g., to answer beneficiary questions and provide ombudsman services.

§423.46 Late enrollment penalties and §423.780(c) Premium subsidy

A Part D eligible individual must pay a late premium penalty. The penalty is applied for individuals who do not enroll in Part D during their initial enrollment period, when the individual has a continuous

period of 63 days or longer without creditable prescription drug coverage or was not enrolled in a PDP or MA-PD plan. For individuals enrolled in the full low-income subsidy, the penalty is 20% of the standard late enrollment penalty for the first 60 months (or 5 years).

Full benefit duals should be exempt from late enrollment penalties – Full benefit dual individuals should be exempt from late enrollment penalties for Part D. This exemption has precedence based on State buy-ins for Medicare Part B for the duals. The late enrollment penalty would be burdensome for the full benefit duals who previously had no such requirement under Medicaid. If duals cannot pay, they will lose their pharmacy coverage. Nursing home duals will have to use their patient pay amounts and will spend down faster into Medicaid coverages. [Similarly, full benefit duals should not be required to pay monthly premium amounts over the low-income subsidy benchmark. See comments under Subpart P.]

§423.56 Procedures to determine and document creditable status of prescription drug coverage

If a beneficiary has *creditable prescription drug coverage*, late enrollment premiums for Part D are not applicable. Creditable prescription drug coverage can be attained by specified entities only if the actuarial value of the coverage equals or exceeds the actuarial value of the standard Medicare prescription drug benefit. Medicaid and State Pharmaceutical Assistance Programs may qualify.

1. State Medicaid programs should be automatically deemed creditable prescription drug coverage. State Medicaid programs have to meet federal regulations that exceed the standard Medicare prescription drug benefit. Each State Medicaid program has a State Plan agreement with CMS describing its pharmacy coverages. States should not have to submit additional documentation or incur administrative costs to be considerable creditable.

2. State Medicaid agencies should not have to provide notices to full benefit duals regarding the status of Medicare creditable prescription drug coverage. Starting January 1, 2006, States will no longer be responsible for the pharmacy coverages for full benefit duals. As recommended above, full benefit duals should not be responsible for late enrollment penalties and the need for State beneficiary notices would not be needed. States will be providing CMS electronic data files monthly of their duals, so that Medicaid coverage could be tracked.

Provisions of the Proposed Rule for Medicare Prescription Drug Benefit (CMS-4068-P)

Subpart C – Benefits and Beneficiary Protections

This subpart includes Benefits and Beneficiary Protections: Prescription drug benefit coverage, service areas, network and out-of-network access, formulary requirements, dissemination of plan information to beneficiaries, and confidentiality of enrollee records.

§423.100 Definitions

1. Covered Part D drug

a. Over-the-counter (OTCs) products written as "prescription" – Language in Subsection D encourages the use of cost savings mechanisms. One such mechanism would be coverage of OTC Prilosec before Prevacid, Protonix or Nexium. The Medicare definition of covered drug specifically excludes OTCs. The CMS definition of covered drug should include a provision to allow OTCs to be covered if a practitioner writes and orders them using the same process as a prescription item.

b. OTC smoking cessation products – Most smoking cessation products are OTC. Will Medicare cover the prescription types only?

c. Insulin and administration supplies – The Medicare Modernization Act (MMA) stipulates that insulin (and its administration supplies) are covered. The proposed regulations define administration supplies as syringes, needles, alcohol swabs, and gauze. Medicare currently does not consider the syringes, needles, alcohol swabs, and gauze as Part B coverages. Insulin is only covered if administered by a pump. Other diabetic monitoring supply items are considered Part B covered items and are reimbursed by DMERCs through the use of HCPCS codes.

Michigan Medicaid currently covers syringes, needles, lancets, and alcohol swabs as a pharmacy benefit billed with National Drug Codes – the same billing process as insulin. Gauze is not covered through the pharmacy program and does not pose a problem for insulin administration. Diabetic monitoring supply items such as blood glucose test strips and lancets are provided through either a pharmacy or medical supplier. Most Michigan Medicaid beneficiaries receive these items through pharmacies.

- General - The synchronization of billing formats between Medicare and Medicaid, including Part B and Part D coverages is needed. Michigan Medicaid believes strongly that all insulin and diabetic monitoring supply items, e.g**., blood glucose test strips, alcohol swabs, and lancets should be on the NCPDP point-of-sale payment system** to allow

increased access to care and timeliness of payment. To facilitate better coordination of benefits, Michigan recommends that pharmacies bill Part D directly using an NCPDP format and allow the PDPs to determine what products would then need to be routed to Part B for consideration of payment. In this manner, pharmacies would have one entry point for submitting their claims. Once the initial coordination has occurred between Part D and Part B, the claim could then be routed to Medicaid for consideration of any liability of coinsurance or deductible payments.

Billing insulin and blood glucose test strips, alcohol swabs, and lancets directly to the Part D benefit will consolidate services under the Part D payment history and promote disease management and care coordination. Further, because of the NCPDP the point-of-sale (POS) payment system, sophisticated checks to monitor an individual's use of test strips could be implemented. This is not available from the DMERCS under Part B.

- Insulin – Since Part B coverage of insulin is dependent on its method of administration; confusion may result when it is covered for the new Part D coverage. Michigan Medicaid recommends that insulin billed to the Part D entity in all instances.
- Gauze is not covered by the Michigan Medicaid's fee-for-service pharmacy program and could be deleted from Part D.

d. Other supplies and drugs – Other supplies required for the administration of Part D drugs should be considered, including (1) spacers and aerochambers for administration of inhalation products; (2) devices for administration of eye drops; (3) flushing supplies, e.g. saline and heparin for home infusion therapy. (See other comments for infusion therapy in a following section.)

e. Vaccines – Which vaccines licensed under Section 351 of the Public Health Service Act will be included in Part D coverages and under which circumstances?

f. Manufacturer Drug Restrictions to Selected Pharmacies – Part D precludes coverage when a manufacturer restricts sell of a product to selected pharmacies. This provision may inadvertently pose access problems to orphan drugs.

g. Part B Drugs Excluded From Part D – In the preamble to the proposed regulations, CMS stated its intention to ensure Part D "wraps around" Part B drug benefits. "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)." CMS requested comments regarding any drugs gaps that might exist in the combined "Part D & B" coverage package. Michigan Medicaid has identified the following examples of other gaps:

- *Antineoplastic drugs* (e.g., methotrexate) that are used for rheumatoid arthritis and not just for chemotherapeutic agents
- *Antiemetics* (e.g., Kytril, Anzemet, and Zofran) are used for other circumstances, not just nausea after chemotherapy infusion.
- *Inhalation Therapy* – Medicare Part B covers inhalation therapy administered by nebulizers paid by Medicare Part B, but not metered dose inhalers or nebulizers purchased by other insurers.

Michigan Medicaid recommends that Part B self-administered drug coverage should be coordinated between the DMERCs, PDPs, and the States that will pay Part B coinsurance amounts. Representatives from State Medicaid programs, PDPs, DMERCs, and CMS should develop *behind-the-scene automation* that is seamless for pharmacies – one that does not require pharmacies to figure who, when, and which billing format to use. (See comments related to blood glucose test strips above.)

h. Part D Restricted Drugs – MMA stipulates that benzodiazepines and barbiturates are not covered Part D drugs by reference to 1927 (d) of the Social Security Act. However, Michigan Medicaid believes that these drug classes were inadvertently included by the general reference to Medicaid law. Since the early 1990s when 1927 (d) was written, these drug classes are important, cost-effective therapies used many times for seizure control. As such, they should be included in the Part D benefit under a classification for "seizure control."

i. *Comparability of Services Within The Group* – Section 1902 (a) of the Social Security Act requires that State coverages shall not be less in amount, duration, or scope than the medical assistance made available within the categorically and medically needy groups. Michigan Medicaid would like clarification in regulation that MMA, with its federalism of the full dual pharmacy benefit, takes precedence over the amount, duration, or scope provisions of Section 1902 (a).

2. Dispensing Fee

In the preamble of the proposed regulations, CMS presents three options for defining *dispensing fee*.

- Option 1: Activities related to the transfer of possession of Part D drugs from the pharmacy to the beneficiary, including charges associated with missing drugs, delivery, and overhead.
- Option 2: The dispensing fee would include the activities from Option 1 plus would include amounts for the supplies and equipment necessary to administer the drugs.
- Option 3: The dispensing fee would include the activities in Option 2, and also 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.

CMS supports option 1. However, CMS also recognizes options 2 or 3 would eliminate current coverage gaps for home infused drugs. CMS limited options 2 and 3 to cases of home infusion, believing it is the only circumstance where additional services associated with administering the drug would not already be covered under Medicare Part A or B and would be necessary to ensure drug delivery. Michigan Medicaid supports the CMS recommendation for option 1. Recognition of supplies necessary for administration of home infusion therapy is addressed in our comments under §423.120.

3. Long-term care facility

CMS proposes the long-term care facility be defined based on Medicare's definition for skilled nursing facility and Medicaid statute for nursing facility, but asked whether ICF/MRs should be included. Michigan Medicaid understands that PDP pharmacies servicing long-term care facilities might be different from retail pharmacies in the following ways.

- Long-term care pharmacies may be exempted from the MMA requirement to provide information on generic availability and pricing.
- Full benefit duals residing in long-term care facilities do not have copays.
- PDPs *may* have higher payment rates to long-term care pharmacies.

Michigan Medicaid recommends the following be included in the definition of long-term care:

- Assisted living facilities
- County medical care facilities
- Home- and Community-Based providers
- Hospice
- Hospital long-term care facilities
- Intermediate care facilities for the mentally retarded (ICF/MRs) described in Sec. 440.150

- Program All-Inclusive Care for the Elderly (PACE) organizations

Medicaid programs may have State Plans approved by CMS that include prescription drugs in per diem (or cost center) rates paid to a facility. Under Part D, to avoid paying for prescription drug costs twice (in the Phased-Down State Contribution and in these rates), States would have to establish a tiered rate structure – one for duals and one for non-duals. The complexities of doing so will be administratively cumbersome.

§423.120 Access to covered Part D drugs

1. P&T composition and other requirements – If a PDP or MA-PD establishes a formulary, there must be a P&T committee that makes *binding* determinations for coverage. At least one pharmacist and one practicing physician must be "independent and free of conflict" with respect to the sponsor, the plan, and pharmaceutical manufacturers. What is implied – simply not employed by the PDP/MA-PD or a manufacturer; not owning stock; not accepting honorariums; etc? What are the size requirements for a P&T? What percent of the P&T should be independent reviewers? What is the term cycle for membership on the P&T – indefinite or will a rotation cycle be expected?

2. P&T formulary decisions based on clinical and cost data – State Medicaid agencies are required to first consider clinical impacts and then cost issues of their preferred drug lists. Similar requirements from Section 1927 of the Social Security Act should be applied to the PDPs and MA-PDs.

3. Mechanism for States to appeal PDP formularies – CMS should implement a process for States to report problems to CMS regarding individual PDP formularies. Further, States should have *electronic* access to PDP formularies.

4. Formularies acceptable with at least 2 drugs in a class - The United States Pharmacopeia (USP) is developing a Part D model drug classification, which will be used to evaluate Part D formularies. CMS interprets that PDPs will be required to include *at least two drugs* within each covered therapeutic class. Michigan Medicaid's experience is that its formulary classes have more than two products. A PDP's formulary must ensure continuity of therapeutic regimens for the dual eligible transitioning from Medicaid to the Medicare pharmacy benefit. States need to avoid problems with duals switching medications by allowing sufficient time for prescribers to switch to a Part D covered drug or obtain prior authorization for critical non-covered medications.

5. Periodic evaluation of the formulary – PDPs should be required review new products entering the marketplace "quarterly." The entire formulary should be reviewed "annually." Deletions from the

formulary and changes in preferred status should be made after 30-days notice to prescribers and pharmacies. However, in cases when the FDA determines a product is being withdrawn for safety reasons, formulary re-evaluations must be permitted to fill potential coverage gaps.

6. PDP formulary management tools – PDPs may use financial incentives to encourage generic use, tiered cost-sharing, prior authorization procedures, therapeutic interchange, step therapy, and use of mail order to procure savings for plans and for Medicare. CMS is concerned that certain vulnerable populations (enrollees in long-term care facilities or those suffering from mental illness or chronic diseases such as AIDS) might be negatively impacted financially if they do not have access to a wide range of drugs. CMS seeks comments on ways to balance flexibility for a *risk-based* plan with the needs of certain special populations.

- Long-term care- Michigan Medicaid has not had problems operating a preferred drug list that applies to both ambulatory and long-term care individuals. CMS mandating open formularies for long-term care is not recommended. Doing so would provide a disincentive to home- and community-based care.

- Home infusion– From the preamble of the proposed regulations: "Home infusion providers generally bill private insurance plans for these services by billing separately for the drug, and also charging a per diem for other services. The per diem charge represents the average daily expense associated with non-pharmaceutical expenses (including nursing services), such as equipment, supplies, labor, and non-nurse clinical services involved in the compounding, preparation, delivery, administration, and monitoring for a given drug therapy. While Parts A and B pay for some home infusion therapies (through, for example, the drugs and supplies that are provided incident to the provision of a home infusion pump), in other cases home infusion therapies would not be covered by Medicare Parts A and B (for example, when the drug is administered in the home through an intravenous drip and not a pump). In addition, infusion therapy policies may vary from region to region based on local DMERC coverage policies." For Medicare Part B, the CMS Transmittal B-03-024 stipulated home infusion pharmacies as professional pharmacies and required them to bill home infusion drugs and associated supplies on X12N837.

  Confusion will result by treating drugs for home infusion therapy differently based on whether Medicare covers them under Part A, Part B, or Part D. Michigan Medicaid

believes that home infusion therapy and associated administration supplies/equipment should be billed to Part D on the NCPDP billing format. Use of one billing format for Part D drugs would streamline administrative costs plus provide a better mechanism for disease management activities, manufacturer rebate documentation, etc.

The synchronization of billing formats between Medicare and Medicaid, including Part B and Part D coverages is needed. To facilitate better coordination of benefits, Michigan Medicaid recommends that (1) pharmacies bill Part D directly using NCPDP formats and (2) the PDPs determine what products would then need to be routed to Part B for consideration of payment. In this manner, pharmacies would have one entry point for submitting their claims. Once the initial coordination has occurred between Part D and Part B, the claim could then be routed to Medicaid for consideration of any liability of Part B coinsurance or deductible payments.

- Children's Special Health Care Services – Michigan administers a pharmacy benefit under Title V of the Public Health Services Act. Medicaid and Medicare also cover some individuals participating in this benefit. Therefore, these individuals will be impacted by the new Part D formularies.

7. Full benefit duals and other insurance coverage – Many full benefit duals will have "other insurance" coverage that partially pays for prescriptions. The other insurers might also have formularies that do not coincide with an individual's PDP formulary. How will full benefit duals be protected so that they are not liable for the other insurer's higher cost sharing? Or will the Part D benefit ignore the other insurance coverage?

8. Copays – For purposes of copays, how will cross-licensed drugs be classed – as generics or brands? Similarly, what is the copay for multiple-source brand name prescriptions that are ordered as "dispense as written" for a brand drug equivalent to a generic?

Provisions of the Proposed Rule for Medicare Prescription Drug Benefit (CMS-4068-P)

Subpart M- Grievances Coverage, Reconsideration, and Appeals

This subpart includes coverage determinations by sponsors, exceptions procedures, and all levels of appeals by beneficiaries.

1. The Medicare process is more complex and less responsive than Medicaid. A beneficiary may appeal and gain access to a non-formulary drug – if the individual's doctor certifies that the drugs available on the formulary are not as effective or would adversely impact the beneficiary. Applying the Medicare Advantage appeal process for medical services, as proposed, is not appropriate for prescription drugs.

CMS is proposing that Medicare PDPs have 14 days to respond to a request for drug coverage determination and another automatic additional 14-day extension – for a total of 28 days. Notable is the Medicare process does *not* include the following mandatory Medicaid provisions listed at Section 1927 (d) of the Social Security Act.

- 24-hour response by telephone or other telecommunication device to a prior authorization for coverage exceptions, and
- Provision of at least a 72-hour supply of a requested drug in emergency situations

Michigan Medicaid believes these requirements should be included in the Part D coverage determination process. Also, CMS should monitor the PDP grievance process for atypical patterns of authorization.

2. Continuity of Care. A PDP's formulary must ensure continuity of therapeutic regimens for the dual eligible transitioning from Medicaid to the Medicare pharmacy benefit. States need to avoid problems with duals switching medications by allowing sufficient time for prescribers to switch to a Part D covered drug or obtain prior authorization for critical non-covered medications.

States can best prevent potential problems associated with medication changes for their dual eligible population by auto-enrolling them in a PDP with a formulary that best matches their own. This issue is discussed in the Eligibility and Enrollment section of this document.

Provisions of the Proposed Rule for Medicare Prescription Drug Benefit (CMS-4068-P)

Subpart P, Premiums and Cost-Sharing Subsidies for Low-Income Individuals

This subpart includes eligibility determinations and payment calculations for low-income subsidies.

§ 423.772 Definitions

1. Definition of institutional individual – CMS must clearly define what is meant by institutional and inpatient medical institution. Michigan Medicaid recommends the following be included as institutional:

- Assisted living facilities
- County medical care facilities
- Home- and Community-Based providers
- Hospice
- Hospital long-term care facilities
- Intermediate care facilities for the mentally retarded (ICF/MRs) described in Sec. 440.150
- Program All-Inclusive Care for the Elderly (PACE) organizations

2. *Changes to Medicaid Long-Term Care Rates* – Medicaid programs may have State Plans approved by CMS that include prescription drugs in per diem (or cost center) rates paid to the facility. In order to avoid paying for prescription drug costs twice (in the Phased-Down State Contribution and in these rates), States would have to establish a tiered rate structure – one for duals and one for non-duals. The complexities of doing so will be administratively cumbersome.

§ 423.774 Eligibility determinations, redeterminations, and applications

Michigan Medicaid recommends that SSA makes the eligibility determination for subsidy individuals and handles the redetermination and appeals of low-income subsidy eligibility. States could establish a process to distinguish income of 100%, 135%, and 150% federal poverty levels and more efficient data sharing process between Medicaid agencies and SSA.

§423.780 Premium subsidy

Full benefit duals are responsible for paying premium amounts over the low-income benchmark subsidy. Auto-enrollment into a PDP or MA-PD might prevent duals from enrolling in PDPs with higher premiums. However, if an individual voluntarily enrolls in a higher cost plan, the individual must pay the difference in cost. Full-benefit duals should *not* pay additional amounts over the low-

income benchmark premium. If a dual enrolls in a plan with a higher premium, the fault is with the enrollment process and a person's drug coverage should not be jeopardized.

If duals cannot pay premiums, they may lose Part D drug coverage. Nursing home duals will have to use *patient pay amounts* for Part D premiums and will spend down faster into Medicaid coverages.

§423.782 Cost-sharing subsidy

1. Full benefit dual and copay requirements – Some Medicaid beneficiaries might have difficulty paying the required $1 or $3 Part D copayment for prescription drugs. Under current Medicaid requirements, a beneficiary is allowed to receive the first prescription free if he/she cannot afford Michigan Medicaid's current $1 co-payment, subsequent prescriptions for the same beneficiary can be denied by the pharmacy if the $1 copayment is not received. The proposed regulations do not address a full-benefit dual's inability to meet the cost sharing requirements. CMS should add the requirements listed at 42 CFR 447.15 for full benefit duals. This regulation stipulates "… The provider may not deny services to any eligible individual on account of the individual's inability to pay the cost-sharing amount imposed by the plan… An individual's inability to pay does not eliminate his or her liability for the cost sharing charge."

2. Medically needy full-benefit duals and copays – Do the medically needy full-benefit duals qualify for copay subsidies of $1 and $3 for 2006 – even though they have income levels over 100% FPL?

3. Full Benefit Copays and full-benefit duals – For purposes of copays, how will cross-licensed drugs be classified – as generics or brands? Similarly, what will be the copay for multiple-source brand name prescriptions that are ordered as "dispense as written" for a brand drug equivalent to a generic?

4. Full Benefit Duals & Copays – Subpart C explains that PDPs may develop "alternative prescription drug coverage" that is actuarially equivalent to the standard benefit. Is this concept applicable to the full benefit duals – for example, copays of $0 for generics and $4 for brands? Michigan Medicaid recommends that the copays specified for the full duals not be set more than the maximums specified in the law ($1 and $3 for individuals under 100% FPL and $2 and $5 for individuals at or above 100% FPL)

§ 423.800 (e) Administration of subsidy program, Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy

Medicare retroactive eligibility – The proposed regulations specify the PDP or MA-PD plans must reimburse low-income subsidy individuals any out-of pocket costs relating to excess premiums and cost-sharing paid before the date the individual is notified of subsidy eligibility.

If an individual is subsequently determined low-income subsidy – will PDPs, MA-PDs, or CMS be required to reimburse State prescription costs made for beneficiaries prior to the date of low-income subsidy eligibility was determined? Michigan Medicaid's recommendation is that Medicare retroactive dual eligibility be ignored for purposes of the Phase-Down State Contribution (See Subpart S). If it is not, CMS should reimburse State prescription costs made on behalf of these individuals – since States would be paying a Phase-Down State Contribution for the same period of time.

Subpart S – Special Rules for States; Eligibility Determinations for Subsidies and General Payment Provisions

This subpart includes State/Medicaid program's role in determining eligibility for low-income subsidy and other issues related to the Part D benefit, including the Phased-Down State Contribution.

§423.902 Definitions

1. Actuarial value of capitated prescription drug benefits –

Michigan Medicaid policy includes disenrollment of duals from capitated managed care organizations. Per state policy, as soon as a Medicaid beneficiary becomes Medicare-eligible they are given dual status, disenrolled from their Health Plan, and put into fee-for-service coverage. However, due to delays in identification of newly eligible duals, the State's claim system shows duals enrolled in managed care for short periods of time. This tends to occur with Medicare retroactive eligibility determinations. In such a case, the State has already paid a capitation for the beneficiary and coverage is valid through the end of the month.

Because this represents a procedural anomaly, the impact of these duals on the Per Capita Expenditure will be minimal, especially considering the weighted average of the calculation. We recommend that this component be ignored for Michigan Medicaid.

The application of a standard actuarial value developed from national managed care data to measure the managed care pharmacy component of the Per Capita Expenditure (PCE) calculation is exceedingly unfair to Michigan. Not only is Michigan's dual eligible managed care population a statistical aberration, but psychotropic drugs, which are the most expensive classifications, have been carved out of the managed care rates and are paid fee-for-service. A nationally based calculation of the pharmacy benefit for duals in managed care would grossly overstate Michigan's experience and lead to higher payments in 2006 and beyond.

Michigan Medicaid proposes one of three options be considered. The first suggestion is for CMS and the Office of the Actuary to develop state-specific values, which better reflect the true pharmacy benefit for the duals in managed care. Failing that, Michigan Medicaid proposes adjustment factors that could be applied to a national value to compensate for circumstances where duals in managed care do not receive a full pharmacy benefit. Finally, Michigan Medicaid would proffer that CMS recognize

the dual population in managed care plans in Michigan for the data anomaly that it is and disregard them in the calculation of the base year Per Capita Expenditure amount for Michigan.

2. Applicable growth factor for each of 2004, 2005, and 2006 – HR 1 Section 103(c)(4)(A) stipulates that the applicable growth factor to be applied to the base year (2003) per capita expenditure calculation to trend it forward to 2006 for "each of 2004, 2005, and 2006 is the average annual percentage change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure (NHE) projections for the years involved)." The illustrative calculation in Subpart S refers to a "cumulative increase from 2003 through 2006."

- *Growth Factor NHE Table* - Clarification is needed as to whether the Act intends this factor to be derived (a) from the "Average Annual Percentage Change from Previous Year Shown" table amounts listed in the NHE projections or (b) from a *calculated* annual percentage change amount from the "Per Capita Amounts" table in the NHE projections. Michigan Medicaid supports the second of these options, as the result is much more conservative rate of growth and one that better reflects Michigan's experience.
- *Total Expenditures versus Medicaid NHE Projection* - The question has been raised in a number of forums whether the most appropriate factor is the NHE projection for *Total Expenditures* (i.e., all payers) or the projection figure specifically for *Medicaid*. Currently, there is no Medicaid-specific "Per Capita Amounts" in the NHE projections. Michigan Medicaid supports the use of the more conservative statistic, which generally is the Total Expenditure projection.
- *NHE Per Capita Change Cumulative or Compounded?* - The illustrative calculation makes it appear that the appropriate growth factor is a cumulative function of the individual annual amounts. The Act suggests that the factor is a compounded figure, which would be intuitively correct.
- *Base Year 2003 with Growth Factor Inherently Misrepresents State Spending* - The method of trending 2003 experience into the future by using any national trend rate is inherently unfair to states like Michigan who have been proactive and aggressive in limiting the rate of growth of

pharmacy expenditures in the past few years. Also, States with historically liberal pharmacy benefits and less restrictive formularies are penalized in perpetuity.

- *Lock-Down 2004 – 2006 Growth Factor*. Even though the 2004 – 2006 "per capita" amounts in the National Health Expenditure report are projections and subject to annual revision, Michigan Medicaid recommends a "lock-in" and not changed so States must provide adjusted Phased-Down State Contribution payments for previous months. When will CMS confirm the NHE projection amount for 2004 through 2006?

3. Applicable growth factor for 2007 and after - The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for the 12-month period *ending in July* of the previous year.

- For 2007, the growth factor definition (in both MMA and proposed regulation) is not feasible, since Part D starts January 2006.
- Michigan Medicaid recommends that there be a fail-safe mechanism to protect States from atypical or extreme Part D "per capita" inflation (e.g. 20%) higher than national trends or inflation due to added benefits or protection from non-preferred status of selected classes (e.g., psychotropics).

4. Base year Medicaid per capita expenditures – The following items have been identified for comment regarding the calculation of the base year Per Capita Expenditure.

- *MSIS reporting logic* – MSIS reporting is based on date of payment, not date of service. CMS should clarify which they will be using for base year Per Capita Expenditure (PCE). It includes, therefore, claim data for expenditures incurred in previous periods. CMS representatives in conference call with States have indicated that the data would be cleaned to only include 2003 dates of service. CMS should clarify which logic (date of service or payment) will be used.
- *Claim adjustments for MSIS reporting for quarters during calendar year 2003*. CMS should clarify how it will recognize claims adjustments to the 2003 expenditures recognized for the Per Capita Expenditure calculation. There should be a limit set for how far out these adjustments can be made.

- *Part B drugs excluded from the calendar year 2003* – States have received the CMS preliminary list of Part B drugs to be excluded from the base year. Time should be allotted to resolve State issues with the CMS determination, i.e., an appeal process.

- *Full benefit duals in the base year (2003)* – Since the MSIS report is quarterly, any monthly enrollment figures for the State must be inferred by comparing to prior and subsequent quarters. This method of determining monthly enrollment is, at best, inexact and can lead to significant errors in the calculation of the PCE. This can put the State at a disadvantage throughout the life of the program. Michigan Medicaid is willing to submit its MSIS eligibility records for calendar year 2003 by individual months. If this proposal is not feasible, then the beneficiaries identified in the MSIS reports should be considered to have eligibility throughout the entire period for the purpose of calculating the PCE.

- *Logic of per capita calculation and count of dual eligibles* – In several CMS conference calls with States, CMS indicated that it is planning to determine the number of beneficiaries by counting the number of duals with MSIS pharmacy prescriptions for the denominator of the PCE calculation. Such a calculation would be a gross mismatch when applied to the number of full benefit dual eligibles (actually enrolled) in calculating the phased-down state contribution payment. Michigan Medicaid urges the total number of full benefit dual eligibles for a pharmacy benefit be use to calculate the PCE and not the number of duals who have had pharmacy claims in 2003.

- *Retroactive Medicaid eligibility for full-benefit duals* – Michigan Medicaid believes that Medicaid retroactive eligibility issues for the 2003 base year period should be largely resolved by the time the base year calculations are made. Therefore, no additional adjustments should be sought.

- *Retroactive Medicare eligibility for full*-benefit duals – Impact of this retroactive eligibility for 2003 is likely to be negligible. Their pharmacy costs will be similar to the current population. Therefore, no additional adjustments should be sought.

5. Phased-down State contribution factor – Michigan Medicaid realizes that the CMS regulations cannot change the definition of this factor. However, Michigan Medicaid would like to go on record in opposition to this schedule. States are at a disadvantage until the point at which the phased-down

factors meet or exceed the annual trend percentage. A more equitable formula would be to recognize that disparity in the initial rates and adjust the phased-down amount accordingly.

§423.906 General payment provisions [for determinations of low-income subsidy eligibility]

This proposed regulation stipulates regular federal match for the administrative services related to low-income subsidy determinations. FMAP should be 100% for administrative costs. This is a Medicare program and States are already paying the phased-down State contribution to support it.

§423.910 (b) Requirements State contribution payment calculation

1. Rebate Adjustment Factor – Michigan Medicaid has the following comments on this adjustor.

- *Rebate revenues lag behind expenditures*. HR 1 Section 103(c)(3)(B)(iii) states that the rebate adjustment factor "shall be determined based on information reported by the State in the Medicaid financial management reports (form CMS-64) for the 4 quarters of calendar year 2003 and other such data as the Secretary may require." Due to the billing process in place for most states, there is an unavoidable lag between the accrual of the gross pharmacy expenditure and the receipt of the associated rebate payment, at least one to two quarters. Given that expenditures (and thus accrued rebates) continue to grow over time, this lag would lead to an understating of the true ratio between expenditures and rebates. While the difference might only be a fraction of a percentage point, it is magnified when placed in context of the overall state contribution calculation, which will be used in perpetuity. To enhance the accuracy of the calculation of the rebate adjustment factor while maintaining administrative simplicity, CMS should use the gross pharmacy expenditures for each of the 4 quarters of 2003 as reflected in the CMS-64 reports and the rebate information reported in the *second subsequent* quarter, i.e. the final two quarters of 2003 and the first two quarters of 2004.
- *Intensity factor for rebates*. Some States have reported that elderly and disabled patients, who make up the dual population, tend to use more branded and higher cost drugs than the general population. These are drugs that generally have higher rebate amounts attached. The rebate adjustment calculation set forth in MMA would understate the true level of rebate attributable specifically to the dual population. For those States able to demonstrate the actuarial impact of such a premise, CMS should allow an intensity factor for this phenomenon. Other States would be assigned a default intensity factor of "one."

2. MSIS Gross Adjustments - Preliminary research seems to indicate that the primary sources of gross adjustments for pharmacy originate from third party liability settlements. With Medicaid the "payer of last resort," it would seem reasonable to expect that the TPL adjustments would lower the level of pharmacy expenditures during 2003, thus reducing the calculated PCE and the ensuing phased-down state contributions.

Inasmuch as TPL recoveries represent valid offsets to the state's 2003 pharmacy expenditures, CMS should allow an adjustment to be made to the calendar year 2003 MSIS report to reflect the amount of third party insurance recoveries. Realistically, this can be a one-time adjustment factor (i.e., percentage similar to the rebate factor), since the majority of recoveries should be known at the time of the calculation.

3. Actuary value of prescription drug costs under capitated plans – See discussion under Subpart S definitions.

4. Applicable growth factor – See discussion under Subpart S definitions.

Number of full-benefit duals for the month – Following are a number of issues related to the count of full-benefit duals once phased-down State contributions begin after January 2006.

5. Retroactive eligibility determinations & phased-down State contributions after 2006 – For a variety of reasons, both Medicare and Medicaid frequently grant retroactive eligibility that could potentially impact the state's contribution calculation. Additional eligible months and the associated costs would come into play in the calculations of both the base year PCE and the monthly phased-down state contribution. It is currently unclear what CMS intends to do regarding retroactive eligibility periods. If it is determined that the states would be liable for adjusted phased-down contribution payments, those calculations would be complicated by changing growth factors, FMAP percentages, and monthly reduction factors. Cost settling existing claims between Medicaid and Part D would face obstacles such as formulary differences, FMAP coverage, Federal rebate repayments, budgetary timing, payment procedures, and the like. There exists a "quid pro quo" relationship in the questions surrounding retroactive eligibility here. Ostensibly, Medicaid will have paid for any pharmacy claims in the interim period. The state would be theoretically liable for Part D contribution payments for each eligible month as well. But to do so would be "double jeopardy" for the state. One or the other must be eliminated. Michigan Medicaid suggests that CMS not make any adjustments for retroactive eligibility periods in the calculation of the phased-down state contribution. Medicaid would cover the pharmacy

liability for those periods as though the person were not dually eligible. Administrative and operational simplicity is the overriding factor. Any alternative plan would make the cost of those claims untenable for both CMS and the state. Michigan Medicaid believes that Medicaid eligibles given retroactive Medicare eligibility are not likely to be enrolled in Part D, since they have Medicaid pharmacy coverage.

- *State eligibility file submission* – State Medicaid agencies and CMS should quickly determine the format and schedule for submission of the State's duals.
- *Federal matching funds for generation of the monthly eligibility files*. States should receive federal matching funds for generation of eligibility files supporting the monthly phased-down state contribution. What FMAP will be provided for the associated administrative costs? Michigan Medicaid strongly believes the FMAP should be specified in the proposed regulations.
- *CMS data sharing with turn-around file* – This file should include at least the following minimum data set.

  Social Security Number
  Name
  Date of Birth
  Sex
  For Part A: Begin and End Dates of Coverage by Enrolled Plan
  For Part B: Begin and End Dates of Coverage by Enrolled Plan
  For Part C: Begin and End Dates of Coverage by Enrolled Plan
  For Part D: Begin and End Dates of Coverage by Enrolled Plan

6. Appeal process for the January 2006 phased-down amounts - States must be given the details of the calculations involved in the monthly phased-down state contribution calculation in a timeframe that would allow sufficient review. There should be a mechanism to allow States to verify, question, and if necessary, appeal the items in the calculation.

Subpart T - PACE Organizations

This subpart of the preamble contains various issues - one to PACE organizations.

Provisions of the Proposed Rule for Medicare Prescription Drug Benefit (CMS-4068-P)

1. General Comments Regarding Part D & PACE Organizations - CMS should develop workgroups with the National PACE Association and States to further discuss impacts – particularly related to the following two issues.

2. Phased-Down State Contribution & PACE Capitation Rates – CMS specifies that "Prescription drug coverages for PACE enrollees enrolled in Medicaid who are not Medicare beneficiaries would continue to be funded by the State through their monthly capitation payment to the PACE organization." Nearly ninety-eight percent of the Michigan Medicaid PACE enrollees are dual eligibles. For the dual eligible PACE enrollees, CMS specifies that individuals would "receive coverage for covered Part D drugs under Part D…" Also, Subpart S of the proposed regulations requires that States provide monthly Phased-Down State Contribution payments for the dual eligible PACE enrollees. To avoid paying for prescription drug costs twice (in the Phased-Down State Contribution and in PACE capitation rates), state Medicaid agencies would have to establish two PACE capitation rates – one for duals and one for non-duals. Given the small percentage of non-dual enrollees, the complexities of doing so may not be justifiable.

3. PACE Organization As Part D Plans – Because of the cost benefits of the PACE setting over a traditional nursing home; implementation of the Part D should not place excessive administrative burdens on these entities.

CMS-4068-P-1040

Submitter : Mr. Tom Wildsmith **Date & Time:** 10/04/2004 06:10:14

Organization : The Hay Group

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the Hay Group, I would like to submit the attached comment letter regarding the proposed rule (CMS-4068-P) for implementing the Medicare prescription drug benefit established by the Medicare Prescription Drug, Improvement and Modernization Act (MMA).

CMS-4068-P-1040-Attach-1.doc

Hay Group. Inc.
Suite 500
4301 North Fairfax Drive
Arlington, VA 22203
USA

October 3, 2004

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

HayGroup®

Dear CMS:

The Hay Group appreciates this opportunity to comment, on behalf of our clients, on the proposed rule (CMS-4068-P) for implementing the Medicare prescription drug benefit established by the Medicare Prescription Drug, Improvement and Modernization Act (MMA).

The Hay Group is one of the world's largest human resources consulting firms providing service to organizations in both the private and public sectors throughout the world. Hay's Benefit Division provides a full range of health & welfare and pension services, including actuarial consulting, benefit plan design, total remuneration analysis, executive benefits, regulatory compliance, administration & outsourcing advice, and employee communications. Our consultants embody a wide range of expertise and industry experience. Huggins and Company, one of the predecessor organizations to the Hay Group, was founded in 1911, making it one of the first consulting organizations in the United States to provide independent actuarial services.

Hay works with employers of all sizes. For over 35 years, the Hay Group has collected detailed plan design and cost information for a large number of employers in the government, industry, and service sectors, and integrated it into the world's largest benefits comparison database. The 2004 the Hay Benefits Report (HBR) has data on 1,003 employers – including information on the prevalence, design and cost of post-retirement medical benefits.

We also help our clients manage their post-retirement medical benefits, assisting with plan design and contribution strategies, and providing actuarial valuations of their post-retirement medical liabilities in accordance with FAS 106 and GAS 45. Currently, we are working with clients to help them understand the impact of the new Medicare drug benefit on their post-retirement medical programs, the choices facing them as plan sponsors, and the impact of those choices on their current cash costs and financial liabilities. Hay is well positioned to address the likely impact of the proposed rule on employers, the concerns employers have in managing post-retirement medical benefits, and their likely responses to the new rule.

We have comments in the following specific areas:

- The actuarial equivalence test for the 28 percent employer subsidy;
- The treatment of cost-management programs in actuarial equivalence calculations;
- Rebating the Part D premium to retirees, covered by employers, who enroll by mistake;
- Allowing prescription drug plans under Medicare Part D (PDPs) to provide a "private label" Part D plan to multiple employers by making a single filing for that plan design, and the need for clearer rules on employer sponsorship of Part D plans;
- Coordination with employer-sponsored "wrap-around" plans; and
- The impact of induced demand in populations with employer-sponsored coverage.

Actuarial Equivalence Test for the Employer Subsidy
(Section 423.884 – Requirements for qualified retiree prescription drug plans)

According to the 2004 *Hay Benefits Report*, based on a survey of more than 1000 employers, a little less than half of all employers (45 percent) currently offer post-retirement medical benefits to individuals over age 65. Of those, almost a third (29 percent) are "access only" plans where the retiree pays the entire premium. Such plans provide an important coverage option to retirees. Benefits parallel those available to younger workers, and retirees benefit from group purchasing.

We do not yet know what benefits, beyond the standard package, Part D plans will offer, and many retirees may be reluctant to sign up for an unfamiliar program when it first becomes available. Paying a higher premium to stay with an access only plan that provides richer benefits may be a rational decision for many. Precluding that choice by applying an actuarial equivalence test that would result in employers discontinuing "access only" drug coverage (e.g., a two-prong test) would harm Medicare eligible retirees who currently benefit from access only programs.

We believe the term "actuarial equivalence" in the MMA should and does refer to gross benefits. That interpretation is consistent with its use for creditable coverage and in the bid submissions of PDP plans, and would suggest a "one prong" test. The Preamble to the proposed rule suggests that one of the goals for the definition of "actuarial equivalence" is that it not result in a windfall to employers who qualify for the employer subsidy but who do not pay for any part of the retirees' prescription benefit. Avoiding employer "windfalls" is a legitimate concern. However, it is important to carefully consider what constitutes a windfall in this context, and whether the equivalence test is the correct mechanism for preventing windfall payments.

Regardless of the definition of actuarial equivalence chosen, employers will see a reduction in the cost of their post-retirement drug benefits. Some will discontinue their programs, others will coordinate with or "wrap around" Part D, others will sponsor Part D plans for their retirees, and still others will claim the 28 percent employer subsidy. In some cases – such as a wrap-around plan – the subsidy provided by the employer may be less than the subsidy provided by the Medicare program through the Part D benefit. This is neither unexpected nor inappropriate.

Given this background, we believe that an inappropriate "windfall" should be understood as an employer plan sponsor receiving the 28 percent employer subsidy, applying less than the amount

received through that subsidy towards the cost of the retiree drug benefit, and pocketing the difference. Thus, we recommend a single prong test of actuarial equivalence, with the requirement that if the amount of Part D employer subsidy exceeds the employer's contribution towards the plan, any excess subsidy payments must be used by the employer to reduce the cost of the program to enrollees.

Allowing this option will not harm retirees – enrollment in an access only plan is voluntary, and they will still have the option of enrolling in a Part D plan instead. Retirees will only enroll if they believe the combination of cost and benefits available under their employer-sponsored plan is superior to the other alternatives available to them. Using our proposed definition of "actuarial equivalence" will not increase Medicare costs. If fact, if retirees enroll in a Part D plan or Medicare Advantage plan instead, the cost to Medicare will be much larger. Because participation would be voluntary, one might initially be concerned about gaming by retirees or employers with higher than average costs; the concern is unjustified in this case. Because the subsidy base excludes catastrophic claims, it provides protection against adverse selection inflating the size of the employer subsidy.

As an alternative to the above proposal, we ask that CMS consider using our approach as a transition for one or two years, while employers evaluate their options. This would ease the transition for retirees currently covered under employer-sponsored plans.

Cost-Management & Actuarial Equivalence
(Section 423.56 – Procedures to determine and document creditable coverage status of prescription drug coverage; Section 423.884 – Requirements for qualified retiree prescription drug plans)

The cost of a pharmacy benefit program depends on more than the benefit provisions (the definition of covered expenses and cost sharing requirements); it also depends on the population covered, negotiated discounts and rebates, and cost-management programs such as formularies. The definition of creditable coverage and the qualification standards for receiving an employer subsidy are based on the standard Part D benefit as specified by the MMA, and not on any particular Part D plan. A generally recognized actuarial principle is that when testing whether two plan designs are actuarially equivalent, the same underlying population should be used for both benefit packages. Extending this principle to the context of determining if coverage is creditable, and of the first prong of the actuarial equivalence test for qualifying for the 28 percent employer subsidy, we believe that discounts and cost-management efforts should also be held constant.

Some negotiated savings and cost management programs will be completely invisible to the beneficiary – such as drug manufacturer rebates. While these affect the cost of providing benefits, they do not affect the value of those benefits to the beneficiary. Thus, they clearly should be held constant when measuring the actuarial equivalence of alternative benefit designs. Others, such as negotiated prices, may have an indirect effect on beneficiary out-of-pocket costs. For instance, the difference between a 20 percent discount and a 25 percent discount on a $40 drug will reduce the patient cost under a deductible or coinsurance requirement (but not under a

$10 co-payment requirement). However, because the test is against the statutory definition of the standard Part D benefit, rather than any particular Part D plan, there is no clear benchmark for the discount, formulary or cost-management practices to assume. Furthermore, the purpose of the test is to measure the coverage and cost-sharing provisions of another plan against those of the standard Part D benefit package, rather than the cost of providing those benefits. Thus, we believe that discounts and other cost-management features should be held constant also.

Rebating Part D Premiums for Retirees Enrolling by Mistake
(Section 423.884 – Requirements for qualified retiree prescription drug plans)

Medicare eligible retirees will be faced with a confusing variety of new coverage options in 2006, when Medicare prescription drug coverage first becomes available. Some will erroneously enroll in both Part D and an actuarially equivalent employer-sponsored program, resulting in duplicative coverage and unnecessary premium costs. In addition to increasing premium costs for retirees, this unnecessary, duplicitous coverage will create a serious problem for employers. Because they will be unable to claim the 28 percent employer subsidy for retirees who also enroll in Part D, employers will be forced to choose between coordinating with Part D plans on a claim-by-claim basis, or incurring higher costs on those enrollees. Duplicative coverage will also increase the cost to the Medicare program, since the federal subsidy for Part D coverage will exceed the average value of the employer subsidy.

We recommend that the rule permit retirees who have erroneously enrolled in a Part D plan, and have actuarially equivalent coverage from another source, to voluntarily disenroll from Part D and receive a premium refund. This would prevent retirees from paying Part D premiums unnecessarily, simplify plan administration for employers, and reduce the cost to the Medicare program.

We suggest that CMS permit a retroactive disenrollment from a PDP for up to 12 months of premiums, provided that during the period no claim has been filed with that PDP and the enrollee was continuously enrolled in another plan providing creditable prescription drug coverage. A PDP would not be required to permit retroactive disenrollment more than once for any person. Also, a PDP would be allowed to charge a nominal processing fee beginning in 2007, thereby allowing for a reasonable transition period.

Importance of "Private Label" Part D Plans and Need for Clearer Rules on Employer Sponsorship of, or Contracting with, Part D Plans
(Section 423.458 – Application of Part D rules to MA-PD plans on and after January 1, 2006)

Employers will undoubtedly appreciate the opportunity to sponsor a Part D prescription drug plan (PDP) either directly or through contract with a PDP. We believe that the final rule should facilitate employer sponsorship of Part D plans. Employer-sponsored Part D plans would provide an attractive option to many retirees. Enrollment could be coordinated with the rest of an employer's post-retirement benefit program. Allowing employers to sponsor their own PDPs would provide employers with an attractive way to supplement the standard Part D benefit

package. Unlike a "wrap-around," any supplemental or enhanced prescription drug benefits would be integrated with the standard Part D benefits into a single comprehensive program. The result would be simpler for retirees to understand and use, and has the potential to be easier for employers to administer.

Only the very largest employers or union plans, however, will have enough retirees to directly sponsor a Part D plan. (And most of them will not want to administer a drug program – just as most employers with self-funded medical benefit programs choose to use third party administrators.) For most employers, sponsoring a Part D plan will only be a viable option if done through a contract with a commercial Part D plan sponsor.

Most employers are very unlikely to sponsor a Part D plan for their retirees if the employer has to go through the same bid submission process required of a local or regional Part D plan. Rather, they are likely to look for packaged solutions. We recommend that commercial Part D plan sponsors be allowed to submit bids for packaged "turnkey" Part D products that they may then market to employers – much as an insurer or HMO will file a health policy with a state insurance department once, and then market it to multiple employers.

This approach would allow for detailed review of Part D plans marketed to employers without unduly burdening those employers – and would significantly streamline the CMS bid review and approval process. Employers would be able to evaluate this option on the same basis that they do any other health benefit plan – based on benefit design, cost, and the administrative capabilities of the vendor – without taking on bid requirements more appropriate for a health plan itself. A commercial Part D sponsor considering entering this market would have bid requirements commensurate with that for offering a local or regional Part D plan.

It should be expressly stated in the rule that once the PDP obtains approval for a particular plan design, an employer that contracts with the PDP for that plan design is not required to seek further CMS or other approvals. An employer should be able to contract with a PDP for a limited group of Medicare-eligible retirees, subject to any applicable non-Medicare law.

For either direct employer sponsorship or sponsorship through a turnkey product to be of significant use, CMS should issue more specific guidance (whether in the preamble or the rule itself) about what employers will have to do to take advantage of these opportunities. Following are examples of further guidance we think would be very helpful to employers.

The final rule should provide safe harbors for the types of waivers that will be available to an employer that wants to sponsor its own PDP; such as: permission for an employer to cover exclusively all retirees (or all retirees in a particular geographic region or from a particular business unit, such as a subsidiary or division), wherever they reside; permission for an employer to contract to a third party PDP compliance while the employer retains ultimate responsibility and liability for compliance; and automatic permission for an employer that sponsors a PDP to undergo a merger, acquisition or other business reorganization that does not necessitate re-applying for PDP status, provided the terms of the transaction expressly require ongoing compliance with the PDP requirements by the successor organization.

With respect to the waiver process, we support the final rule containing expedited waiver procedures whereby an applicant may cite to two or more previously granted, publicly available, waivers, which have the same fundamental facts as those represented in the applicant's submission. The rules could provide that the grant of the waiver is dependent upon the applicant's representation that all relevant facts are the same.

Coordination with Employer-Sponsored "Wrap-Around" Plans
(Section 423.464 – Coordination of Benefits with Other Providers of Prescription Drug Coverage)

We are concerned that employers that want to provide a "wrap-around" plan which supplements the retiree's Part D coverage will have difficulty administering this type of plan in 2006 and perhaps longer because necessary computer systems are not yet working. To accommodate these employers and PDPs, we suggest CMS consider a transition rule that would allow an employer (directly or through a third party) to accumulate all Part D claims and submit them electronically for reimbursement on behalf of the Part D enrollee. Depending on how the technology develops, CMS could terminate the transition rule or modify it as necessary.

Impact of Induced Demand in Employer-Sponsored Populations
(Section 423.56 – Procedures to determine and document creditable coverage status of prescription drug coverage; Section 423.104 – Requirements related to qualified prescription drug coverage; Section 423.884 – Requirements for qualified retiree prescription drug plans)

The proposed rule requires the "increased cost over the average" from the availability of enhanced or alternative drug coverage to be included in the cost of the supplemental coverage, rather than in the cost of the standard coverage.

While many actuaries have experience with pricing health care costs for different drug benefit designs, few have experience with measures of induced demand. Further, unless a standardized method for measuring induced demand is included in the final rule, this requirement will lead to a wide variation in bid costs for very similar plan designs.

The Hay Group has extensive experience with health actuarial measurements and with the Medicare Current Beneficiary Survey data, which CMS has determined is the best available resource for measuring prescription drug utilization among Medicare beneficiaries. Using the Hay MCBS-based health actuarial model, we have estimated the cost of the standard Part D benefits in 2006 using (a) the full MCBS database, (b) just those records identified as having employer insurance, and (c) the full MCBS database excluding those records that are identified as having employer insurance. The following table shows the actuarial values in 2006 of the standard Medicare Parts A and B benefits, Parts A, B, & D, and therefore by subtraction the value of the Part D benefit coverage. The table also shows the demographic characteristics of the group included in each measurement, and illustrates the difficulty of allocating the "induced demand" measurement in the cost between the standard benefit and an alternative or enhanced benefit.

Group Included in the Measurement	Actuarial Value of Parts A & B	Actuarial Value of Parts A, B, & D	Estimated Cost of Part D	Average Age	Percent Female
All Medicare Beneficiaries	$8,519	$10,345	$1,826	73.1	**57%**
Just those with Employer Insurance	$8,538	$10,862	$2,324	73.9	**53%**
Excluding those with Employer Insurance	**$8,466**	**$10,043**	**$1,577**	**72.7**	**59%**

- The table shows that there are slight differences in the demographic characteristics among the groups. Those Medicare beneficiaries who also have employer insurance can be expected to be slightly older and have more males than the overall Medicare population.

- The differences in the value of Medicare Parts A & B benefits are very small -- $8,519 for the overall population, and under one-half percent higher for those with employer insurance. This is consistent with the general observation that the "induction" effect for hospitalization benefits is quite small. In the Hay model we typically use an induction parameter of 30% for hospitalization benefits and 70% for outpatient benefits.

- There is, however, a significant difference in the cost of the Part D benefits for the different groups. Based on the underlying prescription drug usage collected in the MCBS survey, for those Medicare beneficiaries who have employer coverage, and only measuring the cost for the portion of these expenditures covered by Part D, the estimated cost is 27 percent higher than the all-Medicare average and 47 percent higher than the cost for those Medicare beneficiaries who do not have employer insurance.

Thus, based on the MCBS data, we observe that the availability of employer insurance (equivalent to the availability of enhanced coverage) has a significant effect on overall prescription drug usage – such that the value of just the Part D coverage is almost 50 percent higher for those with such coverage compared to those without such coverage.

We believe it would be incorrect for an actuary preparing a bid using prescription drug experience from plans which had broad coverage (i.e. current employer plan designs) to assign the cost of $1,577 to the standard Part D plan, when the current underlying claims experience indicates it is $2,324. Similarly, if the actuary had access to a health actuarial model similar to the Hay model based on the MCBS data, it would be wrong for the actuary to assume that the availability of prescription drug coverage would have no effect on expected expenditures, and therefore use of $1,577 cost would be inappropriate.

We believe it is inappropriate for the rule to require an allocation of the induced demand cost between the Part D benefits and enhanced benefits.

That said, if it is decided to include this requirement in the final regulations, we believe that the competitive bid process would be enhanced if all bidders had access to the Hay MCBS-based health actuarial model so that the induced demand costs can be determined from a common base.

The model allows for the selection of parameters to reflect induced demand, so bidders would be able to choose their own assumptions, however as the underlying data would be common, the results of the allocation of costs more equitable. The model was developed initially for the Congressional Research Service, and as such is in the public domain.

* *

Thank you for the opportunity to comment on this proposed rule. We believe the implementation of the new Medicare prescription drug benefit in a way that broadens seniors' access to prescription drugs, rather than undermining access to existing coverage, is a significant challenge. Successfully meeting that challenge will require careful consideration of the impact of the program on employer-sponsored post-retirement medical plans. If you have any questions about these comments, please contact Adam Reese (703-841-3119 or Adam_Reese@haygroup.com) or Tom Wildsmith (703-841-3135 or Tom_Wildsmith@haygroup.com).

Sincerely,

Adam Reese, FSA, MAAA, EA
Senior Consultant

Tom Wildsmith, FSA, MAAA
Consultant

CMS-4068-P-1041

Submitter : Ms. joan johnson **Date & Time:** 10/04/2004 07:10:39

Organization : Ms. joan johnson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for this opportunity to comment on the proposed Medicare Prescription Drug Benefit program, CMS-4068-P, and, on behalf of all Medicare benefit recipients, thank you to all who worked so hard developing this much-needed benefit.
Access to healthcare providers is so important to good patient care, but is becoming more and more difficult to provide in rural areas such as North Dakota where I have practiced clinical pharmacy in a hospital for 24 years. Subpart C: Benefits and Beneficiary Protections addresses access requirements. I would ask that you consider requirements for averaging access standards locally to actually provide good access, not just make the averages look good!
Requiring plan sponsors to include hospital pharmacies not only makes sense to provide quality of services, but also improves access.
I am suspicious of allowing different tiers of services, such as preferred and non-preferred pharmacies or allowing some pharmacies to charge different copays for differing quantities of medication. This will steer patients to certain types of providers, negating the attempts to provide good access to all beneficiaries.
The regulations for payment to pharmacists for cognitive services such as the Cost Control & Quality Improvement Requirements outlined in Subpart D will assure that patients will get good assessment and follow-up of their medication therapy regimen. As partners in the healthcare team and as primary providers for optimizing therapy with a consideration for cost-effectiveness, clinical pharmacists have demonstrated an excellent return-on-investment for years. In the hospital I practice in, a system is in place to document activity and interventions made by pharmacists. The interventions number in the thousands and the cost-savings and cost-avoidances are in the hundreds-of-thousands of dollars, not only with appropriate dosing per age or renal function, assessment for appropriateness of an agent for a disease state, patient education, monitoring of lab and culture results, drug information searches and therapy recommendations, fostering a culture of quality management services for conditions such as pain, pneumonia, congestive heart failure (and others), assessing patients for ability to pay for and be compliant with their regimen (including suggestions for alternative therapy or enrollment in assistance programs), adverse drug event monitoring, investigational drug study participation, nutrition therapy, participation in patient care rounds as well as formulary management through Pharmacy and Therapeutics committees. Opportunity to be paid for these services will certainly encourage pharmacies to actively participate in MTMS without risking going under financially, especially as dispensing fees are becoming less and less. Pharmacists, both BS and Doctors of Pharmacy should be recognized as a mid-level practitioner, a view shared by our colleages at the nurses station such as Physicians and Nurse Practitioners. Allowing the

Submitter : Mr. Christopher Rogers **Date & Time:** 10/04/2004 06:10:52

Organization : UNC School of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed regulation to establish preferred and non-preferred pharmacies will significantly affect my ability to serve patients in the future. Plans will be able to drive beneficiaries to a certain pharmacy. Doing this will undermine the intent of Congress to allow patients to choose the pharmacist and pharmacy of their choice. Beneficiaries must not be persuaded to use a particular pharmacy. In addition, beneficiaries must be able to receive the same benefits at community pharmacies and through mail-order pharmacy. They must be able to receive extended supplies at each location without drug cost being the main deterrent. This type of coercing should not be allowed.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

As a future pharmacist, I want to be able to serve my patients as effectively as possible. In order to do this, my belief is that CMS should require plans to meet the TRICARE requirements on a local level. This is the only possible way that each beneficiary has convenient access to a local pharmacy. Requiring pharmacists to meet the total access standard "on average" across the plan's service area gives less incentive to offer pharmacies acceptable contracts to enroll them in the plan's pharmacy network. Congress made this promise and it should be honored by CMS.

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

I agree with CMS that pharmacists should be the primary providers of MTMS. With the education that we are currently receiving in pharmacy school, there is no health profession more qualified to provide these services. As a result, pharmacists should be properly compensated for providing this service. Each pharmacist should be subjected to receive the same fess whether preferred or non-preferred. The fees must also adequately represent the service provided by the pharmacist. In order to accurately serve the beneficiaries, face-to-face service should be provided when possible. Beneficiaries that qualify for MTMS should be those individuals on 2 or more drug therapy regimens and 2 or more disease states. There should be methods to identify those individuals that would benefit from MTM, and pharmacists should have an opportunity to identify those individuals as well. This will also allow us to provide services to those individuals who are designated as non-targeted beneficiaries. Those individuals should be allowed to be billed directly for the services offered.

CMS-4068-P-1043

Submitter : Dr. Dan McPherson **Date & Time:** 10/04/2004 06:10:43

Organization : Dr. Dan McPherson

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I appreciate that CMS recognizes that beneficiaries will require different MTM services such as health assessment, medications treatment plan, monitoring and evaluating response to therapy. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am quite concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

CMS-4068-P-1044

Submitter : Dr. Debra McPherson **Date & Time:** 10/04/2004 06:10:53

Organization : St. Alexius Medical Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

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:

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.

? Subpart C: Benefits & 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 plan?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 and that my patients will be able to continue to use my 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. 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 Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans

I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: blood pressure monitoring, diabetic education, insulin instruction, nutrition support, outpatient clinic management and anticoagulation monitoring. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to allow us to meet the access requirements on a local level to assure access to all beneficiaries, contract with all pharmacies again to assure access and to identify pharmacists as the primary provider with regard to medication management issues as they are the most qualified group of health care professional to provide this invaluable service.

Thank you for considering my view.

Sincerely,

Debra Johnson McPherson, Pharm.D., BCNSP
Clinical Pharmacist, Neonatology and Pediatrics

Board Certified in Nutrition Support Pharmacy
St. Alexius Medical Center
900 E Broadway, Box 5510
Bismarck, ND 58506-5510

CMS-4068-P-1045

Submitter : Ms. jill leslie drell **Date & Time:** 10/04/2004 07:10:32

Organization : Walgreen Co

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BACKGROUND

BENEFITS AND BENEFICIARY PROTECTIONS

423.120(a) Assuring Pharmacy Access

Beneficiaries of each PDP and MA-PDP are to have access to retail pharmacies based on the Department of Defense's TriCare standards. These standards were a reflection of congressional intent to ensure that a Medicare beneficiary has the opportunity to receive prescription services from a pharmacist face to face. The TriCare access standards reference availability of a pharmacy in urban, suburban and rural areas. The proposed regulations would appear to thwart the Act's intent to provide reasonable access by allowing a PDP or MA-PDP to average the access standards across the rural, urban and suburban regions. The proposed regulation's allowance of averaging would, in effect, render the TriCare coverage requirements meaningless. It is well documented that the access to correct medication and the management of medication, can be vital to reducing overall healthcare costs.

The proposed regulations allow a PDP to establish a 'minimal' network within a region. This small group of pharmacies can be identified as a 'preferred network' and might offer a more favorable cost sharing arrangements to beneficiaries. While some beneficiaries might benefit, greater numbers might be disadvantaged if burdened to travel great distances or pay more for the benefit. One effect may be the steerage of beneficiaries to a mail service pharmacy. In no case should the cost to the beneficiary using a non-preferred provider differ by more than the difference in reimbursement paid by a PDP to the preferred vs. non-preferred providers. The difference in reimbursement to the provider should also be used for determining any difference in costs to the beneficiary using a community pharmacy rather than mail order. The final regulations should require that the TriCare access standards be achieved based on the 'preferred' network alone and not the combination of 'preferred' and 'non-preferred' networks.

CMS has not as of yet defined the PDP regions so there are many unanswered questions concerning coverage, which will have to be determined once the regions are established. Regardless of the region definitions, beneficiaries are entitled to have access to community pharmacy providers as required and intended by Congress. The proposed regulation circumvents the intent of the TriCare coverage requirement and CMS should address this in the final regulations so that PDPs are required to have adequate access to retail pharmacies by beneficiaries for face-to-face delivery of services. The final regulations should specify that distances are to be measured based on established roads or driving distances and on a local or zip code level.

423.120(a)(4) Pharmacy Network Contracting Requirements

The final regulations should be clear about what can be required of pharmacies by PDPs and MA-PDPs in contracting for a network. The regulations should clearly state that program risks can not be contracted out to or forced upon pharmacies.
?423.120(b) Formulary Requirements

Pharmacy and Therapeutics Committees (P&T) that establish the clinical effectiveness of formulary drugs should be used to establish the 2006 benefit. P&T members should be making their decisions relying on evidence-based medicine and pharmacoeconomic data. Only when there are multiple products that are considered equally safe and effective, and produce similar outcomes, should a P&T committee consider economics. The financials that the P&T members consider should be based on prescription costs net of rebates. The impact on the overall cost to Medicare for the drug and medical care should be integral to the decisions of the P&T committees.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

423.464 Coordination with Plans and Programs that Provide Prescription Drug Coverage

It is critical to the health of the dual eligibles that CMS ensure an orderly transition from Medicaid to Medicare. In the absence of adequate coordination, there will be formulary differences between the plans resulting in possible disruptions in therapy and possible overlap in coverage.

423.452-464 Coordination with Plans and Programs that Provide Prescription Drug Coverage

In order to ensure the correct tracking of a beneficiary?s out-of-pocket expenditures, the final regulations should clearly establish what is to be included and who has the responsibility to ensure validity. NACDS has commented extensively on this topic and the importance of ensuring that there are on-line or real time exchanges between a PDP and pharmacies to track TrOOP, COB and other similar informational exchange requirements. We direct the reader to review this section and reinforce the comments that it is critical for CMS to move toward real time information sharing and to require the same for PDPs and MA-PDPs in their exchanges with pharmacies.

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

423.153(d) Medication Therapy Management Programs (MTM)

The proposed regulations state that Medication Therapy Management programs are to be offered by PDPs and MA-PDPs for those beneficiaries taking multiple medications or suffering from chronic medical conditions. However, no guidance or standards are offered by CMS regarding program elements or requirements. To ensure that a Medicare beneficiary is the recipient of a sound and effective program, CMS needs to define guidelines for MTM programs. The PDPs should be provided with minimal standards for programs to ensure the programs are designed to achieve positive clinical outcomes and at the same time realize effective overall healthcare expenditures by CMS. In addition, the final regulations need to define how beneficiaries are to be selected to participate in a MTM program. CMS should clarify in the regulations that PDPs include retail pharmacies and pharmacists in the delivery of the MTM programs.

The Medicare population confronts specific clinical issues which the MTM programs need to address, including
- polypharmacy conditions
- inappropriate medications for elderly
- sub-optimal therapy (patients not receiving medication indicated by national consensus guidelines and peer reviewed scientific literature; for example, a diabetic not on ACE inhibitors or statins, congestive heart failure patients not on ACE inhibitors or long-acting beta blockers)
- medication compliance
- injection site training
- brand dose preparation

Not only do the PDPs need to know what CMS expects; beneficiaries have a right to know what type of services a PDP should be expected to provide. Benefit description offered by PDPs should include descriptions of the programs so a beneficiary and family members, if applicable, can evaluate the programs.

Providers are to be reimbursed for providing the clinical services to beneficiaries separate from any dispensing fee. CMS needs to require the PDPs to pay providers a fee commensurate with the professional time required. The fair market value of a pharmacist!|s time needs to be included and an annual cost adjustment based off a designated index should be established by CMS through the regulatory process.

ELIGIBILITY, ELECTION, AND ENROLLMENT

423.30-423.50 Beneficiary Protection Eligibility and Enrollment
In addition to requiring approval by CMS of a PDP?s marketing and enrollment material, it is important that CMS establish a series of questions and answers for each PDP to include in marketing material. This will provide Medicare beneficiaries with an easy-to-read format so comparisons can be made between plans. Descriptions of benefits, cost sharing, drug coverage and provider networks, among other topics, should be stated in marketing material to ensure that Medicare beneficiaries have the opportunity to understand the offerings and the differences between PDPs. It was Walgreens Health Initiatives? experience from being a Discount Card Program Sponsor that segments of the Medicare population need very clear and unambiguous descriptions of program specifics.
Our retail pharmacists interact daily with the Medicare population and will be asked questions about the various PDP programs. It would be of assistance to beneficiaries if CMS were to issue materials that health care providers, such as pharmacists, can use to advise and answer beneficiary

questions on how to select a PDP.

GENERAL PROVISIONS

To CMS:

This Company is well aware of the challenges facing CMS in developing and delivering a quality prescription drug benefit to senior citizens and other Medicare qualified individuals. Our comments on the Part D prescription drug benefit program are intended to address areas that we believe are important in achieving your goal and at the same time carry out the intent of Congress in the Medicare prescription legislation.

We are supportive of the comments offered by the National Association of Chain Drug Stores and incorporate by reference issues raised by that organization. We also are in support of comments offered by American Pharmacists Association concerning the professionalism and capabilities of pharmacists and their importance in delivering pharmacy benefits to the Medicare population.

Rather than repeat the details raised by NACDS and others in their comprehensive comments, Walgreen Co will very briefly address selected topics with which we have experience from operating retail, mail order and specialty pharmacies. We also are offering comments on behalf of our subsidiary company, Walgreens Health Initiatives, which operates a pharmacy benefit management company and is a sponsor of a Medicare Discount Card.

CONCLUSION.

In a very short period of time, CMS has had to issue regulations in furtherance of the Medicare prescription drug program. It was a daunting task. Many complex issues had to be addressed. Possible problems had to be identified and solutions developed. Nonetheless, the prescription program shall be provided to Medicare beneficiaries in 2006. Our comments along with others in the healthcare industry are offered to ensure that the program can be structured and implemented fairly to all concerned, including beneficiaries, PDPs and providers.
We stand ready to help you in any way we can as you work toward accomplishing this incredibly complex and profoundly important objective. If you have any questions or wish to discuss any of the comments offered above, please contact me.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

423.120(a)(6) Level Playing Field between Mail Order and Retail Pharmacies

Medicare beneficiaries were intended to have the choice the pharmacy where their prescription benefit and MTM services would be delivered, either mail or retail. The coverage is supposed to be the same, including days supply, whether obtained by a beneficiary at a preferred or non- preferred pharmacy. The proposed regulations do not prohibit PDPs from creating different cost sharing requirements. The final regulations should clearly carry out the legislation to allow beneficiaries to receive face-to-face pharmacy services at a community pharmacy and not be unfairly steered to a preferred pharmacy or a mail pharmacy.

The 'charge' of obtaining a prescription from a retail or community pharmacy in lieu of a mail pharmacy, if any, can be assumed by the beneficiary; however, there is no specific definition in the proposed regulation of what constitutes this 'charge'. The proposed regulation, however, does provide for the 'net cost' to be the charge. The effect would be to allow plans to use rebates, including volume/dollars attributed to retail dispensing, obtained from manufacturers to subsidize the cost of mail order prescriptions. It was not the intent of the legislation for PDPs to offer inducements to beneficiaries beyond the actual costs incurred. This would affect the level playing field between mail and retail pharmacies and, in the long run, beneficiaries would pay the price if a real choice were not provided by a PDP. The final regulations should state that only the differences in reimbursement paid to a pharmacy can be the ?charge? passed on to the beneficiary. Further, this is the same logic that should be applied if a beneficiary chooses to go to a non-preferred vs. preferred provider.

Issues 11-20

FALLBACK PLANS

The final regulation should be revised to clearly set forth the criteria of what is considered acting as a subcontractor or an 'integral part' of a PDP's activities. We believe CMS is trying to encourage groups to become PDPs and, therefore, limiting opportunities of Fallback Entities to provide

services to PDPs would be counterproductive. Clarification should be provided so a prospective PDP who requires administrative services can obtain contractors and the contractors are not precluded from acting as a Fallback Entity in other PDP regions. In commercial plans under certain circumstances, when services are needed contractors are obtained. A service provider who desires to become a Fallback Entity should not have to decline opportunities to help a PDP because there is confusion as to what constitutes being an 'integral part'. 'Integral part' should be defined in the final regulation as bearing risk for program costs to avoid the unintended effect of decreasing the numbers of PDPs.

CMS-4068-P-1045-Attach-1.doc

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CMS-4068-P-1045-Attach-1.doc

October 4, 2004

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

RE: CMS 4068-P, RIN 0938-AN08

To CMS:

This Company is well aware of the challenges facing CMS in developing and delivering a quality prescription drug benefit to senior citizens and other Medicare qualified individuals. Our comments on the Part D prescription drug benefit program are intended to address areas that we believe are important in achieving your goal and at the same time carry out the intent of Congress in the Medicare prescription legislation.

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<u>§423.30-423.50 Beneficiary Protection Eligibility and Enrollment</u>

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Our retail pharmacists interact daily with the Medicare population and will be asked questions about the various PDP programs. It would be of assistance to beneficiaries if CMS were to issue materials that health care providers, such as pharmacists, can use to advise and answer beneficiary questions on how to select a PDP.

§423.120(a) Assuring Pharmacy Access

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The proposed regulations allow a PDP to establish a "minimal" network within a region. This small group of pharmacies can be identified as a "preferred network" and might offer a more favorable cost sharing arrangements to beneficiaries. While some beneficiaries might benefit, greater numbers might be disadvantaged if burdened to travel great distances or pay more for the benefit. One effect may be the steerage of beneficiaries to a mail service pharmacy. In no case should the cost to the beneficiary using a non-preferred provider differ by more than the difference in reimbursement paid by a PDP to the preferred vs. non-preferred providers. The difference in reimbursement to the provider should also be used for determining any difference in costs to the beneficiary using a community pharmacy rather than mail order. The final regulations should require that the TriCare access standards be achieved based on the "preferred" network alone and not the combination of "preferred" and "non-preferred" networks.

CMS has not as of yet defined the PDP regions so there are many unanswered questions concerning coverage, which will have to be determined once the regions are established. Regardless of the region definitions, beneficiaries are entitled to have access to community pharmacy providers as required and intended by Congress. The proposed regulation circumvents the intent of the TriCare coverage requirement and CMS should address this in the final regulations so that PDPs are required to have adequate access to retail pharmacies by beneficiaries for face-to-face delivery of services. The final regulations should specify that distances are to be measured based on established roads or driving distances and on a local or zip code level.

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The "charge" of obtaining a prescription from a retail or community pharmacy in lieu of a mail pharmacy, if any, can be assumed by the beneficiary; however, there is no specific definition in the proposed regulation of what constitutes this "charge". The proposed regulation, however, does provide for the "net cost" to be the charge. The effect would be to allow plans to use rebates, including volume/dollars attributed to retail dispensing, obtained from manufacturers to subsidize the cost of mail order prescriptions. It was not the intent of the legislation for PDPs to offer inducements to beneficiaries beyond the actual costs incurred. This would affect the level playing field between mail and retail pharmacies and, in the long run, beneficiaries would pay the price if a real choice were not provided by a PDP. The final regulations should state that only the differences in reimbursement paid to a pharmacy can be the "charge" passed on to the beneficiary. Further, this is the same logic that should be applied if a beneficiary chooses to go to a non-preferred vs. preferred provider.

§423.153(d) Medication Therapy Management Programs (MTM)

The proposed regulations state that Medication Therapy Management programs are to be offered by PDPs and MA-PDPs for those beneficiaries taking multiple medications or suffering from chronic medical conditions. However, no guidance or standards are offered by CMS regarding program elements or requirements. To ensure that a Medicare beneficiary is the recipient of a sound and effective program, CMS needs to define guidelines for MTM programs. The PDPs should be provided with minimal standards for programs to ensure the programs are designed to achieve positive clinical outcomes and at the same time realize effective overall healthcare expenditures by CMS. In addition, the final regulations need to define how beneficiaries are to be selected to participate in a MTM program. CMS should clarify in the regulations that PDPs include retail pharmacies and pharmacists in the delivery of the MTM programs.

The Medicare population confronts specific clinical issues which the MTM programs need to address, including

- polypharmacy conditions
- inappropriate medications for elderly
- sub-optimal therapy (patients not receiving medication indicated by national consensus guidelines and peer reviewed scientific literature; for example, a diabetic not on ACE inhibitors or statins, congestive heart failure patients not on ACE inhibitors or long-acting beta blockers)
- medication compliance
- injection site training
- brand dose preparation

Not only do the PDPs need to know what CMS expects; beneficiaries have a right to know what type of services a PDP should be expected to provide. Benefit description offered by PDPs should include descriptions of the programs so a beneficiary and family members, if applicable, can evaluate the programs.

Providers are to be reimbursed for providing the clinical services to beneficiaries separate from any dispensing fee. CMS needs to require the PDPs to pay providers a fee commensurate with the professional time required. The fair market value of a pharmacist's time needs to be included and an annual cost adjustment based off a designated index should be established by CMS through the regulatory process.

§423.120(a)(4) Pharmacy Network Contracting Requirements

The final regulations should be clear about what can be required of pharmacies by PDPs and MA-PDPs in contracting for a network. The regulations should clearly state that program risks can not be contracted out to or forced upon pharmacies.

§423.464 Coordination with Plans and Programs that Provide Prescription Drug Coverage

It is critical to the health of the dual eligibles that CMS ensure an orderly transition from Medicaid to Medicare. In the absence of adequate coordination, there will be formulary differences between the plans resulting in possible disruptions in therapy and possible overlap in coverage.

§423.452-464 Coordination with Plans and Programs that Provide Prescription Drug Coverage

In order to ensure the correct tracking of a beneficiary's out-of-pocket expenditures, the final regulations should clearly establish what is to be included and who has the responsibility to ensure validity. NACDS has commented extensively on this topic and the importance of ensuring that there are on-line or real time exchanges between a PDP and pharmacies to track TrOOP, COB and other similar informational exchange requirements. We direct the reader to

review this section and reinforce the comments that it is critical for CMS to move toward real time information sharing and to require the same for PDPs and MA-PDPs in their exchanges with pharmacies.

§423.120(b) Formulary Requirements

Pharmacy and Therapeutics Committees (P&T) that establish the clinical effectiveness of formulary drugs should be used to establish the 2006 benefit. P&T members should be making their decisions relying on evidence-based medicine and pharmacoeconomic data. Only when there are multiple products that are considered equally safe and effective, and produce similar outcomes, should a P&T committee consider economics. The financials that the P&T members consider should be based on prescription costs net of rebates. The impact on the overall cost to Medicare for the drug and medical care should be integral to the decisions of the P&T committees.

§423.851-423.875 Fallback Plans

The final regulation should be revised to clearly set forth the criteria of what is considered acting as a subcontractor or an "integral part" of a PDP's activities. We believe CMS is trying to encourage groups to become PDPs and, therefore, limiting opportunities of Fallback Entities to provide services to PDPs would be counterproductive. Clarification should be provided so a prospective PDP who requires administrative services can obtain contractors and the contractors are not precluded from acting as a Fallback Entity in other PDP regions. In commercial plans under certain circumstances, when services are needed contractors are obtained. A service provider who desires to become a Fallback Entity should not have to decline opportunities to help a PDP because there is confusion as to what constitutes being an "integral part". "Integral part" should be defined in the final regulation as bearing risk for program costs to avoid the unintended effect of decreasing the numbers of PDPs.

Conclusion

In a very short period of time, CMS has had to issue regulations in furtherance of the Medicare prescription drug program. It was a daunting task. Many complex issues had to be addressed. Possible problems had to be identified and solutions developed. Nonetheless, the prescription program shall be provided to Medicare beneficiaries in 2006. Our comments along with others in the healthcare industry are offered to ensure that the program can be structured and implemented fairly to all concerned, including beneficiaries, PDPs and providers. We stand ready to help you in any way we can as you work toward accomplishing this incredibly complex and profoundly important objective. If you have any questions or wish to discuss any of the comments offered above, please contact me.

Very Truly Yours,

Jill Leslie Drell
Director of Governmental Affairs
Walgreens Health Services

Submitter : Mr. Leo R. Blais **Date & Time:** 10/04/2004 06:10:00

Organization : PV Prescription and SurgicaL Ctr.,Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4068-P-1046-Attach-1.doc

Pawtuxet Valley Prescription and Surgical Ctr., 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.

We are a privately held; family owned and operated pharmaceutical care company located in Coventry, RI. We employ approximately 70 people and service 150 to 175 patients per month. Medicare Choice programs provided by Blue Cross-Blue Shield of RI and United Healthcare currently cover some of these patients.

Pawtuxet Valley Prescription and Surgical Ctr., 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, 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 .

- 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,

Leo R. Blais, R.Ph.
President
Pawtuxet Valley Preswcription and Surgical Ctr., Inc.

CMS-4068-P-1047

Submitter : Helen Spencer **Date & Time:** 10/04/2004 06:10:06

Organization : Helen Spencer

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1047-Attach-1.doc

M. HELEN SPENCER
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mhspencer@earthlink.net

October 4, 2004

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

RE: Comments on Proposed Rule -- Medicare Part D Prescription Drug Benefit
Adverse Impact on American Indians/ Alaska Natives and Indian Health Programs
Notice of August 3, 2004, 69 Federal Register 46632
File Code CMS-4068-P

Dear Administrator:

I have represented elderly and disabled American Indians, Canadian Indians and Alaska Natives for more than 24 years, and have been involved in various legislative and administrative rule-making efforts to expand health care to Native populations. The Medicare Modernization Act (MMA) significantly threatens health care systems that have been systematically developed over the years to address the unique status and health care needs of Indian health program users and to balance their right to Indian health coverage with their right to Medicaid and Medicare benefits.

I strongly oppose your decision to include Indian health programs in your prescription drug benefit program without regard to the Federal Trust Responsibility, the promise of health care in Indian Treaties, the Indian Health Care Improvement Act, and principles of Tribal-Self Determination. The proposed regulations will cause a great loss of Medicaid revenue for Indian health programs, which will not be adequately replaced by the Medicare drug program, and require many elderly and disabled tribal members to pay significant amounts toward prescription drugs which are now available without charge through Indian health programs. This is unprecedented and unworkable.

Elderly and disabled American Indians and Alaska Natives should be exempted from the provisions of the Medicare Modernization Act and the proposed regulations that eliminate their Medicaid coverage effective January 1, 2006. The Medicaid system has the flexibility to address uniqueness status of Tribes and Indian health programs through state policy and Medicaid waivers. The Medicare Act could remove the ability of states

and Indian organizations to negotiate in behalf of Indian health programs and their program users in regard to prescription drugs, unless those concerns are adequately address in final regulations.

Should the Indian health programs and their elderly and disabled patients not be entirely exempted from the Voluntary Medicare Prescription Drug Benefit program, the final regulations must provide for:

1. Exemption for elderly and disabled Indian health program users from prescription drug deductibles, premiums, copayments, coinsurance and coverage gap.

2. Mandatory agreements between prescription drug plans and Indian health pharmacy programs with terms that are responsive to the unique status of each Indian program.

3. 100% reimbursement to Indian health programs for prescription drugs provided to elderly and disabled program users who are enrolled, or who are eligible for enrollment, in private prescription drug plans; Medicare reimbursements under the Medicare prescription drug benefit should not be less than current Medicaid reimbursements.

4. Default enrollment of Medicaid and Medicare "dual eligible" American Indians and Alaska Natives in Indian health pharmacy programs, not in private prescription drug plans.

5. Elimination of "coverage gap": The coverage gap is particularly inappropriate for the elderly and disabled users of Indian health pharmacy programs. Without specific authority or mention in the enabling legislation, it is improper to include Indian programs in the ambiguous phrase "or otherwise," to preclude Indian health programs from being reimbursed for significant, catastrophic drug expenditures. The recent history of Indian health programs is that Congress and DHHS support and encourage reimbursement from Medicaid and Medicare for Indian programs. This is evident from the MMA itself which will expand Medicare Part B reimbursements. Preventing reimbursement for drug expenditures during the program user's coverage gap is inconsistent with Congress' development of modern Indian health programs, with the Federal Trust Responsibility that applies to all federal agencies (including CMS), and with MMA itself, which intends to expand and not diminish drug coverage. It is also *not* true that the Indian programs are now *not* reimbursed for catastrophic drug costs, as Medicaid's Medically Needy program often provides catastrophic drug coverage for Indian health program users, which then affords savings or reimbursements to the Indian programs.

6. Countable "income" and "resources:" The National Indian Health Board comments which include by reference the Medicaid Manual are correct, but may not include the following clarifications based on decisions, opinions, and regulations of the Bureau of Indian Affairs, the Supplemental Security Income program, administrative law judges and Courts:

a) The proceeds from the sale of timber, gravel and sand are resources in the month received (and thus do not count against benefits) and are only countable if they are retained in the following month in excess of the SSI or related program's allowable resources limit. So the MMA subsidy programs will need to allow retained resources up to the limits permitted for the various subsidies. At least one Administrative Law Judge has stated that all the proceeds from the sale of trust land should be exempt for SSI purposes.

b) Current information on the treatment of income held in Department of Interior individual Indian money (IIM) accounts: Under 2001 regulations contained in the revision of 25 CFR Part 115, funds held in a "restricted" IIM account pursuant to a hold by the tribal credit program or because of supervision of the account by BIA or tribal social services are not countable, although released funds may be counted under SSI or SSI-related income guidelines.

I incorporate by reference into my comments all of the remaining comments on Part D prepared by the National Indian Health Board and separately forwarded to CMS as part of the comments of many Tribes and Indian Health Boards.

I urge you to carefully consider the comments of all who are protesting the financial losses that Indian health programs will suffer if the final regulations do not adequately protect funding for Indian health programs. Plans to impose cost sharing on elderly and disabled American Indians and Alaska Natives, whose right to health care has a very unique and different basis from other Americans', can only cause confusion and decrease access to services; cost sharing for American Indians and Alaska Natives must be avoided in final regulations.

Sincerely,

M. Helen Spencer

CMS-4068-P-1048

Submitter : Kim Musheno **Date & Time:** 10/04/2004 06:10:23

Organization : Association of University Centers on Disabilities

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BACKGROUND

Thank you for the opportunity to provide comments regarding the implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Association of University Centers on Disabilities (AUCD) is the national organization that promotes and supports the national network of interdisciplinary centers advancing policy and practices through research, education and services for and with individuals with developmental and other disabilities, their families, and communities. Sixty-one Centers, at least one in every state and territory, are located in university settings.

AUCD is very concerned that these proposed rules do not to provide adequate safeguards to ensure that beneficiaries with disabilities have access to the medications they need. The lack of needed protections under the rules will fall heavily on people with dual-eligibility for Medicare and Medicaid, because their drug coverage will shift from Medicaid to Medicare in 2006 under the new Medicare drug-benefit law. We offer the following recommendations:

BENEFITS AND BENEFICIARY PROTECTIONS

AUCD is concerned that 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. Also, the timeframes for plan decisions are unreasonably long. AUCD urges CMS to 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.

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; 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.

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.

AUCD is concerned about provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (? 423.44). These provisions create enormous opportunities for discrimination against individuals with developmental disabilities, mental illnesses, and other cognitive conditions. The preexisting Medicare Plus Choice (M+C) regulation allowing for disenrollment for disruptive behavior states that M+C plans may not disenroll an individual if the behavior at issue is "related to the use of medical services or diminished mental capacity." The NPRM for Part D plans would lessen the degree of protection for beneficiaries against involuntary disenrollment for disruptive behavior. The proposed regulations state that "disruptive behavior may not be based on noncompliance with medical advice." This standard would unfairly deny protection for beneficiaries who complied with medical advice, for example, by trying an on-formulary drug instead of the drug needed, and as a result experienced a bad reaction causing their disruptive behavior. We strongly urge that CMS not include in the final regulation this lower standard for involuntary disenrollment for disruptive behavior that it has proposed in the NPRM. 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.

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

It is extremely important that individuals with disabilities receive access to the medication that they require. AUCD urges 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.

ELIGIBILITY, ELECTION, AND ENROLLMENT

AUCD recommends delaying transfer of drug coverage from Medicaid to Medicare for dual eligibles by at least six months. It will be an extremely difficult task for CMS to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (November 15th - January 1, 2006). 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. This does not take into consideration the unique and complex set of issues raised by the dual eligible population.

Targeted and hands-on outreach to Medicare beneficiaries with disabilities will be extremely important in the enrollment process. AUCD urges CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations. For example, AUCD?s network of university-based training programs (e.g., University Centers for Excellence in Developmental Disabilities Education, Research, and Service; P.L. 106-402, Subtitle D), is in a unique position to help assist CMS effectively address issues of importance to people with disabilities. Our Centers work with people with disabilities, members of their families, state and local government agencies, and community providers in projects that provide training, technical assistance, service, research, and information sharing, with a focus on building the capacity of communities to sustain all their citizens. These Centers, along with other disability organizations, could help CMS in its efforts to provide technical assistance, develop materials 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.

AUCD strongly supports the suggestion in the proposed rule to provide special treatment to special populations due to their unique medical needs, and the enormous potential for serious harm if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. These special populations should 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 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; people who have pharmacologically complex condition such as epilepsy, Alzheimer?s disease, multiple sclerosis, mental illness, HIV/AIDS.

GENERAL PROVISIONS

CMS-4068-P-1048-Attach-1.doc

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CMS-4068-P-1048-Attach-1.doc

AUCD
ASSOCIATION OF UNIVERSITY CENTERS ON DISABILITIES
RESEARCH, EDUCATION, SERVICE

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October 1, 2004

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

Docket: CMS-4068-P - Medicare Program; Medicare Prescription Drug Benefit

Dear Mr. McClellan:

Thank you for the opportunity to provide comments regarding the implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Association of University Centers on Disabilities (AUCD) is the national organization that promotes and supports the national network of interdisciplinary centers advancing policy and practices through research, education and services for and with individuals with developmental and other disabilities, their families, and communities. Sixty-one Centers, at least one in every state and territory, are located in university settings.

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treatment apply to the following 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; people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

It is extremely important that individuals with disabilities receive access to the medication that they require. AUCD urges 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.

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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; 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.

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.

AUCD is concerned about provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44). These provisions create enormous opportunities for discrimination against individuals with developmental disabilities, mental illnesses, and other cognitive conditions. The preexisting Medicare Plus Choice (M+C) regulation allowing for disenrollment for disruptive behavior states that M+C plans may not disenroll an individual if the behavior at issue is "related to the use of medical services or diminished mental capacity." The NPRM for Part D plans would lessen the degree of protection for beneficiaries against involuntary disenrollment for disruptive behavior. The proposed regulations state that "disruptive behavior may not be based on noncompliance with medical advice." This standard would unfairly deny protection for beneficiaries who complied with medical advice, for example, by trying an on-formulary drug instead of the drug needed, and as a result experienced a bad reaction causing their disruptive behavior. We strongly urge that CMS not include in the final regulation this lower standard for involuntary disenrollment for disruptive behavior that it has proposed in the NPRM. 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.

Thank you for taking our comments into consideration as you prepare the final regulations governing this important law. In addition to these brief comments, we have signed on to comments prepared by the Consortium for Citizens with Disabilities and the Medicare Consumers Working Group. If you have any questions about these comments, please contact Kim Musheno in our national office at 301-588-8252.

Sincerely,

/s/ David Johnson
President

Submitter : Mr. Edward Cotter **Date & Time:** 10/04/2004 06:10:39

Organization : Health Net Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Health Net, Inc. provides these comments to CMS to ensure the success of the Medicare Modernization Act Part D Drug Benefit. We recommend continuing dialog with all stakeholders and especially with the healthcare industry so that the regulatory decisions can be implemented effectively in the marketplace.

CMS-4068-P-1049-Attach-1.doc

Issue #	File Code CMS - 4068-P Federal Register Proposed Rules Subparts	Comments to CMS
	Subpart B: Eligibility, Election and Enrollment	
B1	Price comparison information (Preamble p. 46643). CMS explains that it is proposing to extend "the price comparison requirements to PDP sponsors and MA organizations… making comparative information about Part D plans' negotiated prices available to beneficiaries through www.medicare.gov." In contrast, MA organizations offering exclusive Medicare-approved prescription drug discount cards were not obligated to post price comparison information. CMS is also asking for comments regarding how it can improve its website and the information that it provides to enrollees.	**Part D Information That CMS Provides to Beneficiaries Section 1860D-1(c)(1)** This requirement would require differentiation between regions for price variation (that goes beyond the nationally contracted cost). MA-PD's will have an exclusive arrangement with their enrolled members so posting prices for these plans may lead to confusion for other eligible beneficiaries. Also, variations in cost to members may exist depending on the point in time, in relation to the benefit, the medication is accessed (i.e. deductible, catastrophic level, employer group coverage). We recommend that CMS allow MA-PD plans to post pricing on their proprietary MA sponsor site rather than on a CMS price comparison website.
B2	Approval of marketing materials and enrollment forms (§423.50, p. 46643-4). Acceptance of enrollment forms in pharmacies. The preamble notes CMS' existing policy that MA enrollment forms may not be completed and accepted in provider offices. CMS asks whether it is appropriate to continue this policy. CMS' point is that the relationship between PDP sponsors and pharmacies may be different than between MA plans and providers.	**Approval of Marketing Materials and Enrollment Forms (423.50) Section 1860D-1(b)(1)(B)(vi)** We recommend that the enrollment forms be submitted to the MA-PD plans as opposed to the pharmacy. Certain pharmacies have incentives to promote competing programs, therefore creating a conflict of interest. Pharmacies are not a place for this type of administrative function; there are more important functions, like filling prescriptions correctly, monitoring drug therapy, performing acceptable counseling, etc. Members should be directed to Medicare regarding information on Part D plans as opposed to retail pharmacies.
B3	Selling additional products to PDP enrollees (p. 46644). CMS is inviting comment on the advisability of allowing PDPs to market additional products, such as, financial services, in conjunction with PDP services and the appropriate limitations on such activities. The preamble states that PDPs could provide additional tools to help beneficiaries manage their expenses and financial security, and the ability to do so could be a strong incentive for potential PDP sponsors to participate in Part D. The preamble also notes that such marketing would need to be in compliance with the HIPAA privacy rules.	**Approval of Marketing Materials and Enrollment Forms (423.50)(a)(3) Section 1860D-1(b)(1)(B)(vi)** We would pose the question of whether this excludes MA-PD's from participating in these activities. Requesting clarification of whether such cross-marketing is consistent with HIPAA.
B4	Sharing Personal Information with MA-PD and PDPs (Preamble p. 46644). The preamble states that the statute gives CMS the authority to provide PDP sponsors and MA organizations with information about Part D eligible individuals so that these organizations may facilitate the marketing and enrollment of beneficiaries in their PDP and MA-PD plans. CMS is asking how it should operationalize this requirement in a manner that does not have an adverse effect on Medicare beneficiaries. The following are some specific issues raised by CMS: To the extent CMS shares such information with PDP sponsors and MA organizations, should beneficiaries be given the ability to choose not to have their information shared with these entities?	**Information Provided to PDP Sponsors and MA Organizations (423.50)(a)(3) Section 1860D-1(b)(4)(A)** Beneficiaries should be given the option of not having their information shared with PDP or MA-PD plans. We recommend that information shared for marketing purposes to PDPs and MA-PDs include only traditional FFS Medicare beneficiaries. This would prevent information for beneficiaries enrolled in a Medicare Advantage plan from being provided to PDP and other MA-PD plans due to the exclusive nature of the MA plan.

B5	To the extent that such information is shared for purposes of marketing, should PDP sponsors and MA organizations be able to use this information to contact beneficiaries only through written communications, or should telephone contacts be permitted, and, if so, under what circumstances?	**Information Provided to PDP Sponsors and MA Organizations (423.50)(a)(3) Section 1860D-1(b)(4)(A)** We recommend that information shared for marketing purposes be permitted by written communications as well as through telephonic methods.
B6	CMS also asks whether such information should be provided by CMS upon request, or only at specific, scheduled times during the year (for example, just prior to the Annual Coordinated Election Period).	**Information Provided to PDP Sponsors and MA Organizations (423.50)(a)(3) Section 1860D-1(b)(4)(A)** We recommend that information provided by CMS be only at specific periods, not on request.
B7	Further, CMS would like to know what specific information it could provide to PDP or MA organizations that would facilitate their marketing and enrollment activities. At the extreme, plans would be permitted to market directly to Medicare beneficiaries, based on contact information CMS provides, using approved materials, but otherwise bypassing CMS. At the other extreme, current rules regarding the marketing activities of MA plans would remain unchanged.	**Information Provided to PDP Sponsors and MA Organizations (423.50)(a)(3) Section 1860D-1(b)(4)(A)** We recommend that specific information regarding "the available plans in a member's area" be provided to facilitate marketing and enrollment activities. We also request information on which potential members have Part A & Part B.
	Subpart C: Benefits and Beneficiary Protections	
C1	Covered Part D Drug (§ 423.120) (p. 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.	**Voluntary Prescription Drug Benefit and Beneficiary Protections a. Covered Part D drug (423.100) Section 1860D-2** We recommend that the associated tests or monitoring services should also not be exclusively provided by a single entity which has contracted with the manufacturer. Exclusive contracts should not be provided with laboratories as well (ex. requirements associated with the dispensing of Clozaril).
C2	Covered Part D Drug (§ 423.100) (p. 46647): 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.	**Voluntary Prescription Drug Benefit and Beneficiary Protections a. Covered Part D drug (423.100) Section 1860D-2** The current legislation may often allow covered Part B self-injectables to be covered as Part D self-injectables. It would be difficult to determine at the point of sale through retail pharmacies, which Medicare benefit the medication will fall under (ex. Epogen and immunosuppressants). There is potential for overlapping when combining Part B & Part D. A national list for Parts A & B is needed.

C3	Dispensing Fees (§ 423.100) (p. 46647-48): 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. · 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. · 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.	**Voluntary Prescription Drug Benefit and Beneficiary Protections b. Dispensing Fees (423.100) Section 1860D-2(d)(1)(B)** Our recommendation regarding dispensing fees is: Option 1 which would include only those activities directly related with the mixing, delivery and overhead pertaining to the dispensing of a medication reads as status quo. We do not recommend either option 2 or 3 below. Option 2 – reimbursement for supplies and equipment necessary "for the drugs to be provided in a state in which they can be effectively administered". This requirement is confusing since many commercially available pharmaceuticals are packaged in a manner which cannot be effectively administered without pharmaceutical preparation, such as the reconstitution of solutions and suspensions, the measurement of doses from multi-dose packages (oral and injectable products such as vaccines), admixture of injectable and ophthalmic products in a sterile environment – involving an IV admixing hood, diluents, syringes, needles, and other ancillary supplies. Without a clear definition, there exists a potential for introducing high costs. Option 3 – as above, but activities associated with "ensuring proper ongoing administration of the drugs", without clear definition, can lead to higher costs since this was has not been a reimbursable service.
C4	Dispensing Fees (§ 423.100) (p. 46648): There may be related issues with respect to the administration of other drugs (for example, vaccines and injectable long-acting antipsychotic drugs), and we solicit comments regarding any implications for our proposed options for defining dispensing fees.	**Voluntary Prescription Drug Benefit and Beneficiary Protections b. Dispensing Fees (423.100) Section 1860D-2(d)(1)(B)** For the administration of other drugs such as vaccines and long-acting antipsychotic medications, we recommend the same option 1 as above in issue C3.
C5	Long-Term Care Facility (§ 423.100) (p. 46648-46649): 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.	**Voluntary Prescription Drug Benefit and Beneficiary Protections c. Long-Term Care Facility (423.100) Section 1819(a), 1919(a)** We are requesting clarification on whether custodial care facilities and hospice services under the definition of Long Term Care would be excluded under Medicare's special coverage definition.

C6	Standard Prescription Drug Coverage – 340B Drug Pricing Program (§ 423.100) (p.46651): We welcome comments on how to maximize the savings for people in need of HIV/AIDS medications under the 340B program. In particular, is it feasible for ADAP programs to participate with prescription drug plans so that the drugs offered to individuals with HIV/AIDS can be offered at 340B prices? In addition, because it is of critical importance for Medicare beneficiaries with HIV/AIDS to comply with their drug regimens, we are soliciting comments regarding the coordination of ADAP and Medicare Part D benefits.	**Requirements Related to Qualified Prescription Drug Coverage (423.104) a. Standard Prescription Drug Coverage Section 1860D-2** We foresee operational and systems COB issues with ADAP programs if: · ADAP pays for premiums · Subsidies for deductibles or cost-sharing · If such subsidies do not count as incurred costs then it would be less likely that the beneficiary would incur costs greater than the annual OOP threshold and thus impact the beneficiary to qualify for the catastrophic cost-sharing · Difficulty in coordinating and assuring 340B drug pricing
C7	Standard Prescription Drug Coverage – Multiple Source Drug (§ 423.104) (p.46649): A multiple source drug is defined under section 1927(k)(7)(A)(i) of the Act as a drug for which there are two or more drug products that are (1) rated as therapeutically equivalent by the Food and Drug Administration (FDA), (2) are pharmaceutically equivalent and bioequivalent, as defined in section 1927(k)(7)(C) of the Act, and as determined by the FDA, and (3) are sold or marketed in a State during the relevant time period.	**Requirements Related to Qualified Prescription Drug Coverage (423.104) a. Standard Prescription Drug Coverage Section 1860D-2** The definition provided of a multiple source drug needs to be defined further to isolate the generic multi-source drug from the originator product multi-source drug.
C8	Standard Prescription Drug Coverage – Generic Drug (§ 423.104) (p.46649): Section 423.4 of our proposed rule defines a generic drug as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved. To clarify, generic drugs are both bioequivalent and therapeutically equivalent to an innovator drug.	**Requirements Related to Qualified Prescription Drug Coverage (423.104) a. Standard Prescription Drug Coverage Section 1860D-2** We recommend that CMS allow Part D sponsors to use national drug data warehouses in determining the definition of a generic drug.
C9	Standard Prescription Drug Coverage – Data Sources (§ 423.104) (p.46651): We request comments regarding possible alternative data sources we could use to determine the annual percentage increase in the first several years of the Part D program.	**Requirements Related to Qualified Prescription Drug Coverage (423.104) a. Standard Prescription Drug Coverage Section 1860D-2** Prominent sources for data used by most PBMs is First Databank and Medispan. We recommend using one or both as alternative data sources.
C10	Basic Alternative Coverage (§ 423.104(f)) (p.46653): Although basic alternative prescription drug coverage within the parameters described above is allowed, it is unclear because of utilization effects whether PDP sponsors and MA organizations could, in fact, offer coverage that meets the statutory requirements other than by modifying cost-sharing as already allowed under actuarially equivalent standard coverage. We invite comments on whether there are basic alternative benefit designs that go beyond actuarially equivalent standard coverage.	**Requirements Related to Qualified Prescription Drug Coverage (423.104) i. Basic Alternative Coverage Section 1860-D2(c), (a)(1).** Other basic design elements can include richer formularies, non-mandatory generic requirements, and reduction or elimination of prior authorization and step therapy requirements.
C11	Enhanced Alternative Coverage (§ 423.104(g)) (p.46653): Enhanced alternative coverage would include . . . supplemental benefits. These supplemental benefits would supplement basis prescription drug coverage, providing for a package of benefits that exceeds the actuarial value of defined standard coverage. We propose interpreting “value” to mean the total value as described in section 1860D-2(c)(1)(A) of the Act. We request comments on this interpretation.	**Requirements Related to Qualified Prescription Drug Coverage (423.104) ii. Enhanced Alternative Coverage Section 1860D-2(c)(1)(A)** Clarification is needed on whether a MA-PD does not file for supplemental benefits if they can be added on and charged to employer groups under the group waiver policy.

C12	Pharmacy Access Standards (§ 423.120) (p.46656): 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. . . 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.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(C)** We recommend that CMS extend the option for MA-PD's to be exempt from the TRICARE access standards consistent with the implementation of the Medicare Drug Discount Card.
C13	Pharmacy Access Standards (§ 423.120) (p.46656): We are considering allowing prescription drug plans and MA-PD plans to count I/T/U pharmacies toward their network access requirements. . . 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.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(C)** The I/T/U pharmacy must be able to transmit claims on-line to the contracted PBM.
C14	Pharmacy Access Standards (§ 423.120) (p.46657): 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.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(C)** We recommend plan sponsors only provide a retail/mail network, and only be "strongly encouraged" to contract with long-term care facilities. This would provide an incentive for long term facilities to contract for appropriate/fair rates.
C15	Pharmacy Access Standards (§ 423.120) (p.46657): [W]e 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 . . .We encourage comments regarding these two approaches, their advantages and disadvantages, and their ramifications for AI/AN enrollees who are eligible to enroll in Part D.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(C)** We recommend that retail pharmacies must be able to transmit claims on-line to the contracted PBM. I/T/U facilities have limited medications on hand and will not necessarily stock all Part D drugs.
C16	Pharmacy Access Standards (§ 423.120) (p.46658): We solicit comments on permissible ways for us to assure Part D enrollees' access to FQHC and rural pharmacies, among others.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(C)** We recommend that FQHC and rural pharmacies must agree to the MA-PD's contracted rates and provisions.
C17	Pharmacy Access Standards (§ 423.120) (p.46658): We are considering using the authority in section 1860D-4(b)(1)(C) of the Act to require that both MA-PD plans and prescription drug plans contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees . . . We seek public comment regarding the advantages and disadvantages of such an approach, how such a requirement could be structured, and any other issues we should consider.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(C)** We are requesting a definition of a "sufficient number" of home infusion pharmacies. A large number reduces opportunities for competitive contracts and would raise costs.

C18	Pharmacy Access Standards (§ 423.120) (p.46658): We seek comment on whether, in order to guarantee that any pharmacy willing to meet a PDP sponsor's or MA organization's contracting terms and conditions could participate in a plan's pharmacy network, we should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-** Offering contracts to any willing pharmacy to contract would impact our ability to negotiate rates in specific service areas. Specific States have Any Willing Provider language mandated by the State and contracts are offered to any pharmacy willing to contract. State laws should be expressly preempted.
C19	Pharmacy Access Standards (§ 423.120) (p.46659): 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. Since any such differential costs would be associated with benefits covered under a Part D plan, we seek comments on our proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold consistent with the definition of "incurred cost" in § 423.100.	**Access to Covered Part D Drugs (423.120) a. Pharmacy Access Standards Section 1860D-4(b)(1)(D**) Such action may require the indirect disclosure of contracted rates with the MA-PD mail order vendor to the retail network pharmacy when they adjudicate such claims. This proposal will reduce the volume of 30+day prescriptions actually filled at the mail order pharmacy. As many mail order reimbursement rates are based on volume, this benefit may actually result in the cost of a mail order scripts (and therefore the equivalent script filled at retail) to increase. In order to minimize overall costs, we suggest that this benefit be only available through the mail order channel. To encourage members to work within the design of the benefit, we recommend that CMS consider not counting the differential as an incurred cost toward the out-of-pocket threshold.
C20	Formulary Requirements (§ 423.120) (p.46659): 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.	**Access to Covered Part D Drugs (423.120) b. Formulary Requirements Section 1860D-4(b)(3)(A)** We recommend that CMS not explicitly interpret the specified formulary requirements in the final regulations. Plans should be encouraged to consult with an independent accreditation firm, (for ex. National Committee for Quality Assurance (NCQA)) for formulary design and maintenance. P&T committee decisions should not be binding but will be an important factor in formulary design.
C21	Formulary Requirements (§ 423.120) (p.46659): In addition, we solicit public comment with respect to the appropriateness of strengthening the statutory requirement in section 1860D-4(b)(3)(A)(ii) of the Act by requiring, in our final regulations, that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict.	**Access to Covered Part D Drugs (423.120) b. Formulary Requirements Section 1860D-4(b)(3)(A)(ii)** This statutory requirement should not be expanded.
C22	Formulary Requirements (§ 423.120) (p.46660): USP Model Guidelines—The goal of the public meeting would be to solicit comments on a draft of the model guidelines, which would be developed on the basis of the aforementioned consultations, as well as USP's research and recommendations.	**Access to Covered Part D Drugs (423.120) b. Formulary Requirements Section 1860D-4(b)(3)(C)i**i No comment.
C23	Formulary Requirements (§ 423.120) (p.46660: We invite comments regarding standards and criteria that we 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.	**Access to Covered Part D Drugs (423.120) b. Formulary Requirements Section 1860D-11(e)(2)(d)(i), 423.272(b)(2)** We believe that sponsors can best address the needs of all populations regardless of "special needs" through the development, maintenance and administration of drug formularies using processes in compliance with an independent accreditation firm (for ex. the National Committee for Quality Assurance (NCQA) standards).

C24	Formulary Requirements (§ 423.120) (p.46661): We seek comments on ways to balance plans' flexibility to use some of the mechanisms described above to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees.	**Access to Covered Part D Drugs (423.120) b. Formulary Requirements Section 1860D-11(e)(2)(d)(i), 423.272(b)(2)** In addition to the response directly above, premium adjustments for special populations of Part D enrollees may introduce selection bias. Well managed special needs populations have higher drug costs and lower medical costs which need to be factored in the risk adjustment methodology.
C25	Formulary Requirements (§ 423.120) (p.46661): We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well suggestions regarding the particular special populations for whom we may want to make allowances.	**Access to Covered Part D Drugs (423.120) b. Formulary Requirements Section 1860D-11(e)(2)(d)(i), 423.272(b)(2)** We believe that sponsors can best address the needs of all populations regardless of "special needs" through the development, maintenance and administration of drug formularies using processes in compliance with an independent accreditation firm (for ex. the National Committee for Quality Assurance (NCQA) standards).
C26	Formulary Requirements (§ 423.120) (p.46661): 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).	**Access to Covered Part D Drugs (423.120)(b)(4). Formulary Requirements Section 1860D-4(b)(3)(F)** We recommend using standards established by an independent accreditation firm (for ex. National Committee for Quality Assurance (NCQA) standards) with an annual drug formulary review as a basis for a periodic evaluation and analysis of protocols and procedures.
C27	Formulary Requirements (§ 423.120) (p.46661): Section 1860D-4(b)(3)(E) of the Act requires that 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) many 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.	**Access to Covered Part D Drugs (423.120)(b)(5). Formulary Requirements Section 1860D-4(b)(3)(E)** We recommend excluding from the provision of notice regarding formulary changes the requirement to notify members obtaining a brand name drug that will move to a higher tier copayment because the generic drug is now available. This movement of brand name drugs to a higher tier or to otherwise incur a higher copayment when the generic is now available at a lower copayment is a standard and well accepted practice. Notification in these circumstances would be an unnecessary administrative burden.
C28	Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§ 423.124) (p.46662): Given the inherent difficulties in establishing emergency access standards for covered Part D drugs, we propose to meet the requirements of section 1860-D(4)(b)(1)(C) by establishing a broader out-of-network access requirement . . . We request comments on our proposed out-of-network access requirements.	**Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (423.124) Section 1860D-4(b)(1)(C)(iii)** OON pharmacies should not include foreign pharmacies or internet (non-participating) "virtual" pharmacies. Attempts should be made by the beneficiary to access a participating network pharmacy before any use of a non-network pharmacy. A "reasonable" driving distance requires clarification.
C29	Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§ 423.124) (p.46663): 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.	**Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (423.124)(a) Section 1860D-4(b)(1)(C)(iii)** We recommend that the OON pharmacy claims adjudicate at in-network rates. Determination would be necessary regarding which in-network rate to use. Because we cannot control these costs, we suggest that any cost above our standard contract rate not be counted as an incurred cost against any OOP threshold. There are also operational challenges for capturing and housing the price differential and applying towards incurred costs and benefit deductibles.

C30	Dissemination of Plan Information (§ 423.128) (p. 46663): We solicit comments on how best to coordinate the requirements of § 423.128 and § 422.111 of our proposed rule for MA-PD plans.	**Dissemination of Plan Information (423.128) Section** Recommend that CMS facilitate the creation of model member material and guidelines for plans to use in disseminating information to members.
C31	Dissemination of Plan Information (§ 423.128) (p. 46664): As provided in § 423.128(d)(1)(i) and (ii) of our proposed rule, plans' customer call centers would be required to be open during usual business hours and provide customer telephone service, including to pharmacists, in accordance with standard business practices. 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 (for example, on out-of-network pharmacy access) and request comments on whether we should require the more stringent 24-hour-a-day/7-day-a-week standard in our final regulations.	**Dissemination of Plan Information (423.128) c. Provision of Specific Information Section 1860D-4(a)(3)** The inclusion of a pharmacist availability requirement into the customer call center regulations would add additional costs to administer the program. A 24/7 requirement for call centers is not reasonable considering the very low volume of calls during off hours. The benefit of a 24/7 requirement does not justify the costs.
C32	Dissemination of Plan Information (§ 423.128) (p. 46664): In addition, per § 423.128(d)(2)(ii) and (iii) of our proposed rule, plans would have to post current versions of their formularies, update these formularies at least weekly, and use the website as one mechanism to provide notice (at least 30 days in advance, as discussed in section C.4.b of this preamble) of upcoming formulary or changes, including the removal of covered Part D drugs from a formulary or changes to the tiered or preferred status of covered Part D drugs	**Dissemination of Plan Information (423.128) c. Provision of Specific Information Section 1860D-4(a)(3)** We recommend not requiring the formulary information to be updated at least weekly. While some changes in the pharmacy claims processing drug databases can occur weekly, such as new generic manufacturers of already available generic products, most changes occur quarterly in response to the decisions of the health plan Pharmacy & Therapeutics Committee. A monthly time frame would be most reasonable to reflect all changes and allow for timely information to members.
C33	Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132) (p.46665): 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.	**Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132)** We are requesting that MA-PD plans should be allowed to request a waiver of this requirement.
C34	Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132) (p.46666): 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.	**Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132)** We are requesting that MA-PD plans should be allowed to request a waiver of this requirement.
	Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans	

D1	Cost Effective Drug Utilization Management (§ 423.153) (p.46667): Although we have not included proposed regulations, we are considering for the final rule a requirement that these tools [e.g., prior authorization, step therapy, tiered cost-sharing] 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.	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.150) a. Cost Effective Drug Utilization Management Section 1927(k)(7)(A)(i)** We agree with the oversight and direction of the drug utilization management program being the responsibility of the Pharmacy & Therapeutics Committee as this is the current structure and works well for a coordinated pharmacy benefit management approach.
D2	Quality Assurance (§ 423.153) (p. 46667): We solicit comment 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. Therefore, we have chosen not to add further specification in the regulation text. We also understand that some members of industry use additional quality assurance measures and systems. We invite comments on whether there are industry standards, above and beyond those mentioned above, that we might adopt. Furthermore, PDP sponsors and MA Organizations offering MA-PD plans will be required to have systems and measures established to ensure that network pharmacy providers are complying with their quality assurance requirements. We are requesting comments on the costs and challenges associated with these systems and measures.	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.153) b. Quality Assurance 1927(g)(2)(A)** We recommend consultation of an independent accreditation firm (for ex. National Committee for Quality Assurance (NCQA)) recognized by the industry for guidelines on quality assurance programs.
D3	Quality Assurance (§ 423.153) (p. 46667): We invite comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We are particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how this data could be best communicated to providers and beneficiaries to improve medication use.	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.153) b. Quality Assurance 1927(g)(2)(A)** We recommend not placing the specific elements of quality assurance system in the program requirements but rather refer to industry standards with an independent accreditation firm (for ex. National Committee for Quality Assurance (NCQA)).
D4	Quality Assurance (§ 423.153) (p. 46667): We note that the MMA does not define or explain the term “medication error.” . . . [W]e 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.	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.153) b. Quality Assurance 1927(g)(2)(A)** We would recommend NOT mandating error reporting within the Part D pharmacy benefit as it would be redundant with other governmental and industry programs. Examples include the FDA MedWatch error reporting system, and the Institute for Safe Medication Practices (ISMP) reporting. Publically reporting "error rates" should only be pursued after further discussion with stakeholders and a meaningful consumer metric is developed.

D5	Quality Assurance (§ 423.153) (p. 46667-68): We are citing this definition in this preamble as the one we would use initially in interpretive guidance [referring to definition found in a March 14, 2003 FDA proposed rule (68 FR at 12500) and in guidance by the National Coordinating Council for Medication Error Reporting and Prevention] . . . We invite comments on this definition. (Definition of a medication error—p.46667)	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.153) b. Quality Assurance 1927(g)(2)(A)** We would agree with the NCCMERP medication error definition, however we would recommend NOT mandating error reporting within the Part D pharmacy benefit as it would be redundant with other governmental and industry programs. Examples include the FDA MedWatch error reporting system, and the Institute for Safe Medication Practices (ISMP) reporting.
D6	Fraud, Abuse and Waste (§ 423.153) (p. 46670): We would expect these plans [PDP sponsors and MA organizations sponsoring MA-PD plans] as prudent purchasers, to implement programs to control their expenditures. We would be interested in comments on the following discussion as to possible requirements in this area over and above the incentives operating in at risk plans. 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 efficiently research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste. Fraud, Abuse and Waste (§ 423.153) (p. 46670): 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. . . We seek comments on the likely value of these requirements. We also seek comments on the implementation, scope, and operation of an effective and robust fraud, abuse, and waste control program for plan sponsors.	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.153) d. Fraud, Abuse and Waste** Abuse detection is not cost effective to the plan in that common abuse is difficult to distinguish from legitimate pharmaceutical claims. The overwhelming majority of pharmacies are not abusive and the pharmacy/plan relationship would be damaged by the underlying suspicion that is communicated. A preventative measure through the use of tight adjudication edits that would minimize the potential for abuse.
D7	Electronic Prescription Program (§ 423.159) (p. 46671): We are particularly interested in comments that help us identify consensus or reach consensus on e-prescribing standards ahead of the statutory time frame, and to help us identify and evaluate industry experience based on pilot programs engaged in e-prescribing activities in 2004 and 2005.	**Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (423.159) 4. Electronic Prescription Program Section 1860D-4(e)** We support the NCPDP SCRIPTS Standard as the official eprescribing standard to be used for Medicare.
	Subpart J: Coordination Under Part D Plans with Other Prescription Drug Coverage	

J1	Application of Part D Rules to MA-PD Plans on and after January 1, 2006 (§ 423.458) (p. 46697): We ask for your comments on both the process we propose for authorizing additional waivers under this section and for what additional waivers should, or should not, be permitted under this waiver authority.	**Application of Part D Rules to MA-PD Plans on and After January 1, 2006 (423.458) Section 1860D-21(c)(1)** We request clarification on what CMS intends by this section. It appears that CMS will allow some type of waivers. There is an overlap of coverage for some drugs that the MA-PD would clearly be responsible for covering (either as a Part B drug under a Part C benefit, or Part D drug under the voluntary Part D benefit). However it would impose some hardship for members (and pharmacies, and the MA sponsor) to determine which benefit would apply. As pharmacies claims are paid in real time through a POS system, no payment could be made and the member may not receive the drug until information was supplied to the MA-PD sponsor to make a determination which benefit applied. (Example: Immunosuppressent drug. Should it pay under Part B benefit due to covered transplant, or should it pay under the Part D benefit due to non-Medicare covered transplant. In many cases, the prescribing physician will not even have this level of information.) See issue J4 below.
J2	Coordination of benefits (§ 423.464) (p. 46702): We request comment on this proposed approach (to include SPAP information in a coordination of benefits system) 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.	**Coordination Of Benefits With Other Providers Of Prescription Drug Coverage (423.464) c. Coordination of Benefits Section 1860D-23(a)(1)** Any claim sent from a Part D sponsor to a SPAP cannot be assumed to be used in calculating the TrOOP amount. Many drugs are NOT covered by the SPAP plan (as with Part D) and the member may simply choose not to obtain the drug or return to the provider for alternative medication choices. These costs cannot be attributed to TrOOP if the member never obtains the services. There are strong doubts that a system can be built in the timeframe allowed that would tell pharmacies which insurance plan to bill in which order. This poses a question of who would build such a system and who would pay for it. There are many pharmacy vendor software systems available. Until a national standard is established first, software vendors could not make the necessary changes to their proprietary systems.
J3	Coordination of benefits (§ 423.464) (p. 46702): We request public comment on other situations that may involve benefit coordination between States and Part D plans (other than situations where the State is acting as an employer). In general, we invite comment on the other administrative processes and requirements that we might identify in order to help coordination between Part D of Medicare and other prescription drug plans	**Coordination Of Benefits With Other Providers Of Prescription Drug Coverage (423.464) c. Coordination of Benefits Section 1860D-23(c)(1**) Stakeholder collaboration is needed here. COB presents a major challenge to all stakeholders. CMS will need to be flexible and imaginative in developing a practical solution to this complex issue.

J4	Coordination of benefits (§ 423.464) (p. 46703): We are considering whether a drug denied Part B coverage for this reason should become a covered Part D drug, and the claim should thus be processed under Part D, and would like to receive comments on the relative likelihood of this occurrence and on alternative means of addressing such circumstances	**Coordination Of Benefits With Other Providers Of Prescription Drug Coverage (423.464) c. Coordination of Benefits Section 1860D-2(e)(2)(B)** - We need clarification on what CMS's expectation is on how MA-PD sponsors should set up adjudication for drugs that may be covered as Part B drugs. It seems clear that the MA-PD sponsor will be responsible to pay for the claim, but until a determination of which benefit the claim applies to (Part B or Part D) is made, a MA-PD sponsor does not know which benefit to apply the claim to. In a Point of Service Pharmacy Claim system, we are requesting clarification on whether CMS expects us to withhold adjudication until the sponsor can determine which benefit should apply. Some of that information (clinical indication) is only available via the prescribing provider, and in some cases that information is only available from CMS or the beneficiary.
J5	Coordination of benefits (§ 423.464) (p. 46703): We are also considering whether a drug denied Part B coverage for any other reason should become a covered Part D drug. . . We welcome comment in this area.	**Coordination Of Benefits With Other Providers Of Prescription Drug Coverage (423.464) c. Coordination of Benefits Section 1860D-2(e)(2)(B)** We recommend that any denied Part B drug not be allowed to be covered as a Part D drug. If a drug is not covered under Part B due to benefit guidelines of Part B, then yes it should fall into Part D. If however a drug is not covered under Part B due to the inappropriate medical use of the drug, then it should (for the same reasons) not be covered under Part D. For PDP sponsors, if a Part B drug is denied due to the provider not being a Medicare provider, then the drug should NOT automatically be covered under Part D. This would be allowing two Part D benefits to be applied differently under the same sponsor plan. Office administration of Part B drugs should not be eligible for reimbursement under Part D.
J6	Coordination of benefits (§ 423.464) (p. 46703-46704): We also believe that similar cross-over procedures for any physician-administered drugs that may be covered under Part B or Part D will need to be developed. . . We particularly welcome comment on the feasibility of these proposed Part D and Part B coordination of benefits proposals and welcome suggestions on other methods or procedures that might be more efficient or better suited to coordination of prescription drug benefits	**Coordination Of Benefits With Other Providers Of Prescription Drug Coverage (423.464) c. Coordination of Benefits Section 1860D-2(e)(2)(B)** A claim submitted via the pharmacy system, does not provide enough information to determine where that drug will be administered. Some may be self-administered, while others may be brought to the physician's office for administration. Does that imply that any injectable billed by a pharmacy provider is a Part D drug? CMS needs to find a way to allow these drugs to be consistently addressed. Part D medication administered in a Part B setting should be excluded.
J8	Tracking true out of pocket (TrOOP) costs (§ 423.464) (p. 46706): We are requesting comments concerning the development of this system (the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query.)	**Tracking true out of pocket (TrOOP) costs (§ 423.464) Section 1860D-24(a)(3)** We expect that this system is going to be a large operational and financial issue even without factoring in the time constraints. The infrastructure to support tracking does not exist today to track member reimbursements. We recommend that TrOOP be tracked by a CMS sponsored vendor and not by the plans.

J9	Tracking true out of pocket (TrOOP) costs (§ 423.464) (p. 46707): We ask for comment on these options and are seeking input on the best means to ensure an efficient and effective coordination of benefits related to the Part D Medicare program. We are also interested in discussion of other temporary or phased-in approaches that may be necessary or advisable given the short timeframe between publication of the final rule and program implementation. Under any of the scenarios presented it is clear that the ultimate responsibility for calculating TrOOP belongs to the Part D plan. The only issues are what role in facilitating TrOOP tracking CMS should have, if at all.	**Tracking true out of pocket (TrOOP) costs (§ 423.464) Section 1860D-12(b)(3)(D)** A phased in approach should be taken. A single TrOOP facilitation contractor would have several advantages, but even those will not work in a real time POS pharmacy adjudication system. This procedure has to be coordinated by a central body overseen by CMS.
J10	Tracking true out of pocket (TrOOP) costs (§ 423.464) (p. 46707): In addition, we request public comment on methods for Part D plans to receive information from beneficiaries or others regarding payment made by entities that do not participate in this coordination of benefits system, since there is no requirement that third-party payers participate in this voluntary system.	**Tracking true out of pocket (TrOOP) costs (§ 423.464) Section 1860D-24(a)(3)** See comment to issue J9 above.
	Subpart M: Grievances, Coverage, Reconsiderations, and Appeals	

M1	Exceptions to a Plan's Tiered Cost-Sharing Structure. In the preamble, CMS explains that, at a minimum, in order for the plan to be obligated to move a formulary drug to a more favorable enrollee cost structure, the prescribing physician would have to determine that the preferred drug either would not be as effective for the individual or would have adverse effects for the individual, or both. The statute then requires that each PDP sponsor establish exceptions procedures consistent with guidelines issued by the Secretary for making determinations on such requests. CMS notes that unfavorable determinations constitute coverage denials that would be subject to all the appeals rights discussed in subpart M of part 423. In the preamble, CMS stated that it believes that the uncertainty around how PDP sponsors will implement their tiering structures strongly suggests that the proposed regulations not include overly prescriptive requirements with respect to a PDP's exceptions criteria. Instead, CMS is providing general guidance on the scope of issues that must be addressed under a PDP's exceptions criteria on the procedural elements of that process, but still allow for flexibility and innovation in this regard as CMS gains experience with the new program. In its exceptions process, a PDP sponsor must address 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 tiered cost-sharing structure changes at the beginning of a new plan year; and (3) there is no pre-existing use of the drug by the enrollee.	**Formulary Exceptions Procedures (423.578) a. Exceptions to a Plan's Tiered Cost-Sharing Structure Section 1860D-4(g)(2)** The proposal to move a drug to a preferred formulary status is much too broad and permissive. Rather than allowing exceptions at the written request of a physician based on an opinion, we recommend that decisions of this type should require medical evidence or demonstrated failure of previous therapy in order to preclude use of preferred products.	

	In addition, in §423.578(a)(2),CMS has proposed the following 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. In the preamble, CMS explained that it considered other exceptions criteria, which it did not adopt. These other possible criteria are: (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) requiring an enrollee who is using a drug that is subsequently removed from the sponsor's formulary or is no longer designated as the ``preferred drug'' 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. CMS also stated that it contemplated the possibility of establishing criteria for the review process used to evaluate plan formularies and tiering structures, and developing exceptions criteria that are specific to particular classes of covered Part D drugs.	

CMS-4068-P-1050

Submitter : Mr. Tony Deans **Date & Time:** 10/04/2004 06:10:19

Organization : Holladay Healthcare

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Thank you for the opportunity to comment on the proposed regulations to implement the Medicare Prescription Drug Benefit. I would like to offer the following comments for consideration.

BENEFITS AND BENEFICIARY PROTECTIONS

I urge you to consider requiring participating plans to meet the TRICARE pharmacy access requirements at the local, rather than plan level. This is the only means of insuring all beneficiaries? access to services at a local pharmacy.

Further, I feel it its important for CMS to require plans to offer standard contract participation to any willing pharmacy provider. Again I feel this is the best way to insure maximization of access to beneficiaries. I also feel it is the best way of avoiding putting many small pharmacy business owners at a disadvantage. These small pharmacies are providers for many otherwise underserved areas (e.g. rural and inner city populations).

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

I am concerned that plans might choose to utilize practitioners other than pharmacists for Medication Therapy Management Services (MTMS). I would like to emphasize that pharmacists are uniquely qualified to provide MTMS in concert with physicians to achieve stated legislative goals.

+ No other profession even approaches the depth/breadth of education and training with regard to medication use as pharmacists.
+ Pharmacists are uniquely positioned to recognize and resolve problems with medication therapy that occur between multiple prescribers.
+ Only pharmacists have a daily working knowledge of the financial impact of alternative medication therapies. I frequently hear shock expressed from prescribers on being imformed of the relative cost of alternative therapies.
+ Pharmacists are, and have been for some time, the most accessible healthcare professionals.

Every time I perform medication therapy review for my nursing home patients. I discover potential problems, cost saving opportunities, and ways to improve patients' quality of life through medication therapy management. Last year, North Carolina AccessCare in concert with the North Carolina Long-term Pharmacy Coalition demonstrated not only tremendous return on investment for intensive medication therapy review by pharmacists (approx. 13:1), but also showed that the cost savings accrued over time unlike many other programs. I see each time I go into the nursing home how I have, in concert with the medical and nursing staff contributed to improving the quality of life for patients and been able to save resources.

GENERAL PROVISIONS

Every time I perform medication therapy review for my nursing home patients. I discover potential problems, cost saving opportunities, and ways to improve patients? quality of life through medication therapy management. Last year, North Carolina AccessCare in concert with the North Carolina Long-term Pharmacy Coalition demonstrated not only tremendous return on investment for intensive medication therapy review by pharmacists (approx. 13:1), but also showed that the cost savings accrued over time unlike many other programs. I see each time I go into the nursing home how I have, in concert with the medical and nursing staff contributed to improving the quality of life for patients and been able to save resources.

Submitter : Mr. Robert Kerr **Date & Time:** 10/04/2004 06:10:18

Organization : South Carolina Medicaid (DHHS)

Category : State Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

Thank you for the opportunity to share these comments. SC DHHS appreciates the enormous effort that is underway at CMS to implement Part D. We look forward to a continued mutually-beneficial dialogue in this regard.

BENEFITS AND BENEFICIARY PROTECTIONS

Long-term Care Residents:
In all references, the definition of long-term care (LTC) facility should extend to any setting where a dual-eligible individual who meets an institutional level of care receives services whether it is a skilled nursing facility, a nursing facility, an intermediate care facility for the mentally retarded (ICF/MR) or a home or community based waiver program. These populations are identical in their need for institutional care and should be treated identically under Part D. Additionally, to ensure full access to Part D benefits for LTC residents, Prescription Drug Plans should be required to include in their networks pharmacies serving LTC facilities.

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

PDP Formularies:
Furthermore, these populations are all uniquely vulnerable to prescription regimen changes, particularly those with special disease states such as HIV/AIDS. Treatment modalities for these individuals change rapidly and a restriction on their medications may produce significant adverse impacts on their health. CMS has taken note of this and, through several different regulations, ensured that Medicaid will provide all drugs required by an individual in a skilled-nursing facility.

CMS should continue this requirement of Prescription Drug Plans by restricting their ability to impose formulary restrictions on LTC residents, including those in a home or community based setting. Should formulary restrictions be imposed, a procedure to accommodate (or ?grandfather?) current drug therapies should be required of all Prescription Drug Plans for individuals entering the Prescription Drug Plan during the initial open-enrollment period.

Finally, CMS should ensure that all Part D drugs are available to individuals who have undergone any Medicare or Medicaid reimbursed transplant procedure. Prescription Drug Plans? formulary restrictions and existing Medicare time limits for coverage might interfere with recovery.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Low-Income Subsidy Eligibility:
SC DHHS feels strongly that the Social Security Administration (SSA) is the most efficient and effective entity to process the Low-Income Subsidy eligibility. We appreciate CMS? collaboration with SSA in this regard and encourage the entities to continue to work together in SSA assuming primary responsibility for this function. Nevertheless, SC DHHS would welcome the opportunity to serve intake functions in this regard.

Auto-Enrollment / Enrollment:
As directed by Congress, CMS should independently handle auto-enrollment of current dual-eligibles. Unlike states with experience in this area through managed care enrollment, SC DHHS has absolutely no such experience and assuming this function would prove administratively burdensome. If required to process auto-enrollment, states should be compensated by CMS for the entire cost of this function.

Additionally, all auto-enrollment should take place at the initiation of the open enrollment period with auto-assigned individuals having until June 2006 to dis-enroll or change plans. This will avoid the potential six month gap in coverage that could occur between January 1, 2006, when all Medicaid federal financial participation for these individuals will end and June of 2006 when they will be auto-enrolled in a Prescription Drug

Plan.

Lastly, states with Pharmacy Plus Waivers should be allowed, if they choose, to assist in enrolling Low-Income Subsidy eligible Pharmacy Plus enrollees into PDP in much the same fashion as State Pharmaceutical Assistance Programs. Significant confusion exists among the senior population in regard to the various opportunities for prescription drug assistance. The drug discount card enrollment process bears out the supposition that this confusion breeds inertia even though moving from one plan to another might result in increased financial benefit for the individual.

Issues 11-20

SPECIAL RULES FOR STATES

Phased-Down State Contribution (PDSC) Baseline:
SC DHHS has significant concerns in regard to the Phased-Down State Contribution baseline and monthly payment calculations. We strongly recommend CMS consider modifying these calculation formulas to more equitably reflect the state?s fiscal pharmaceutical realities.

In calculating the PDSC baseline, it seems illogical to not consider the July 1, 2003, to June 30, 2004, rebate period that correlates to the required 2003 calendar year expenditure period. PDSC payments will not have to be invoiced by CMS until October of 2005 and collected until January of 2006. This leaves ample time to consider the appropriate rebate period in the PDSC calculation.

Additionally, the regulations do not make clear whether baseline expenditures are calculated on Part D Coverable Drugs alone or on all the drugs Medicaid paid for in 2003. This calculation should only include Part D Coverable Drugs. Factoring the baseline on the all drug expenditures is inequitable because it will require the state to subsidize more restricted drug coverage based on the financial expense of more extensive drug coverage, distorting in perpetuity the per capita expenditure on which the monthly PDSC payment is based.

Finally, SC DHHS expects that the removal of the Medicare-eligible population from the Medicaid program will hamper our ability to negotiate supplemental rebates. To help ameliorate this impact, SC DHHS asks CMS to pursue the necessary statutory authority to allow Prescription Drug Plan prices to be included in Medicaid ?best price? determinations.

Part D Covered Drugs:
The Part D Covered Drugs listing should be provided using First DataBank?s Generic Sequence Number (GSN) or Generic Code Number (GCN) rather than National Drug Code (NDC). The GSN is drug-specific, yet it more broad and more static than the NDC and, therefore, would be easier for the states to work with in calculating their Phased-Down State Contribution and in considering state wrap-around services. Additionally, NDCs become quickly out-dated due to the frequently changing market.

CMS-4068-P-1052

Submitter : **Date & Time:** **10/04/2004 06:10:50**

Organization : **National Health Council**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

The National Health Council (NHC) appreciates the opportunity to submit comments on the proposed rule recently published by the Centers for Medicare and Medicaid Services (CMS) for the new Medicare prescription drug benefit (the Proposed Rule) established under the Medicare Modernization Act (MMA).

The NHC, a private, nonprofit umbrella organization of more than 110 national health-related organizations, works to bring quality health care to all people. Its core membership includes more than 50 of the nation?s leading voluntary patient-based health agencies, including the American Cancer Society, American Diabetes Association, American Autoimmune Related Diseases Association, National Mental Health Association, Lupus Foundation of America and the Epilepsy Foundation. These organizations collectively represent approximately 100 million people with chronic diseases and/or disabilities. Other NHC membership categories include professional and membership associations such as the American Academy of Family Physicians; nonprofit organizations with an interest in health such as AARP; and business and industry including Pfizer and Novartis.

The NHC and its member organizations share a common objective: to improve the health of all people, particularly those with chronic diseases and/or disabilities. Through communication, collaboration and consensus, NHC?s member organizations work to achieve this important objective.

The NHC commends CMS? efforts to implement the new Medicare drug benefit, especially given the challenges inherent in balancing the need to provide Medicare beneficiaries with a comprehensive prescription drug benefit against the need to administer a cost-effective benefit.
Recommendations
The NHC proposes the following recommendations to strengthen beneficiary protections within the Part D benefit:
? Increase beneficiary and family member participation in the implementation of the prescription drug benefit;
? Improve patient access to and the quality of a comprehensive prescription drug benefit;
? Encourage clear and effective communication with beneficiaries, their families and their physicians about the new prescription drug benefit;
? Encourage accountability of plan sponsors as well as CMS; and
? Encourage plan flexibility to incorporate new prescription drugs and biologics.
The NHC?s recommendations are grouped into the following four categories:
? Benefit Structure (recommendations 1 through 6);
? Pharmaceutical and Therapeutic Committees and Plan Formularies (recommendations 7 through 10);
? Exception and Appeals Processes (recommendations 11 through 13); and
? Plan Administration and Oversight (recommendations 14 through 18).

CMS-4068-P-1052-Attach-1.doc

NATIONAL HEALTH COUNCIL

Comments of the National Health Council
on the Centers for Medicare and Medicaid Services' Medicare Program; Medicare Prescription Drug Benefit;

69 Fed. Reg. 46632 (August 3, 2004)

Submitted to:
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

October 4, 2004

Contact:
Myrl Weinberg
President
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October 4, 2004

VIA MESSENGER

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; Medicare Program; Medicare Prescription Drug Benefit; 69 Fed. Reg. 46632 (August 3, 2004)

Dear Dr. McClellan:

The National Health Council (NHC) appreciates the opportunity to submit comments on the proposed rule recently published by the Centers for Medicare and Medicaid Services (CMS) for the new Medicare prescription drug benefit (the Proposed Rule)[1] established under the Medicare Modernization Act (MMA).[2]

The NHC, a private, nonprofit umbrella organization of more than 110 national health-related organizations, works to bring quality health care to all people. Its core membership includes more than 50 of the nation's leading voluntary patient-based health agencies, including the American Cancer Society, American Diabetes Association, American Autoimmune Related Diseases Association, National Mental Health Association, Lupus Foundation of America and the Epilepsy Foundation. These organizations collectively represent approximately 100 million people with chronic diseases and/or disabilities. Other NHC membership categories include professional and membership associations such as the American Academy of Family Physicians; nonprofit organizations with an interest in health such as AARP; and business and industry including Pfizer and Novartis.

The NHC and its member organizations share a common objective: to improve the health of all people, particularly those with chronic diseases and/or disabilities. Through

[1] Medicare Program; Medicare Prescription Drug Benefit; 69 Fed. Reg. 46632 (Aug. 3, 2004) (to be codified at 42. C.F.R. pts. 403, 411, 417 and 423).
[2] Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Pub. L. No. 108-173 (2003) creating Section 1860D-1, et. seq. of the Social Security Act (SSA).

communication, collaboration and consensus, NHC's member organizations work to achieve this important objective.

The NHC commends CMS' efforts to implement the new Medicare drug benefit, especially given the challenges inherent in balancing the need to provide Medicare beneficiaries with a comprehensive prescription drug benefit against the need to administer a cost-effective benefit.

Recommendations

The NHC proposes the following recommendations to strengthen beneficiary protections within the Part D benefit:

- Increase beneficiary and family member participation in the implementation of the prescription drug benefit;
- Improve patient access to and the quality of a comprehensive prescription drug benefit;
- Encourage clear and effective communication with beneficiaries, their families and their physicians about the new prescription drug benefit;
- Encourage accountability of plan sponsors as well as CMS; and
- Encourage plan flexibility to incorporate new prescription drugs and biologics.

The NHC's recommendations are grouped into the following four categories:

- Benefit Structure (recommendations 1 through 6);
- Pharmaceutical and Therapeutic Committees and Plan Formularies (recommendations 7 through 10);
- Exception and Appeals Processes (recommendations 11 through 13); and
- Plan Administration and Oversight (recommendations 14 through 18).

A. Benefit Structure

The NHC strongly urges CMS to modify certain components of the Proposed Rule to strengthen beneficiary protections and ensure beneficiary access to a comprehensive drug benefit.

1. **CMS should require that marketing materials, notices relating to formulary changes and all other communications to plan enrollees regarding plan benefits and formularies be written in accordance with the principles of clear health communications so that patients and their families have the ability to obtain, process and understand available health information.**

Literacy skills are a stronger predictor of an individual's health status than age, income, employment status, education level, race or ethnicity. When health literacy (that is, the ability to read, understand and effectively use basic medical instructions and information) is low, individuals are less likely to comply with prescribed treatments and self-care regimens and often fail to seek preventive care. These individuals are at higher risk for hospitalization, they remain in the hospital longer, and they generally require additional care that results in higher annual health care costs.[3]

To ensure that Medicare beneficiaries have the ability to obtain, process and understand instructions and information related to the Part D benefit, CMS should require that all enrollee communications be written in accordance with principles of clear health communications. Specifically, all documents should be appropriate for Medicare beneficiaries and family members with low health literacy.

2. **CMS should recognize patients with three or more chronic diseases and/or disabilities as a vulnerable population for purposes of the Part D benefit. Additional protections and restrictions on plan sponsors should be incorporated to protect this vulnerable patient population. For example, plans should be required to provide immediate access to non-formulary drugs while a coverage determination is pursued whenever a formulary drug causes a physical/mental reaction or otherwise is ineffective.**

In the Proposed Rule, CMS expressed concern regarding the potential impact of plans' cost-saving strategies on vulnerable populations. For example, CMS highlighted that Medicare beneficiaries enrolled in long-term care facilities tend to be more sensitive to and less tolerant of many medications. This dynamic has resulted in many long-term care facilities permitting physicians to prescribe a wide variety of medications in different dosages and forms. CMS suggested that these institutionalized patients could suffer as a result of formulary restrictions or cost-sharing requirements that hinder access to necessary medications.[4]

The NHC shares CMS' concern for vulnerable patient populations and urges CMS to recognize patients with multiple chronic diseases and/or disabilities as a vulnerable

[3] Partnership for Clear Health Communication, Partnership for Clear Health Communication Fact Sheet, available at http://www.askme3.org/pdfs/partnership_fact_sheet.pdf.
[4] 69 Fed. Reg. at 46661.

population for purposes of the Part D benefit. Many formulary restrictions and cost-sharing requirements could have significant and disproportionate adverse impacts on patients who are chronically diseased or disabled.

These beneficiaries often rely heavily on multiple medications to treat their conditions and are likely to be more sensitive to and less tolerant of many medications (similar to patients residing in long-term care facilities). To ensure appropriate access to necessary prescription drugs, CMS should provide meaningful beneficiary safeguards for vulnerable populations, including the chronically diseased and disabled.

3. **CMS should ensure that a beneficiary who lives in more than one region of the country during the year has the opportunity to obtain prescription drugs through network pharmacies, regardless of the enrollee's geographic location, such as by enrolling in a national plan that can service the individual in multiple locations. Additionally, CMS should ensure that beneficiaries are well-informed about the potential financial ramifications of enrolling in a plan with network pharmacies in limited geographic areas, especially if the beneficiary will live or frequently travel outside of the plan's service area.**

Many beneficiaries reside in more than one region of the country during the year, and individuals also may relocate on a temporary basis for health or personal reasons (*e.g.*, beneficiaries may temporarily reside with a family member during an illness or change their residence on a seasonal basis). Individuals who relocate or frequently travel outside of their network may face difficulties obtaining new or revised prescriptions or refills on favorable cost-sharing terms if they have enrolled in a plan offering a geographically-limited pharmacy network. To avoid paying the higher costs associated with non-network pharmacies, many enrollees may opt to forgo their medications (a decision that may threaten their health). To ensure continuous access to medication therapies, CMS should ensure that all beneficiaries have the option of selecting a plan with a national pharmacy network.

In addition, CMS should require plans to provide clear and easy to understand information about the potential financial ramifications of enrolling in plans with a pharmacy network that is limited to a specific geographic region. Such information should be developed according to principles of clear health communications.

4. **In its description of beneficiary out-of-pocket costs that count toward the prescription drug benefit thresholds, CMS should retain its proposal to count most out-of-network expenses toward the thresholds that define beneficiaries' financial obligations.**

In the event that beneficiaries must purchase their prescription drugs out-of-pocket from non-network pharmacies, NHC strongly supports CMS' proposal to count out-of-network prescription drug expenses toward the drug benefit thresholds that define beneficiaries'

financial obligations. For example, patients traveling out-of-network who require new or changed prescriptions may be forced to purchase their prescription drugs from non-network pharmacies. These prescription drug expenses may be substantial and should be considered when calculating beneficiaries' financial obligations.

5. CMS should help protect and promote the quality of care provided to Medicare beneficiaries by establishing sufficient incentives for participating pharmacists to dispense pharmaceuticals, counsel patients regarding medication adherence programs and participate in activities designed to minimize adverse drug reactions and medical errors.

CMS should provide adequate incentives for participating pharmacists to ensure that beneficiaries receive appropriate medication therapies. Specifically, plans should be required to reimburse pharmacists for time spent counseling patients on medication adherence or evaluating patient files to identify and prevent adverse drug reactions and/or medical errors.

In addition, pharmacists should be encouraged to counsel beneficiaries on formulary changes – and resulting cost sharing implications – that affect beneficiaries' drug regimens. Pharmacists are well-positioned to provide this type of information, and they also can facilitate communication with the patient and the physician's office regarding alternate medications that may have similar therapeutic uses.

The NHC urges CMS to recognize the integral role that pharmacists can play in providing beneficiaries with a meaningful prescription drug benefit.

6. CMS should eliminate the provisions allowing for disenrollment for "disruptive and threatening" behavior.

The Proposed Rule would permit plans to disenroll individuals due to disruptive, unruly, abusive, uncooperative or threatening behavior.[5] The NHC believes that this provision is inappropriate. For example, some Medicare beneficiaries suffer from mental disorders such as dementia or other neurological diseases that may cause behaviors perceived to be "disruptive." These provisions also create potential opportunities for discrimination against individuals with mental illnesses, physical disabilities, and cognitive impairment. 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 later enrollment penalty increasing their premiums. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must ensure that they do not lose access to drug coverage.

[5] 69 Fed Reg. at 46642; 42 C.F.R. § 423.44(d)(2)(i).

B. Pharmaceutical and Therapeutic Committees and Plan Formularies

Pharmaceutical and therapeutic committees (P&T committees) will play an important role in the administration of drug plans, serving as gatekeepers to medications through the creation of formularies and other utilization controls. P&T committees also will be responsible for reviewing new drugs and biologics and considering their inclusion in the plan formulary. Plan sponsors will have incentives to aggressively administer a cost-effective prescription drug benefit and likely will use a P&T committee to further this goal. As a result, CMS should provide appropriate oversight on the composition and actions of P&T committees to protect plan enrollees.

7. CMS should ensure that the full range of prescription drugs commonly used in clinical practice for treating chronically diseased and disabled populations is available to all Medicare beneficiaries.

Although the MMA directed CMS to request that the U.S. Pharmacopeia (USP) develop a list of categories and classes of drugs that may be used by plans, CMS retains significant discretion under the statute with respect to formulary development. The new Medicare Part D benefit should provide a comprehensive range of medications to Medicare beneficiaries. The scope of prescription drugs covered under plan formularies will dramatically affect beneficiary access to care. As a result, NHC urges CMS to use its authority and work aggressively to ensure that the full spectrum of necessary medications is available.

The NHC believes that the USP's draft Medicare Model Guidelines do not sufficiently take into account evidence-based research and standard clinical practice for many of the categories and classes of drugs. For conditions such as depression, epilepsy and hypertension, the Medicare Model Guidelines are biased toward use of older medications in a way that is contrary to established clinical practice and that will allow plans to avoid providing safer, more effective therapies. Cost considerations must not displace safety, clinical effectiveness or quality-of-life concerns.

The Final Medicare Model Guidelines should reflect a broad range of categories and classes to ensure that Medicare beneficiaries, especially the chronically diseased and disabled, have sufficient access to critical prescription drug therapies. In some instances, the USP's Draft Model Medicare Guidelines are too narrow to encompass drugs needed by Medicare beneficiaries and could create barriers to access. Therefore, NHC urges CMS and the USP to expand the list of categories and classes to ensure timely access to appropriate medications and to prevent barriers to beneficiary access caused by overly restrictive formularies. At a minimum, the NHC believes that the USP's Final Medicare Model Guidelines should have as many categories and classes as Medicare's Prescription Drug Discount Card and the VA health system.

The NHC also recommends that CMS require plan formularies to include subclasses of drugs to ensure that Medicare beneficiaries have sufficient access to prescription drugs. The

USP's Draft Model Medicare Guidelines include categories and classes but contain subclasses merely to illustrate how additional groupings would serve to ensure beneficiary access to medications. The USP recognizes in its Guidelines that subclasses are critical to ensuring beneficiary access to certain prescription drug therapies. Without subclasses, plan formularies could limit drug offerings to as few as two drugs per broad therapeutic category or class, thereby severely restricting beneficiary access. Consistent with the goal of using the private sector as a model for the Medicare program, the Final Medicare Model Guidelines – including the typical level of granularity – should at least be no more restrictive than formularies used by commercial health plans.

The NHC urges CMS to revise its proposal to only require coverage of at least two drugs per formulary category or class. In many instances, especially among the chronically diseased and disabled Medicare populations, two drugs per category or class will not provide sufficient access to prescription drug therapies. Forcing a change in medications could cause adverse health outcomes among this vulnerable population.

8. CMS should revise its requirements relating to P&T committee membership.

Plan sponsors have a financial incentive to contain costs. To better ensure that patients' interests are protected during the formulary development process, CMS should impose certain requirements regarding the composition and requirements of P&T committees. Specifically, NHC urges CMS to adopt the following recommendations:

- CMS should require that at least 40 percent of practicing physicians and practicing pharmacists on a P&T committee be "independent and free of conflict."

- CMS should require that all members of a plan's P&T committee disclose any financial interest, including specific dollar amounts, and other potential ethical conflicts that a member has with respect to the plan sponsor, the plan or any pharmaceutical manufacturer, to CMS. CMS should make the disclosed information available to the public via the CMS website, and provide a hard copy of the information if requested in writing.

- CMS should require that at least 20 percent of P&T committees represent patients and their families.

- CMS should require that P&T committees include members who represent a broad range of clinical specialties to adequately address various disease states in formulary development and drug selection. In addition, P&T committees should be encouraged to include members on an ad hoc basis to lend clinically appropriate expertise when issues arise during formulary development that require specialized clinical knowledge.

These requirements would help ensure that beneficiary interests are adequately represented during development of plan formularies, including classification decisions and medication selection.

9. CMS should revise its requirements relating to P&T committee procedures.

In addition to adopting requirements regarding the composition of P&T committees, CMS should institute procedural requirements for P&T committees, including the following:

- CMS should ensure that evidence-based clinical guidelines weigh heavily in any P&T committee decision relating to formulary coverage or classification.

- CMS should require that P&T committees engage in a timely review of every newly-approved drug or biologic and every newly-approved therapeutic use of an approved drug or biologic within 90 days of FDA approval. While the P&T committee undertakes this review, enrollees should have access to the new drug or biologic (or new therapeutic use) through a plan sponsor's exception request process.

- NHC recommends that patient and physician organizations as well as other stakeholders be provided an opportunity to provide timely and meaningful comments as part of the review of new drugs and biologics and therapeutic uses.

- NHC recommends that plans provide public notice of all P&T committee meetings. Such public notice could include listing the meeting on the plans' website, sending the information electronically to plan members via a listserve, and/or in writing**.** NHC recommends that P&T committee meetings be open to the public to ensure transparency in P&T committee determinations related to formulary coverage and classification decisions.

Without implementation of these procedural safeguards, beneficiaries may encounter barriers, such as potentially long and unnecessary delays that hinder their access to medication therapies.

10. CMS should create standards for off-label use of prescription drugs as well as combination therapies.

CMS states in the Proposed Rule that physicians and other health care professionals may prescribe drugs for off-label indications, although CMS strongly encourages physicians to clearly document and justify the off-label use in patients' clinical records. Plan sponsors also may assign an FDA-approved drug to a category or class based on an off-label use so long as

the FDA has not determined that such use is unsafe.[6] The NHC does not believe that the language in the Proposed Rule is sufficient to protect beneficiaries' access to appropriate off-label use of medications.

The NHC strongly recommends that CMS preserve the flexibility for drugs to be prescribed for "off-label" uses.[7] CMS should ensure that the USP's Medicare Model Guidelines are constructed to include sufficient categories and classes of drugs that will include the drugs most often used for their off-label uses. Access to off-label use of life-saving and life-enhancing drugs is critical to ensure that chronically diseased and disabled beneficiaries have access to medically necessary therapies. In addition, coverage for off-label uses of formulary drugs, including cost-sharing requirements equivalent to the formulary's most favorable terms, should be provided, regardless of whether the drug is classified under the formulary for treating the enrollee's specific condition.

C. Exception and Appeals Processes

Exception and appeals processes are not adequate solutions to an inadequate formulary or overly-restrictive P&T committee requirements. Nonetheless, effective exceptions and appeals processes are important components of this new benefit, and these processes should be both timely and simple to provide adequate protections for beneficiaries.

11. CMS should require that plan sponsors provide enrollees taking a prescription drug with at least 90 days notice of a change in formulary coverage of the medication unless exceptional circumstances apply, such as the removal of the drug from the U.S. market for safety reasons.

The Proposed Rule requires that plan sponsors provide only 30 days notice of an intended formulary change, such as removal of a drug or a change in the drug's preferred or tiered cost-sharing status.[8] The NHC believes that 30 days does not provide beneficiaries and their providers sufficient time to respond to a formulary change.

Accordingly, NHC strongly recommends that CMS require plan sponsors to provide enrollees with at least 90 days notice of a formulary change. The 90-day time period would permit beneficiaries to consult with their physicians regarding alternative medication therapies or request an exception to the coverage determination.

NHC recommends that CMS require plan sponsors to provide immediate notification to patients who attempt to refill an existing prescription or fill a new prescription when that

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[6] 69 Fed. Reg. at 46660.
[7] For purposes of these comments, the term "off-label use" is defined as the use of any drugs or biologics approved by the FDA with a medically accepted indication included in the USP Drug Information Compendium or is supported by peer reviewed medical literature published in a reputable medical journal.
[8] 69 Fed. Reg. at 46661.

drug is not covered by the enrollee's plan formulary. Suggested protocols could include requiring pharmacists to notify the enrollee at the point of purchase and assisting the enrollee in obtaining an alternative medication.

Additionally, NHC recommends that CMS require plans to provide patients with a 72 hour supply of the prescription drug if it has been removed from the formulary.

12. CMS should ensure that there is sufficient consistency in the exceptions processes among all plans in a given region so that providers can assist beneficiaries in an efficient and effective manner.

The Proposed Rule requires that plan sponsors establish and maintain a process through which enrollees (including their authorized representative or their physician) can seek exceptions to the application of a plan's tiered cost-sharing structure as well as exceptions to a plan sponsor's decision not to include a drug in its formulary.[9] Although the Proposed Rule provides some guidelines for plan sponsors to follow when establishing exceptions processes, plan sponsors nonetheless retain significant discretion to develop their own procedures for determining coverage of non-formulary drugs.

The potential variation in plans' exceptions processes could create substantial challenges for Medicare providers who seek to assist beneficiaries in requesting exceptions across a number of plans. To ensure that beneficiaries and their providers can access necessary prescription drugs through the exceptions process, NHC strongly recommends that CMS develop a standardized process to minimize the burden on providers and patients.

13. CMS should adopt its proposal that enrollees be permitted to obtain refills of medications at the same cost-sharing level without requesting additional approvals once a plan extends an initial approval.

Under the Proposed Rule, a plan sponsor must continue to cover a drug approved under an exception request, including refills, so long as the drug continues to be prescribed for the enrollee and is considered safe for treating the enrollee's condition.[10] Plan sponsors also are prohibited from imposing a special formulary tier, co-payment or other cost-sharing requirement that applies only to drugs that have been approved under the exceptions process.

The NHC strongly supports this requirement and urges CMS to adopt it in the Final Rule. Such a requirement would ensure that beneficiaries for whom certain drugs have been determined to be necessary will have uninterrupted access to these important medication therapies.

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[9] 69 Fed. Reg. at 46720-21.
[10] 69 Fed. Reg. at 46721.

D. Plan Administration and Oversight

Although plan sponsors will have direct responsibility for administering their individual prescription drug plans, CMS is obligated to oversee plan sponsors' administration of the new prescription drug benefit. In particular, CMS should analyze the overall effects of plan formularies, appeals and exception processes, and other rules that impact beneficiaries' access to prescription medications.

14. CMS should engage in a comprehensive and on-going analysis of the effects of plan formularies on beneficiary access to prescription drugs, including reviewing plan sponsors' utilization controls and the number of beneficiary requests for exceptions to the plan's formulary.

The NHC recommends that CMS undertake an ongoing analysis of the effects of plan formularies, appeals and exceptions processes and other plan rules on beneficiary access to prescription drugs. Such action is necessary to identify and remove potential barriers to medication access and prevent discrimination in plan enrollment. In addition, an ongoing review of plan sponsors' use of medication utilization controls should provide CMS with a stronger foundation for its annual consideration of plan bids.

15. CMS should implement additional safeguards to protect dual eligibles and preserve their access to necessary medications.

Congress has recognized that Medicare beneficiaries who qualify for medical assistance under state Medicaid programs – so called "dual eligibles" – require more support and protection under the Medicare program than most beneficiaries. Congress specifically provided that dual eligibles would be eligible to receive Part D benefits as well as financial assistance for cost-sharing requirements. The NHC urges CMS to implement the Part D benefit in a manner consistent with Congress' intent to protect dual eligibles' access to a meaningful prescription drug benefit.

The Proposed Rule offers inadequate protections for this vulnerable population. For example, there is a strong likelihood that dual eligibles who gain Part D coverage through the automatic enrollment process will be assigned to Part D plans with the lowest cost-sharing requirements. Less costly plans may not offer the full range of benefits needed by dual eligibles, who are likely to be chronically diseased and disabled. In addition, with less revenue derived from beneficiary coinsurance, these plans may use more aggressive cost-saving techniques, such as restrictive formularies and complicated exceptions and appeals processes.

As the beneficiaries with the fewest financial resources, dual eligibles will rely heavily on the subsidies provided to them for the Medicare Part D benefit. Often on multiple medications,

dual eligibles' health may be threatened by gaps in coverage and/or inadequate coverage, restrictive formularies or high out-of-pocket costs. Additional beneficiary protections are necessary to ensure that dual eligibles receive continuous prescription drug coverage during the transition to Part D plans and are not harmed by restrictive plan formularies or other cost-saving techniques.

The NHC urges CMS to ensure that dual eligibles receive continuous access to a comprehensive prescription drug plan and adequate financial assistance to pay for more comprehensive prescription drug plans with above average cost-sharing requirements. These Part D safeguards should help to ensure that this vulnerable population will have access to a meaningful prescription drug benefit.

16. To the extent that CMS shares in any cost-savings achieved by prescription drug plans, CMS should ensure that such funds are dedicated to improving beneficiary access to prescription drugs as well as enhancing the quality of care provided to beneficiaries.

In the Preamble to the Proposed Rule, CMS states that any cost-savings achieved by the prescription drug plans will be directed back into the Medicare Trust Fund.[11] Instead, NHC urges CMS to dedicate such cost savings to specific efforts to improve beneficiary access to prescription drugs and to improve the quality of beneficiary care. For example, cost savings could be used to improve the medication therapy management program, implement an electronic medical record or implement chronic care improvement programs.

17. CMS should engage beneficiary and physician organizations for on-going assistance in identifying existing and future recommendations that will protect beneficiary access to a comprehensive prescription drug benefit.

The launch of the Part D benefit in 2006 will mark the first time that prescription drug benefits are made available to the entire Medicare population. This unprecedented benefit will require on-going technical and pragmatic adjustments as it is implemented. The NHC strongly urges CMS to establish a process for engaging beneficiary, physician and other stakeholder organizations for on-going assistance in highlighting potential access and quality problems for beneficiaries.

Without on-going participation by beneficiaries, their families and providers, the Part D benefit could fall short of meeting the needs of Medicare beneficiaries. Providing a method for beneficiary, family, physician and other stakeholder groups to provide feedback and recommendations will help ensure that beneficiaries continue to have a meaningful prescription drug benefit.

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[11] 69 Fed. Reg. at 46691.

NHC recommends that CMS create a program to educate pharmacists, physicians, and other relevant health care providers about the new benefits under Medicare Part D, paying particular attention to patient protections for access to medications such as the providers' role in facilitating the exceptions and appeals process for patients.

18. NHC strongly encourages CMS to ensure that the design of all plans and their respective benefits (including any formulary and tiered-formulary structure), including those that conform to the USP Classification Model, do not discourage enrollment of people with chronic diseases and/or disabilities.

The MMA's anti-discrimination clause prohibits plans from substantially discouraging enrollment by high-risk Part D eligible enrollees. The statute also provides that plans implementing formularies modeled after the USP's Medicare Model Guidelines cannot be determined on the basis of their therapeutic categories and classes alone to violate this statutory provision.[12] As stated in the Proposed Rule, plans that adopt the Medicare Model Guidelines may still be found to discriminate against groups of Medicare beneficiaries based on factors other than their formulary structure. For example, a plan that covers only certain drugs or assigns select drugs to a particular tier in the cost-sharing structure, thereby imposing higher cost-sharing requirements on the beneficiary, may be found to discourage enrollment by individuals requiring those medications.[13]

The NHC urges CMS to adopt the following recommendations:

- CMS should clarify that it intends to vigorously review all plans for antidiscrimination behavior that may impact beneficiaries access to prescription drugs. The NHC further recommends that CMS enforce the antidiscrimination provision by implementing other beneficiary protections in the formulary development process, including protections discussed elsewhere in these recommendations.

- CMS should establish timeframes to ensure that the USP's Medicare Model Guidelines and plan formularies are reviewed and updated on a regular basis so as to reflect newly-approved drugs and drug uses. CMS should ensure that the USP institutes a standard process for reviewing the Medicare Model Guidelines every two years that includes consultation with patients, their families and patient groups to address problems related to beneficiary access to Part D drugs.

- CMS should require that a plan's P&T committee review the formulary structure as well as established treatment protocols and procedures. During the review process, patient and family groups, physician organizations and other stakeholders should be

[12] SSA 1860D-11(e)(2)(D).
[13] 69 Fed. Reg. at 46660.

provided an opportunity to submit comments to be considered by the P&T committees.

- In addition, CMS should require that P&T committees review the data on their plans' exceptions requests and appeals to assess the impact on plan enrollees of their determinations related to formulary coverage, classification decisions and medication selection.

* * * *

The NHC strongly encourages CMS to implement a Part D benefit that protects the needs of individual patients with chronic diseases and/or disabilities and ensures timely access to appropriate medications. We would be pleased to work with CMS in implementing these recommendations or in developing others that ensure beneficiary access to a meaningful prescription drug benefit. Please contact me by telephone at 202-973-0546 or by e-mail at Weinberg@nhcouncil.org if we can provide additional information or be of further assistance.

Sincerely,

Myrl Weinberg

Myrl Weinberg, CAE
President

CMS-4068-P-1053

Submitter : Ms. Mary Dewane **Date & Time:** 10/04/2004 06:10:54

Organization : Schaller Anderson

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached document

CMS-4068-P-1053-Attach-1.doc

Comments on 42 CRF Parts 417 and 422 (CMS-4068-P)

Subpart A-General Provisions

CMS has invited comment related to requiring Special Needs Plans to cover Part D pharmacy for coordination of care purposes. We strongly concur with this requirement, for the reasons outlined by CMS. However, we believe that CMS also needs to carefully study the pharmaceutical needs of the special needs population and expand the list of covered drugs beyond those selected for the general Medicare population under MA. Because Medicaid and Medicaid plans currently provide for the pharmacy needs of dual eligibles who include the very frail elderly, severely disabled children and adults, and persons with severe mental illness, we strongly recommend that CMS look closely at State Medicaid and Medicaid health plan data to develop a list of drug classes and drugs for this population. CMS seems to recognize the unique needs of the HIV and AIDS members, and those with ESRD. As the conditions of the disabled populations become better known to CMS through the analysis of data from the States, it will become apparent that there are a number of other subpopulations that have unique needs as well.

Subpart B-Eligibility, Election and Enrollment

The proposed rule specifies that MA plans must offer a *unified benefit package* that consolidates both Medicare and Medicaid covered services for dual eligibles. The rule goes on to require all MA special needs plans to include *all* categories of dual eligibles. However, not all categories of duals are eligible under Medicaid for the same set of Medicaid benefits. For example QMBs are not entitled to long term care benefits. Currently there are Medicaid plans that provide Medicaid benefits on a managed care basis to dual eligibles with full Medicaid benefits but not the QMBs, SLMBs, etc. To address the problem we recommend that CMS clarify that plans must uniformly offer the same set of benefits to all classes of duals eligibles as provided under the State's Medicaid program.

Subpart B-Eligibility, Election and Enrollment

This section deems eligible an enrollee who no longer meets the special needs criteria if the dual eligible enrollee meets the special needs criteria within the subsequent six months from the date the enrollee lost eligibility. We strongly concur with the notion of deeming given the enrollment patterns experienced with the Medicaid populations. However, we believe there should be an additional six- month grace period. If eligibility is established retroactively, payments should similarly be established retroactively to plans.

Subpart B-Eligibility, Election and Enrollment

States currently serve large numbers of Medicaid eligibles through managed care plans. It is anticipated that many of these plans will become special needs plans under MA because of their extensive experience in treating the aged, blind, and disabled populations. As the Medicaid population ages, almost all will "age in" to Medicare and MA. The proposed rule, as currently drafted, would have these individuals revert from a MA plan to a FFS environment if they do not make a positive selection. This would be confusing and disruptive to the individual and add administrative burden to the CMS, States, and plans. We propose that instead the language of the rule be changed to allow the individual to remain with their special needs plan as a dual eligible unless or until they make a selection away from the plan during subsequent months or during open enrollment. In addition to minimizing the disruption of members, this approach would be consistent with the "aging in" provision for commercial plans when a worker becomes eligible for Medicare and enrolled in an MA plan.

Subpart C-Benefits and Beneficiary Protections

Under this section, CMS is given the authority to waive certain of the requirements under MA to promote better coordination of benefits with employer groups, plans and Medicaid programs and we think the language allows these entities to restrict and convert the enrollment of individuals who are already part of the employer group or Medicaid plan. For consistency we propose that language be included to specify that individuals already enrolled in an MA special needs plan through Medicaid remain with that plan. This approach is consistent with the current employer group health plan enrollment process, which allows for existing MA plans that convert commercial enrollment as they achieve Medicare eligibility. Similar to the employer group market this will allow for continuity of care and improved coordination with their Medicaid benefits.

Subpart D-Quality Improvement Program

Because of the unique health conditions of the special needs populations, we do not believe that the QI metrics developed for the general Medicare population will necessarily suffice in evaluating health outcomes or enrollee satisfaction for those enrolled in special needs plans. As a result we would recommend that CMA study this issue and develop metrics that consider the size and scope of the population served by special needs plans.

Subpart F-Submissions of Bids, Premiums, and Related Information and Plan Approval

Dually eligible members are significantly more likely to be frail elderly, nursing home certifiable or to reside in a nursing home than the average Medicare enrollee. In addition, many of the duals are disabled children and adults, and persons who are severely

mentally ill. While risk adjustment will help ensure that plans are paid more accurately for the health status of their members, risk adjustment may only partially recognize the health needs of the dually eligible members. This issue is of significant concern for those potential MA special needs plans that currently provide Medicaid benefits to dual eligibles, which may attract a greater proportion of frail elderly and nursing home residents. We propose that CMS implement a frailty adjuster specifically for MA special needs plans. A frailty adjuster will help to ensure that all dually eligible can enroll in and be served by MA special needs plans.

CMS-4068-P-1054

Submitter : Mrs. Lisa Luley **Date & Time:** 10/04/2004 06:10:50

Organization : Infusion Partners

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Infusion Partners 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.

As an employee of a regional home IV provider for 18 years we have seen significant reduction in hospitalization when IV therapies are initiated in the home. These specialized services provided are not the same as a retail pharmacy requiring much more monitoring and hands on care. Many patients who have problems with their intravenous therapies need 24 hour on call assistance from our pharmacists and nurses. I would like to see pricing and coding that is reflective of the specialized services rendered to patiients in liue of hospitalization.

Infusion Partners 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.

CMS-4068-P-1055

Submitter : Dr. John Moorhead **Date & Time:** 10/04/2004 06:10:04

Organization : Oregon Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-4068-P-1055-Attach-1.pdf

OREGON MEDICAL ASSOCIATION

October 1, 2004

Mark B. McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington D.C., 20201

RE: Prescription Drug Benefit Program; File Code CMS 4068-P

Dear Dr. McClellan:

The Oregon Medical Association (OMA) appreciates the opportunity to comment on the proposed regulations regarding the new Prescription Drug Benefit Program. The Association agrees with the preface of the rules that this program is a profound and major change for the Medicare program having significant implications for physicians, patients and dual eligible (Medicaid/Medicare) patients.

Benefit Design and Clinical Issues

The proposed rules create Prescription Drug Plans (PDP) that will use a therapeutic classification system consolidating the range of drug therapies that will be available to patients. Under the proposed rules PDP must then offer at least two drugs per class. The OMA is very concerned that the classification system will place patients and physicians in the position of not having clinically appropriate medications available for particular diseases and illnesses. Furthermore, since the federal legislation preempts state law and regulations, physicians could be vulnerable to litigation because a plan limiting the drug armamentarium available for patients might not comply with the current standard of practice.

The State of Oregon was one of the first states to adopt legislation using evidenced-based information to determine the most clinically appropriate and cost effective medications for the Medicaid program. This legislation, however, provides that physicians may prescribe medications that are not on the formulary based on their medical judgment and the clinical needs of their patient. The Medicaid program does cover the cost of the prescription even though a drug may not be on the preferred drug list. It is particularly troubling for physicians who treat patients with multiple medical problems, such as Medicaid dual eligible patients, if the new federal program forces chronically ill patients to change medications, not only in the initial implementation of the benefit, but conceivably multiple times since the rules allow changes in the formulary after a 30-day notice. Many patients will have difficulty understanding the benefit and benefit changes. The OMA is not aware of any major health insurer who uses a closed formulary.

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Pharmacy and Therapeutic Committees (P & T Committees)

A critical component for determining the scope of benefits (i.e., coverage) limitations, prior authorization, or step therapy restrictions will most likely be based on the recommendations of the P & T Committees of the PDS. The OMA believes that these regulations must be more proscriptive regarding the make-up and authority of these committees. In our opinion, the committee should be composed of a majority of physicians and pharmacists who are independent of the PDP — otherwise the validity of the extent or limitations of the benefit could be called into question based on concerns of whether the benefit design was based more on cost rather than clinical issues. In order to assure the public that the activities of the P & T Committees are based on appropriate clinical considerations, their deliberations should, to the extent reasonable, be open to the public, with public input allowed after appropriate notification prior to finalizing a benefit plan.

Drug Substitution

The preamble to the rule states that drug substitution should require approval of the treating physician. Unfortunately, the draft rule does not specifically require approval of the treating physician. Again, Oregon law has long provided that generic substitution is lawful, unless a physician specifically writes on the prescription to not substitute or says that the prescription, as written, is medically necessary. In addition, Oregon law has never authorized "therapeutic substitution." It is our opinion that it is critical that the treating physician has the authority and control over the medications of his or her patient. Not only is it appropriate in the classic physician-patient relationship, but it is the physician who is legally responsible and liable for the care the patient receives. The idea of excluding the PDP (which under the current rules, could dictate the extent of the benefit) from responsibility only places physicians and their patients in jeopardy.

The OMA strongly recommends that regarding drug substitution the regulations should stipulate that state law would prevail. The Oregon legislature has had numerous opportunities to allow therapeutic substitution but has rejected that policy because of its implications for patient care. Establishing such a policy through administrative or federal preemption will cause significant concern in the medical community.

Dual Eligible Patients

The OMA is also very concerned about the transition of dual eligible patients to Prescription Drug Plans. The preamble acknowledges that no one really knows whether there will be multiple PDP, or regional PDP, and how many pharmacies will have contracts to provide medications to patients. This could be particularly difficult in small rural areas and could be problematic in urban areas if seniors must travel a significant distance. As the rule is currently drafted, dual eligible patients will probably have to change to a new pharmacy after they are assigned to a plan. It is not a far stretch to believe that many of these patients will experience confusion and anxiety by the new program.

The timelines assumed by the program are unrealistic. For example, the rules provide that a patient has three weeks to determine if their medications are covered by the formulary. If a patient's medications are not covered by the plan they will then have to ask physicians to write new prescriptions or request an appeal. Clearly many patients will not be in a position due to medical conditions, like dementia, bipolar disease, or serious mental illness, to successfully work though the system envisioned by the proposed regulations within a three week timeframe.

The OMA urges CMS to determine a more deliberate transition process that fully considers the implications for patients, physicians and state programs that will be forced to deal with a huge surge of confused and bewildered patients who will seek assistance during the limited transition period. To work towards accomplishing this, OMA recommends that the time period for dual eligibles to select a plan (before they are enrolled automatically) be extended beyond two weeks. Additionally, we recommend that Part D plans be required to reimburse current pharmacies for current medications for **at least three months**.

Quality Assurance

The proposed rules outline a variety of quality assurance tools which, in total, could be another issue that drives physicians away from Medicare patients. For example, most state Drug Utilization Review (DUR) programs have good intentions; inevitably, cost concerns always seem to supersede concerns regarding clinical care. A number of years ago the OMA forced the DUR program to reconsider its decision on the appropriate standards for mental health drugs. Ultimately, a panel of expert physicians concluded that the OMA concern that the state was more interested in cost rather than appropriate clinical care was proven to be correct but only after the state legislators made it clear that they would exercise their authority if the program did not adopt the current standard of practice.

The draft rules also establish medication therapy management programs (a "1984" style fraud and abuse reporting program) to be administered by the plans and a provision designed to "speed up" electronic prescribing. HHS may not be aware that the fallout and cost of just implementing HIPAA has barely settled and that extensive new programs, including well-intended fraud and abuse provisions, can only cause additional consternation among those who actually provide medical services to patients and who are often required to comply, free of charge, with new untried solutions to federally and state administered health programs.

It might appear more collaborative from a physician's perspective if DHHS and CMS took steps to assure the success of the new program before it lays the ground work for additional programs that have neither been proven effective nor ready for prime time.

The OMA most certainly is aware of the importance of this program and its component parts. We hope that CMS will work with the medical community to design a system that is less complex, contains fewer pitfalls for patients and mitigates exposure to litigation and clinical second-guessing. In spite of our concerns we still believe that the program has the potential to be beneficial to millions of Medicare and Medicaid patients. It is with this optimistic view that we urge CMS to take a step back and design a system that comports to the reality of providing medical services to the elderly.

Sincerely,

John C. Moorhead, M.D.
President

CMS-4068-P-1056

Submitter : Ms. Leslie Fried **Date & Time:** 10/04/2004 06:10:43

Organization : Alzheimer's Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached files for our comments.

CMS-4068-P-1056-Attach-2.doc

CMS-4068-P-1056-Attach-3.doc

CMS-4068-P-1056-Attach-1.doc

CMS-4068-P-1057

Submitter : Mr. Eben Hopson **Date & Time:** 10/04/2004 06:10:01

Organization : Arctic Slope Native Association, Ltd.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter and comment.

CMS-4068-P-1057-Attach-1.doc

Post Office Box 1232 ● Barrow ● Alaska ● 99723 ● (907) 852-2762 ● FAX (907) 852-2763

October 4, 2004

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

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)

Dear Administrator:

On behalf of the Arctic Slope Native Association, Ltd. , I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

Eben Hopson Jr.
President/CEO

Attachment -- Part D Comments

COMMENTS REGARDING
PROPOSED REGULATIONS TO IMPLEMENT
THE MEDICARE PRESCRIPTION DRUG BENEFIT UNDER
THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND
MODERNIZATION ACT OF 2003
as published in
69 Fed. Reg. 46,632 *et seq.* (Aug. 3, 2004)
File Code CMS-4068-P

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 D's 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" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

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 D does not result in inadvertent and unintended harm to that system.

The regulations governing the Part D prescription drug benefit must be revised to achieve the following goals:

- Guarantee that AI/ANs have a meaningful opportunity to access the benefit *through the pharmacies of the Indian health delivery system*;

- Require private prescription drug plan sponsors (PDPs) and Medicare Advantage organizations offering prescription drug coverage (MA-PDs) to reimburse or contract with the pharmacies in the Indian health system -- those operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (collectively referred to as "I/T/Us");

- Order Indian-specific terms that must be included in those contracts to guarantee that I/T/U pharmacies can collect from PDPs, building on the experience gained from the Medicare Prescription Drug Discount Card program; and

- Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold

harmless" mechanism Congress established for FQHCs in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D 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 D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid 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. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. 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.

[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).

- 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.
- 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 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. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.[5]

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 IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

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.

[4] U.S. Commission on Civil Rights, A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country, July 2003.
[5] Federal Disparity Index Report for 2002, showing an expenditure of $1,384 per HIS user compared to a benchmark price of $2,687 per user.

Pharmacy Services for Dual Eligibles

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[6] and 30,544[7] 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.[8] 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**[9] **and $53.6 million**.[10] 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 rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

Barriers to Part D access of Indian dual eligibles. There are several reasons why the intended conversion of dual eligibles from Medicaid to Medicare could be extremely problematic in the Indian health system:

- Switching payment sources from Medicaid to PDPs under Part D will hurt AI/AN consumers and Indian health providers because most tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. Dual eligibles in those areas will have difficulty accessing the Part D benefit unless they use an Indian health pharmacy admitted to PDP networks.

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[6] This number represents 85 percent of the three-year total of active users.
[7] This is the number of active users, defined as at least one visit in the past three years.
[8] 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.
[9] 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.
[10] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

- Medicaid revenues have been an important source of income for Indian health facilities. **As drug coverage for AI/AN dual eligibles is removed from Medicaid and placed under Medicare, the amount of revenue in jeopardy is estimated to be between $23.8 million and $53.6 million.** Reductions in reimbursements for pharmaceuticals cannot be absorbed by raising rates for other services, as Indian patients are served without charge.

- The level of revenue an I/T/U would collect under Part D will very likely be less than it currently collects under Medicaid for dual eligible drug coverage. Therefore a "wrap around" payment from Medicare, consisting of the difference between the PDP/MA-PD contract amount and the amount the I/T/U would have received under Medicaid, must be utilized to "hold harmless" I/T/Us, if an I/T/U contracts with a PDP/MA-PD.

- If private prescription drug plans are not required to contract with I/T/U pharmacies, there will be little incentive for them to do so, as the service population of these pharmacies is comparatively small and the Indian population tends to be sicker. Without network status or payment for off plan services, an I/T/U pharmacy will not be able to collect for drugs dispensed to any AI/AN enrolled in a Part D plan. This would produce three negative results: (1) a loss of revenue to the I/T/U pharmacy; (2) no meaningful opportunity for the enrolled Indian to use his Part D benefit; and (3) a windfall for the PDP who collects premiums from CMS for a dual eligible, but pays no claims.

- Even if private plans are required to contract with I/T/U pharmacies, this command will be meaningless unless the regulations set out terms specifically drafted to address the unique circumstances of the IHS, tribal and urban Indian pharmacies.

- Even if an Indian beneficiary is enrolled in a Part D plan, the I/T/U pharmacy may not know what PDP or MA-PD to bill. Particularly with automatic enrollments, the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delay in accessing the benefit if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. This situation mirrors the disastrous consequences suffered by the I/T/Us when State mandatory Medicaid managed care enrollment programs were implemented.

- If delays in implementation occur, it is not clear how the I/T/U pharmacies will recoup payment for expenditures made during the period between when the AI/AN is switched from Medicaid to Medicare pharmacy benefits and when the I/T/U pharmacy is an established network provider or able to bill for out of network services. Even if the I/T/U pharmacy is allowed to bill for services provided from the beginning of 2006, they may not have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

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 by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS
Comments regarding: Section 423.120: Pharmacy Access Standards

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To guarantee access to Part D prescription drug benefits for AI/AN beneficiaries by requiring private drug plans to contract with those pharmacies which serve the majority of this population -- I/T/U pharmacies.

Access Issue, Pages 46655-57: Should CMS use its authority under Section 1860D-4(b)(1)(C)(iv) of the Act (authorizing the Secretary to establish standards to provide access for I/T/U pharmacies to participate in the Part D program) to *require* or *strongly encourage* private drug plan sponsors (PDPs) and MA organizations offering MA-PD plans (MA-PDs) to contract with I/T/U pharmacies?

Comment: In order to realize its goals (as communicated on pages 46655 and 46633 of the Preamble) of ensuring convenient access to covered Part D drugs to plan enrollees and broad participation by Medicare beneficiaries in the new prescription drug benefit under Part D, CMS must use its authority under Section 1860D-4(b)(1)(iv) of the Act to **require** PDPs and MA-PDs to contract with I/T/U pharmacies. Without this requirement the private drug plans will have little or no incentive to contract with I/T/U pharmacies.[11] This is true because there is no financial incentive for private plans to contract with I/T/U pharmacies since these pharmacies and the AI/AN beneficiaries they serve are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. If PDPs and MA-PDs are merely "*strongly encouraged"* to contract with I/T/Us[12] they will not do so because of the uniqueness and remoteness of Indian health programs the comparatively small and sicker populations they serve, and the perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.[13]

Failure to include language in the rule requiring private plans to contract with I/T/U pharmacies will have the unintended consequence of *denying* access to the benefit for a majority of AI/AN beneficiaries. This would be contrary to the access requirements of the Act. If I/T/U pharmacies are not included in the PDP or MA-PD network, an estimated 26,000 AI/AN beneficiaries who obtain their drugs from I/T/U

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[11] Allowing the private plans to count I/T/U pharmacies toward access standards may provide incentive for private plans to contract with a few I/T/U pharmacies but only where the private plan needs the I/T/U pharmacy to meet the Tricare access standards. It will not be an incentive to contract with all I/T/U pharmacies.

[12] CMS proposes this option in 69 FR at 46657.

[13] One way to decrease administrative costs while at the same time assuring access for AI/AN beneficiaries who use I/T/U pharmacies is to create special endorsement PDPs and MA-PDs to serve AI/AN beneficiaries similar to the mechanism used in the Temporary Prescription Drug Discount Card Program. This matter is discussed further in our comments regarding §423.120(a)(1).

pharmacies will be unable to access the Part D drug benefit. CMS acknowledges this fact on page 46657 of the Preamble by stating that I/T/U pharmacies may be the only facilities available to AI/AN beneficiaries and recognizes that **access to I/T/U pharmacies should be preserved** because it "would greatly enhance Part D benefits" for AI/AN enrollees.

Access for I/T/U pharmacies to the Part D program is crucial for preserving current revenues. All AI/ANs dual eligibles will lose their Medicaid drug benefits and are required to enroll in a Part D or Part C plan. Those dual eligible who fail to enroll will be automatically enrolled in a private plan. Regardless of such a beneficiary's enrollment in the new prescription drug benefit, an AI/AN beneficiary will continue to utilize his/her I/T/U pharmacy. Absent an agreement with the private drug plans, these pharmacies will be unable to collect reimbursement for prescription dispensed to Medicare beneficiaries. In order for I/T/Us to collect reimbursement for prescription drugs provided to dual eligibles **they must be included in the private plan network.**

Therefore, it is vital that Section 423.120 be modified to include language requiring PDPs and MA-PDs to contract with I/T/U pharmacies, but required contracting is not enough. The unique status of tribes may become an issue in contract negotiations. The standard PDP/MA-PD contract could prove problematic for I/T/Us as CMS acknowledged in the Preamble on page 46657. In order to assist CMS, PDPs, and MA-PDs in resolving this difficulty, we urge that specific contract provisions, which are contained in the draft language below, be required provisions for agreements between PDPs/MA-PDs and I/T/U pharmacies.[14]

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) *Assuring pharmacy access*.

Insert the following new paragraph and re-number all subsequent paragraphs:

"(2) *Access to IHS, tribal and urban Indian pharmacies.* In order to meet access standards under Section 1860D-4(b)(1)(C)(iv), a prescription drug plan or MA-PD plan must offer to contract with any I/T/U pharmacy in its plan service areas, and such contract must include the elements set out in §423.120(a)(4)."

§423.120(a)(4) *Pharmacy network contracting requirements*.

Insert the following new subparagraph (iv):

"(iv) Must incorporate in all contracts entered into with I/T/U pharmacies, within the text of the agreement or as an addendum, provisions that:

(A) Acknowledge 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) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal

[14] We submit as Attachment 1 a model tribal addendum prepared by the CMS Tribal Technical Advisory Group to be utilized by tribal and urban Indian pharmacies participating in the Temporary Prescription Drug Discount Card Program.

Regulations; and the terms of the contract, compact or grant issued to the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.

(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including 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) Recognize that I/T/Us are non-taxable entities.

(E) State that IHS, tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.

(F) State that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.

(G) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.

(H) State that an I/T/U pharmacy is not subject to the PDP formulary.

(I) State that the Agreement may not restrict access the I/T/U pharmacy otherwise has to purchase drugs from the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act.

(J) State that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.

(K) Authorize I/T/U pharmacies to establish their own hours of service."

REGULATIONS MUST PROVIDE A MECHANISM TO ASSURE NO REUDCTION IN REVENUES TO I/T/U PHARMACIES

Comments regarding: §423.120: Access to covered Part D drugs and §423.124: Special rules for access to covered Part D drugs at out-of-network pharmacies

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To include in the regulation a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. We provide four options in our comments to achieve this goal:

ption 1: *In-Network Status + Wrap-Around Payment*. One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network providers and for CMS to provide "a wrap-around payment" modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.

ption 2: *Out of Network Status + Wrap-Around Payment.* In the event that I/T/U pharmacies are not treated as in-network pharmacies, they should be recognized as out-of-network pharmacies eligible for reimbursement from the private plan under §423.124 and receive a supplemental "wrap around" payment from the federal government which would include any increased differential in cost sharing related to use of out of network pharmacies. This supplemental payment would provide reimbursement for the difference between the out of network plan payment and the amount the I/T/U would have received as an in network provider.

ption 3: *Special Endorsement PDP/MA-PD Plans*. Specific PDPs could be designated to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Benefit Discount Card program.

ption 4: *Exemption of AI/AN Dual Eligibles.* Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid. This alternative would allow CMS to avoid the complicated issues of access and revenue loss that we discussed throughout these comments.

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. 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. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for **AI/AN dual eligibles drug costs ranges between $23.8 million[15] and $53.6 million.[16]** 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 rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

We propose that one of the four "hold harmless" provision options be included in the regulation to maintain the current level of revenue I/T/U pharmacies receive under Medicaid.

Option 1: In-Network Status with Wrap-Around Payment

While it would be the responsibility of CMS to establish ways to prevent loss of revenue at I/T/U pharmacies, we propose that CMS:

(a) Require all PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the appropriate rate[17], ***and***

[15] 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.

[16] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

[17] 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."

(b) Provide a "wrap around" payment for drug coverage services similar to the special payment rules for medical services provided at federally qualified health centers (FQHCs) contained in Section 237 of the MMA.

Reimbursement as In-network Provider. We request that the regulations require PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the Medicaid rates. This provision would prevent agreements in which the PDP/MA-PD agrees to pay an artificially low rate to the I/T/U pharmacy, with the knowledge that the I/T/U pharmacy will receive supplemental payments from CMS.

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a "wrap-around payment" to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

We suggest that the following provision or ones similar in nature be added to the Part D rules:

Section 423.120(a)(1): *Convenient access to network pharmacies.*

***

"§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy."

The following language should be inserted into Part 423 at the appropriate place:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 2: Out of Network Status with Wrap-Around Payment

In the even that I/T/U pharmacies are not recognized as in-network providers under Option 1, we propose that the regulations recognize these pharmacies as out of network providers under §423.124 and provide a wrap-around payment to supplement the difference between the out of network reimbursement rate and the Medicaid rate.

We suggest that the following sentence be added to Sec. 423.124(a):

Section 423.124(a) ***

"An I/T/U pharmacy that dispenses covered Part D drugs to an American Indian/Alaska Native beneficiary shall be considered an out of network pharmacy for payment of claims."

Additionally, the following provision should be included in Part 423:

§**423.___**. **Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.**

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 3: Special Endorsements with Wrap-Around Payment

Designating private plans to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Discount Card program is an alternative that could encourage PDP contracting with I/T/U pharmacies. Specifically identifying the PDP serving AI/AN will help I/T/Us to identify and bill the correct PDP or MA-PD. Additionally, designating specific PDPs and MA-PDs to contract with I/T/U pharmacies would allow an AI/AN beneficiary to easily identify which plan includes his/her I/T/U pharmacy, avoiding the need for the individual to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. Of course, to ensure that I/T/U revenues do not decrease under this option, the wrap-around payment provision discussed above would be necessary. Designation of specific PDPs would also facilitate development of specific I/T/U contract terms.

If CMS is unable to secure private plans to offer the benefit, then it could either subsidize the benefit or provide a "fall back" plan as authorized by Section 1860D-2(b) of the MMA. The Part D proposed regulations depend on the private market to drive the benefit; however, because of the unique characteristics of Indian health programs, private plans may not have incentive or interest in serving a predominately low-income population. Establishing specific PDPs and MA-PDs to serve the AI/AN population is entirely feasible since PDP and MA-PD regions have yet to be established.[18]

Option 4: Exemption of AI/AN Dual Eligible Individuals from Part D

We offer an alternative that would allow CMS to avoid the complicated issues of access in Section 423.120, revenue loss to I/T/Us and the "wrap around" mechanism discussed on page 11 of these comments -- **Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid**.

We believe that exempting AI/AN dual eligibles from mandatory enrollment is an efficient and effective alternative for the following reasons:

- Exemption of AI/AN dual eligibles from mandatory enrollment will prevent any loss of revenue to I/T/U pharmacies that will result if drug coverage for dual eligibles is switched from Medicare to Medicaid.

[18] In creating special endorsements for AI/AN CMS could establish:
- A pool of Indian-specific PDP/MA-PD who would serve regions that mirror IHS Areas, or
- Nationwide PDPs/MA-PDs to serve AI/AN in all fifty states

- Exemption of AI/AN dual eligibles will eliminate the barriers dual eligibles, as well as AI/AN basic beneficiaries, will face in accessing the Part D benefit. For example, the MMA strategy to use private plans as a vehicle to provide prescription drug benefits severely restricts access for many AI/ANs because tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks.
- Exemption of AI/AN dual eligibles from mandatory enrollment will eliminate the detrimental impact on reimbursement levels and the increase administrative costs that will occur when the I/T/U pharmacy does not know what PDP or MA-PD to bill. This is particularly true with regard to automatic enrollments because the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

It is important to recognize that exempting AI/AN dual eligibles from mandatory participation in Part D thereby allowing them to continue to receive prescription drug coverage through the State Medicaid Program will have **no budget impact.** This is so because prescription drug coverage costs will be paid by the federal government regardless of whether the benefit is provided under Medicaid at 100% FMAP or Medicare Part D subsidy for dual eligibles.

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)

Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems

Goal: *To ensure that I/T/U pharmacies that participate in PDP pharmacy networks continue to have the option of purchasing prescription drugs for AI/AN Medicare beneficiaries at Federal Supply Schedule (FSS) prices or at the discounts available under the 340B program.*

Terms and Conditions Issue, Page 46658: CMS notes that the proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network. CMS seeks comment on whether it should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.

Comment: As the Preamble recognizes, there are 201 I/T/U pharmacies serving 107,000 elderly and disabled AI/ANs in 27 states (page 46657). These pharmacies currently have access to Federal Supply Schedule (FSS) prices for the prescription drugs they dispense to AI/AN Medicare beneficiaries, or they are covered entities entitled to discounts under the 340B program, 42 U.S.C. 256b, or both. These discounted prices reflect the purchasing leverage of the Federal government and have enabled I/T/U pharmacies to meet the needs of AI/AN beneficiaries, whether or not enrolled in Medicare, in a cost-efficient manner.

We are concerned that PDP sponsors and MA organizations offering an MA-PD plan may require participating pharmacies to purchase drugs through the PDP sponsor or MA organization. This could have the effect of forcing I/T/U pharmacies to choose between participating in Medicare Part D and retaining their current access to FSS prices or 340B discounts, or both. We do not believe Congress intended that I/T/U pharmacies be forced into this choice. We therefore propose that the final rule prohibit PDP sponsors or MA organizations from requiring I/T/U pharmacies to purchase drugs through mechanisms other than FSS or the 340B program. This would not preclude an I/T/U pharmacy that wished to do so from purchasing its drugs through the PDP or MA-PD plan. The option, however, would be that of the I/T/U pharmacy, not the PDP or MA-PD plan.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans should be revised to read as follows (modifications are *italicized*):

"(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;
(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; *and*
(iii) May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b. "

FORMULARY

Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements.

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule.

Goal: *I/T/*Us *should be exempt from formulary requirements and therefore able to utilize permissible substitutes. This exemption is needed to both accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries and to allow I/T/Us to include in their formulary of drugs for which reimbursement will be paid those drugs available through FSS or 340b.*

Comment: Section 423.120(b)(1) permits PDP and MA-PD plans to develop formularies so long as they meet the requirements of this section. We are concerned that plans that develop such formularies will make stocking the drugs in the formulary a requirement of its contracts with participating pharmacies. Many I/T/U pharmacies are small and cannot stock a full range of drugs, particularly if the condition the drug is used to treat is one beyond the scope of the I/T/U clinic and its providers. When establishing their formularies, I/T/U hospital and clinic pharmacies also consider aspects of treatment that may not be generally important, such as the extent of monitoring of the patient that may be required. Since many patients live far from the I/T/U pharmacy, this is an important therapeutic factor. Another factor in whether the I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principle sources of drugs purchased by I/T/U pharmacies. *See* "I/T/U Pharmacies and Federal Supply Schedule (FSS)."

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans in Section 423.120(a)(4) should be further revised to add a new paragraph (iv) to read as follows (new language is *italicized*):

  (v) May not require an I/T/U pharmacy to provide all the drugs in any formulary that may have been adopted by the PDP or MA-PD.

  AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U pharmacies are often the only pharmacy providers (page 46657). It is unfair to the AI/AN beneficiaries and to I/T/U providers to limit reimbursement or increase co-pays when a beneficiary is prescribed a drug that is not on the PDP or MA-PD formulary when that may be the only drug available from the I/T/U pharmacy that provides the same therapeutic effect as the formulary drug. In such cases, the PDP or MA-PD should be required to reimburse the I/T/U as if the drug were on its formulary in an amount equal to that the PDP or MA-PD would have paid for an equivalent drug on its formulary. In this way, neither the PDP or MA-PD or the I/T/U pharmacy is disadvantaged financially, and the patients are able to maintain access and continuity of care.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (v) to read as follows (new language is *italicized*):

  (vi) Must provide for reimbursement to I/T/U pharmacies for all covered Part D drugs whether or not they are on the PDP's or MA-PD's formulary at an amount not lower than the reimbursement that would have been made for an equivalent drug on the formulary.

BENEFITS AND BENEFICIARY PROTECTIONS
Comments on Section 423.100: DEFINITIONS
"Insurance or otherwise" for purposes of "Incurred costs"

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *To ensure that expenditures by I/T/Us on AI/AN beneficiaries (who do not qualify for the cost-sharing subsidy for low-income individuals) on prescription drugs count toward the annual out-of-pocket threshold ($3,600 in 2006).*

Incurred Cost Issue, Pages 46649-46651: CMS notes that, under the proposed rule, AI/AN Medicare beneficiaries who are not eligible for low-income cost-sharing subsidies may receive drug coverage directly from I/T/U pharmacies or under CHS referrals. While these payments will count toward the AI/AN beneficiary's annual deductible, they will not count as incurred cost toward meeting the out-of-pocket threshold ($3,600 in 2006). The reason, in brief, is that "incurred costs" are defined by section 1860D-2(b)(4)(C)(ii) of the Social Security Act to exclude payments by "insurance or otherwise." But this statutory provision does not expressly include the I/T/U programs in this term. Rather, it is CMS, not the law that has defined what is encompassed by the term "insurance or otherwise". The agency has chosen to include I/T/U health programs as "insurance or otherwise," -- but has not explained the basis for that decision, nor

analyzed the impacts of it on the IHS-funded system and affected Indian Medicare beneficiaries, nor acknowledged that failing to count I/T/U pharmacy contributions toward "incurred costs" would be a windfall to the PDP in which an affected Indian is enrolled. Perhaps CMS recognized that this matter requires additional thought, as it asks for comments on "how … IHS beneficiaries will achieve maximized participation in Part D benefits."

Comment: The effect of CMS's decision to treat I/T/U programs as "insurance or otherwise" is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, "most IHS beneficiaries would almost never incur costs above the out-of-pocket limit." (69 FR at 46657). And, as CMS further recognizes, this policy "would likely provide plans with additional cost-savings." (69 FR at 46657). We do not believe that Congress intended Part D to be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as "incurred costs." By using the phrase "not reimbursed by insurance or otherwise," Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not "reimbursed" by their IHS or tribal health care providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. "fulfills the Secretary's unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes." In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

The proposed rule, however, does not recognize this "unique" legal relationship. Instead, the proposed rule would require those AI/ANs who are Medicare beneficiaries but who are not eligible for the low-income subsidy program to pay substantial amounts out of pocket for their Medicare prescription drug coverage in order to meet the out-of-pocket threshold. In this way, the proposed rule violates the federal trust responsibility, under which AI/ANs are entitled to needed health care services, including prescription drugs, at the federal government's expense.

Section 1860D-2(b)(4)(C)(ii) specifies that costs shall be treated as incurred if they are paid "by another person, *such as* a family member, on behalf of the individual." (*emphasis added*). In the "unique relationship" between the federal government and AI/ANs, the I/T/Us are the functional equivalent of a "family member." Their mission, on behalf of the federal government, is to pay for prescription drugs and other health care services needed by AI/ANs. In terms of paying for prescription drugs, there is no functional difference between I/T/Us fulfilling their obligations to AI/ANs and family members fulfilling their obligations to one other. Again, there is nothing in the concept of family members paying incurred costs to suggest that Congress somehow intended that payments by I/T/Us on behalf of AI/ANs not be treated as incurred costs.

In the preamble, CMS explains that contributions made by charities would be considered "incurred costs" and describes in detail the reasons for a desirable objectives achieved by this decision. Many of the considerations recited there apply to the I/T/U system, particularly the outcome that Medicare beneficiaries who are not eligible for the low-income subsidy would be able to qualify sooner for the catastrophic coverage level. In other words, these beneficiaries would have a better opportunity to fully utilize their Part D benefit.

The outcome is just the reverse with regard to an Indian not eligible for subsidy who is served by an I/T/U pharmacy. That Medicare beneficiary would have to pay the same premium for Part D coverage (or have it paid on his behalf by the I/T/U program as CMS suggests at p. 46651), but the benefit received for that premium would be only slightly more than $1000 -- far lower than that of a non-Indian beneficiary. This is so because this Indian patient would never get out of the "donut hole" and thus would never be able to utilize the catastrophic coverage feature of the Part D benefit.

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

Section 423.100-"Insurance or otherwise" for purposes of "Incurred Costs"

The definition of "insurance or otherwise" used to define "incurred costs" for purposes of meeting the out-of-pocket threshold should be revised to read as follows (modifications are *italicized*):

"Insurance or otherwise" means a plan (other than a group health plan) or program *(other than a health program operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act , 25 U.S.C. 1603)*, that provides, or pays the cost of, medical care…, including any of the following: …(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals *(other than American Indians or Alaska Natives or urban Indians as those terms are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603)*."

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL
Comments regarding Section 423.286 Rules regarding premiums.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Tribes/Tribal Health Programs should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.*

Comment: We urge CMS to include I/T/U and/or tribes as permissible payment options and to remove barriers tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules. Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, would elect to pay premiums themselves.

AI/ANs served in an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the IHS based on the Federal Government's obligation to federally recognized Tribes. CMS recognizes this in the Preamble, page 46651, by stating that "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits". It is unlikely that AI/ANs, who are entitled to health care without cost sharing, would elect to pay premiums themselves, therefore, we request that language be included in the regulations recognizing the ability of I/T/Us to pay premiums if they so choose.

WAIVER OF COST SHARING
Comments on Background at 46651 and Section 423.120(a)(4)

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule and Formulary.

Goal. *Assure that I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B (b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.*

Comment: As discussed in the Preamble, the AI/AN beneficiaries receive health services under a unique government-to-government relationship between the United States and Tribes (page 46651). Under this relationship most care is provided directly by or through contract health services administered by I/T/U providers who provide the care without cost to the AI/AN beneficiary. The benefit plans provided under Medicare Part D contemplate patients sharing in the cost of the care they are provided. This is antithetical to the relationship between AI/AN beneficiaries and their I/T/U pharmacies.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (vi) to read as follows (new language is *italicized*):

(vii) *Must authorize I/T/U pharmacies to waive all cost sharing obligations of AI/AN beneficiaries.*

CREDITABLE COVERAGE
Comments Regarding Section 423.56: Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *IHS coverage should be deemed "credible coverage" therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.*

Comment: The CMS TTAG strongly supports the decision of CMS to include in the definition of Creditable Prescription Drug Coverage a "medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U)" in the Medicare Prescription Drug Benefit Proposed Rule at § 423.56(a)(9). The Indian Health Service, Tribe or Tribal organizations, or Urban Indian organizations currently provide pharmaceuticals to AI/AN beneficiaries, either through direct care services or IHS Contract Health Services (CHS), at no cost to the beneficiary. For purposes of not being subject to late

enrollment penalties, this Proposed Rule will protect those AI/AN beneficiaries who might not initially enroll in Medicare Part D because, for example, they receive their pharmaceuticals from an I/T/U pharmacy but later relocate off reservation and therefore need prescription drug coverage under Medicare Part D.

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

EXCLUDE CERTAIN INDIAN-SPECIFIC INCOME AND RESOURCES FOR CONSIDERATION OF ELIGIBILITY OF AMERICAN INDIANS AND ALASKA NATIVES FOR LOW-INCOME SUBSIDIES

Comments regarding Section 423.772: Premiums and Cost Sharing Subsidies for Low-Income Individuals-Definitions

Goal*:* To exclude from the income and resources tests for determination of an American Indian or Alaska Native (AI/AN) Medicare beneficiary's eligibility for a low-income subsidy under Part D certain income and assets that are excluded from consideration when determining eligibility for Medicaid.

Comment. CMS has recognized that certain Indian-specific income and assets are to be excluded when determining the eligibility of an AI/AN for Medicaid. *See, e.g.,* CMS State Medicaid Manual Part 3 -- Eligibility, §3810. These same exclusions should apply to the determination of whether an AI/AN qualifies for a low-income subsidy under Part D. Since all dual eligibles will be moved from Medicaid to Part D for prescription drug coverage, it is appropriate that the same federally-established exclusions should apply to the affected AI/AN dual eligibles.

In **Sec. 423.772,** the definitions of "income" and "resources" should be revised to exclude income that derives from tribal lands and other resources currently held in trust status, from judgment funds awarded by the Indian Claims Commission and the U.S. Claims Court, and from other property held in a protected status, as specified in the Medicaid Manual. In addition, cultural objects, as specified in the Medicaid Manual, should also be exempted from the definitions of these terms.

ELIGIBILITY AND ENROLLMENT

Comments regarding Section 423.48: Information about Part D.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.*

Comment: Without outreach, education and enrollment assistance from Indian health programs, AI/AN are unlikely to enroll in Medicare Part D or Part C. AI/AN are entitled to receive free health care at I/T/Us and

through Contract Health Services, thus they have no incentive to enroll in programs requiring premiums and cost sharing. I/T/Us know who may be eligible for new Medicare programs and how to contact them. AI/ANs trust I/T/U health workers. Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to I/T/U at no cost. As CMS states on Page 46642 of the Preamble, "we would undertake special outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate." In implementing this provision CMS must reach out to AI/AN beneficiaries.

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Plan" or Plan Sponsor") and _____ (herein "Provider") for administration of Transitional Assistance under the Prescription Drug Discount Card program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 at pharmacies and dispensaries of Provider. To the extent that any provision of the Special Endorsed Plan Master Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Special Endorsed plan Master Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Plan Sponsor" means _____ which operates the Prescription Drug Discount Card Plan defined in subsection (b).

(b) The terms "Prescription Drug Discount Card Plan" and "Plan" means a Prescription Drug Discount Card Plan operated by Plan Sponsor that is approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and holds a special endorsement from CMS to administer the Transitional Assistance feature of the Prescription Drug Discount Card program at pharmacies or dispensaries operated by the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations (hereafter "I/T/U endorsement").

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Co-pays, deductibles.

The parties agree that the Provider may waive any co-payments for any Indian who is enrolled in the Plan when such Indian receives services pursuant to the Plan at any pharmacy or dispensary of Provider.

5. Persons eligible for services of Provider.

(a)The parties agree that the persons eligible for services of the Provider under the Special Endorsed Plan Master Agreement and all addenda thereto shall be governed by the following authorities:

(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations
(2) Sec. 813 of the Indian Health Care Improvement Act, 25 USC §1680c
(3) Part 136 of Title 42, Code of Federal Regulations
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Special Endorsed Plan Master Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.;*
(2) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

Provider is a non-taxable entity and as such shall not be required by Plan or Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. A Provider which is an urban Indian organization which holds designation as a Federally Qualified Health Center shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify Plan or Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located, and shall be deemed qualified to provide services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided that such employee is currently licensed to practice pharmacy in any State. To the extent that any State exempts from state regulation a direct employee of Provider, such employee shall be deemed qualified to perform services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements pursuant to 42 CFR §431.110, the Provider shall not be required to hold a State license to receive any payments under the Special Endorsed Plan Master Agreement and any addendum thereto.

11. Re-Enrollment Period.

The Centers for Medicare and Medicaid Services has established as a matter of policy that an enrollee eligible for services from an I/T/U pharmacy shall be permitted to disenroll from a prescription drug discount card plan that does not hold a special I/T/U endorsement and to re-enroll in a plan that has received such endorsement at any time during the life of the Medicare Drug Discount Drug Card Program. Nothing in the Special Endorsed Plan Master Agreement or any other addendum thereto shall be interpreted to impede this right of re-enrollment.

12. Dispute Resolution.

Any dispute arising under the Special Endorsed Plan Master Agreement or any other addendum thereto shall be resolved through negotiation rather than arbitration. The parties agree to meet and confer in good faith to resolve any such disputes.

13. Governing Law.

The Special Endorsed Plan Master Agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between the Special Endorsed Plan Master Agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

14. Pharmacy/Dispensary Participation.

The Special Endorsed Plan Master Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum.

15. Acquisition of Pharmaceuticals.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in the Special Endorsed Plan Master Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

16. Formulary.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's formulary. The Provider is exempt from any provision of the Special Endorsed Plan Master Agreement and all addenda thereto requiring compliance or cooperation with the Plan Sponsor's or Plan's formulary, drug utilization review, generic equivalent substitution, and notification of price differentials.

17. Transitional Assistance Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim. When the toll-free number is used for non-electronic claims, Plan will verify the balance of an enrollee's Transitional Assistance subsidy remaining as of that time and obligate funds from that subsidy for payment of the Provider's claim at the point of sale. Instructions for filing and adjudicating non-electronic claims are attached as Schedule C.

18. Payment Rate.

Claims from the Provider for Transitional Assistance benefits shall be paid at the same rates as the State Medicaid program fee-for-service in the State where the Provider's pharmacy or dispensary is located, pursuant to Schedule A of this Addendum.

19. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Plan shall be supplied by Plan to Provider in paper and electronic format at no cost to the Provider. Provider shall have the right to convert such materials as it deems necessary for language or cultural appropriateness.

20. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Plan, Provider shall provide written notification of its hours of service to the Plan.

Post Office Box 1232 ● Barrow ● Alaska ● 99723 ● (907) 852-2762 ● FAX (907) 852-2763

October 4, 2004

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

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)

Dear Administrator:

On behalf of the Arctic Slope Native Association, Ltd. , I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

Eben Hopson Jr.
President/CEO

Attachment -- Part D Comments

COMMENTS REGARDING
PROPOSED REGULATIONS TO IMPLEMENT
THE MEDICARE PRESCRIPTION DRUG BENEFIT UNDER
THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND
MODERNIZATION ACT OF 2003
as published in
69 Fed. Reg. 46,632 *et seq.* (Aug. 3, 2004)
File Code CMS-4068-P

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 D's 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" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

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 D does not result in inadvertent and unintended harm to that system.

The regulations governing the Part D prescription drug benefit must be revised to achieve the following goals:

- Guarantee that AI/ANs have a meaningful opportunity to access the benefit *through the pharmacies of the Indian health delivery system*;

- Require private prescription drug plan sponsors (PDPs) and Medicare Advantage organizations offering prescription drug coverage (MA-PDs) to reimburse or contract with the pharmacies in the Indian health system -- those operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (collectively referred to as "I/T/Us");

- Order Indian-specific terms that must be included in those contracts to guarantee that I/T/U pharmacies can collect from PDPs, building on the experience gained from the Medicare Prescription Drug Discount Card program; and

- Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold

harmless" mechanism Congress established for FQHCs in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D 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 D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid 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. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. 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.

[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).

- 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.
- 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 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. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.[5]

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 IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

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.

[4] U.S. Commission on Civil Rights, A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country, July 2003.
[5] Federal Disparity Index Report for 2002, showing an expenditure of $1,384 per HIS user compared to a benchmark price of $2,687 per user.

Pharmacy Services for Dual Eligibles

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[6] and 30,544[7] 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.[8] 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**[9] **and $53.6 million**.[10] 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 rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

Barriers to Part D access of Indian dual eligibles. There are several reasons why the intended conversion of dual eligibles from Medicaid to Medicare could be extremely problematic in the Indian health system:

- Switching payment sources from Medicaid to PDPs under Part D will hurt AI/AN consumers and Indian health providers because most tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. Dual eligibles in those areas will have difficulty accessing the Part D benefit unless they use an Indian health pharmacy admitted to PDP networks.

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[6] This number represents 85 percent of the three-year total of active users.
[7] This is the number of active users, defined as at least one visit in the past three years.
[8] 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.
[9] 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.
[10] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

- Medicaid revenues have been an important source of income for Indian health facilities. **As drug coverage for AI/AN dual eligibles is removed from Medicaid and placed under Medicare, the amount of revenue in jeopardy is estimated to be between $23.8 million and $53.6 million.** Reductions in reimbursements for pharmaceuticals cannot be absorbed by raising rates for other services, as Indian patients are served without charge.

- The level of revenue an I/T/U would collect under Part D will very likely be less than it currently collects under Medicaid for dual eligible drug coverage. Therefore a "wrap around" payment from Medicare, consisting of the difference between the PDP/MA-PD contract amount and the amount the I/T/U would have received under Medicaid, must be utilized to "hold harmless" I/T/Us, if an I/T/U contracts with a PDP/MA-PD.

- If private prescription drug plans are not required to contract with I/T/U pharmacies, there will be little incentive for them to do so, as the service population of these pharmacies is comparatively small and the Indian population tends to be sicker. Without network status or payment for off plan services, an I/T/U pharmacy will not be able to collect for drugs dispensed to any AI/AN enrolled in a Part D plan. This would produce three negative results: (1) a loss of revenue to the I/T/U pharmacy; (2) no meaningful opportunity for the enrolled Indian to use his Part D benefit; and (3) a windfall for the PDP who collects premiums from CMS for a dual eligible, but pays no claims.

- Even if private plans are required to contract with I/T/U pharmacies, this command will be meaningless unless the regulations set out terms specifically drafted to address the unique circumstances of the IHS, tribal and urban Indian pharmacies.

- Even if an Indian beneficiary is enrolled in a Part D plan, the I/T/U pharmacy may not know what PDP or MA-PD to bill. Particularly with automatic enrollments, the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delay in accessing the benefit if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. This situation mirrors the disastrous consequences suffered by the I/T/Us when State mandatory Medicaid managed care enrollment programs were implemented.

- If delays in implementation occur, it is not clear how the I/T/U pharmacies will recoup payment for expenditures made during the period between when the AI/AN is switched from Medicaid to Medicare pharmacy benefits and when the I/T/U pharmacy is an established network provider or able to bill for out of network services. Even if the I/T/U pharmacy is allowed to bill for services provided from the beginning of 2006, they may not have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

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 by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS
Comments regarding: Section 423.120: Pharmacy Access Standards

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To guarantee access to Part D prescription drug benefits for AI/AN beneficiaries by requiring private drug plans to contract with those pharmacies which serve the majority of this population -- I/T/U pharmacies.

Access Issue, Pages 46655-57: Should CMS use its authority under Section 1860D-4(b)(1)(C)(iv) of the Act (authorizing the Secretary to establish standards to provide access for I/T/U pharmacies to participate in the Part D program) to *require* or *strongly encourage* private drug plan sponsors (PDPs) and MA organizations offering MA-PD plans (MA-PDs) to contract with I/T/U pharmacies?

Comment: In order to realize its goals (as communicated on pages 46655 and 46633 of the Preamble) of ensuring convenient access to covered Part D drugs to plan enrollees and broad participation by Medicare beneficiaries in the new prescription drug benefit under Part D, CMS must use its authority under Section 1860D-4(b)(1)(iv) of the Act to **require** PDPs and MA-PDs to contract with I/T/U pharmacies. Without this requirement the private drug plans will have little or no incentive to contract with I/T/U pharmacies.[11] This is true because there is no financial incentive for private plans to contract with I/T/U pharmacies since these pharmacies and the AI/AN beneficiaries they serve are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. If PDPs and MA-PDs are merely "*strongly encouraged"* to contract with I/T/Us[12] they will not do so because of the uniqueness and remoteness of Indian health programs the comparatively small and sicker populations they serve, and the perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.[13]

Failure to include language in the rule requiring private plans to contract with I/T/U pharmacies will have the unintended consequence of *denying* access to the benefit for a majority of AI/AN beneficiaries. This would be contrary to the access requirements of the Act. If I/T/U pharmacies are not included in the PDP or MA-PD network, an estimated 26,000 AI/AN beneficiaries who obtain their drugs from I/T/U

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[11] Allowing the private plans to count I/T/U pharmacies toward access standards may provide incentive for private plans to contract with a few I/T/U pharmacies but only where the private plan needs the I/T/U pharmacy to meet the Tricare access standards. It will not be an incentive to contract with all I/T/U pharmacies.

[12] CMS proposes this option in 69 FR at 46657.

[13] One way to decrease administrative costs while at the same time assuring access for AI/AN beneficiaries who use I/T/U pharmacies is to create special endorsement PDPs and MA-PDs to serve AI/AN beneficiaries similar to the mechanism used in the Temporary Prescription Drug Discount Card Program. This matter is discussed further in our comments regarding §423.120(a)(1).

pharmacies will be unable to access the Part D drug benefit. CMS acknowledges this fact on page 46657 of the Preamble by stating that I/T/U pharmacies may be the only facilities available to AI/AN beneficiaries and recognizes that **access to I/T/U pharmacies should be preserved** because it "would greatly enhance Part D benefits" for AI/AN enrollees.

Access for I/T/U pharmacies to the Part D program is crucial for preserving current revenues. All AI/ANs dual eligibles will lose their Medicaid drug benefits and are required to enroll in a Part D or Part C plan. Those dual eligible who fail to enroll will be automatically enrolled in a private plan. Regardless of such a beneficiary's enrollment in the new prescription drug benefit, an AI/AN beneficiary will continue to utilize his/her I/T/U pharmacy. Absent an agreement with the private drug plans, these pharmacies will be unable to collect reimbursement for prescription dispensed to Medicare beneficiaries. In order for I/T/Us to collect reimbursement for prescription drugs provided to dual eligibles **they must be included in the private plan network.**

Therefore, it is vital that Section 423.120 be modified to include language requiring PDPs and MA-PDs to contract with I/T/U pharmacies, but required contracting is not enough. The unique status of tribes may become an issue in contract negotiations. The standard PDP/MA-PD contract could prove problematic for I/T/Us as CMS acknowledged in the Preamble on page 46657. In order to assist CMS, PDPs, and MA-PDs in resolving this difficulty, we urge that specific contract provisions, which are contained in the draft language below, be required provisions for agreements between PDPs/MA-PDs and I/T/U pharmacies.[14]

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) *Assuring pharmacy access*.

Insert the following new paragraph and re-number all subsequent paragraphs:

"(2) *Access to IHS, tribal and urban Indian pharmacies.* In order to meet access standards under Section 1860D-4(b)(1)(C)(iv), a prescription drug plan or MA-PD plan must offer to contract with any I/T/U pharmacy in its plan service areas, and such contract must include the elements set out in §423.120(a)(4)."

§423.120(a)(4) *Pharmacy network contracting requirements*.

Insert the following new subparagraph (iv):

"(iv) Must incorporate in all contracts entered into with I/T/U pharmacies, within the text of the agreement or as an addendum, provisions that:

(A) Acknowledge 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) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal

[14] We submit as Attachment 1 a model tribal addendum prepared by the CMS Tribal Technical Advisory Group to be utilized by tribal and urban Indian pharmacies participating in the Temporary Prescription Drug Discount Card Program.

Regulations; and the terms of the contract, compact or grant issued to the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.

(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including 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) Recognize that I/T/Us are non-taxable entities.

(E) State that IHS, tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.

(F) State that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.

(G) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.

(H) State that an I/T/U pharmacy is not subject to the PDP formulary.

(I) State that the Agreement may not restrict access the I/T/U pharmacy otherwise has to purchase drugs from the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act.

(J) State that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.

(K) Authorize I/T/U pharmacies to establish their own hours of service."

REGULATIONS MUST PROVIDE A MECHANISM TO ASSURE NO REUDCTION IN REVENUES TO I/T/U PHARMACIES

Comments regarding: §423.120: Access to covered Part D drugs and §423.124: Special rules for access to covered Part D drugs at out-of-network pharmacies

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To include in the regulation a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. We provide four options in our comments to achieve this goal:

ption 1: *In-Network Status + Wrap-Around Payment*. One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network providers and for CMS to provide "a wrap-around payment" modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.

ption 2: *Out of Network Status + Wrap-Around Payment.* In the event that I/T/U pharmacies are not treated as in-network pharmacies, they should be recognized as out-of-network pharmacies eligible for reimbursement from the private plan under §423.124 and receive a supplemental "wrap around" payment from the federal government which would include any increased differential in cost sharing related to use of out of network pharmacies. This supplemental payment would provide reimbursement for the difference between the out of network plan payment and the amount the I/T/U would have received as an in network provider.

ption 3: *Special Endorsement PDP/MA-PD Plans*. Specific PDPs could be designated to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Benefit Discount Card program.

ption 4: *Exemption of AI/AN Dual Eligibles.* Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid. This alternative would allow CMS to avoid the complicated issues of access and revenue loss that we discussed throughout these comments.

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. 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. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for **AI/AN dual eligibles drug costs ranges between $23.8 million[15] and $53.6 million.[16]** 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 rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

We propose that one of the four "hold harmless" provision options be included in the regulation to maintain the current level of revenue I/T/U pharmacies receive under Medicaid.

Option 1: In-Network Status with Wrap-Around Payment

While it would be the responsibility of CMS to establish ways to prevent loss of revenue at I/T/U pharmacies, we propose that CMS:

(a) Require all PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the appropriate rate[17], ***and***

[15] 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.

[16] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

[17] 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."

(b) Provide a "wrap around" payment for drug coverage services similar to the special payment rules for medical services provided at federally qualified health centers (FQHCs) contained in Section 237 of the MMA.

Reimbursement as In-network Provider. We request that the regulations require PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the Medicaid rates. This provision would prevent agreements in which the PDP/MA-PD agrees to pay an artificially low rate to the I/T/U pharmacy, with the knowledge that the I/T/U pharmacy will receive supplemental payments from CMS.

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a "wrap-around payment" to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

We suggest that the following provision or ones similar in nature be added to the Part D rules:

Section 423.120(a)(1): *Convenient access to network pharmacies.*

***

"§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy."

The following language should be inserted into Part 423 at the appropriate place:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 2: Out of Network Status with Wrap-Around Payment

In the even that I/T/U pharmacies are not recognized as in-network providers under Option 1, we propose that the regulations recognize these pharmacies as out of network providers under §423.124 and provide a wrap-around payment to supplement the difference between the out of network reimbursement rate and the Medicaid rate.

We suggest that the following sentence be added to Sec. 423.124(a):

Section 423.124(a) ***

"An I/T/U pharmacy that dispenses covered Part D drugs to an American Indian/Alaska Native beneficiary shall be considered an out of network pharmacy for payment of claims."

Additionally, the following provision should be included in Part 423:

§**423.___**. **Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.**

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 3: Special Endorsements with Wrap-Around Payment

Designating private plans to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Discount Card program is an alternative that could encourage PDP contracting with I/T/U pharmacies. Specifically identifying the PDP serving AI/AN will help I/T/Us to identify and bill the correct PDP or MA-PD. Additionally, designating specific PDPs and MA-PDs to contract with I/T/U pharmacies would allow an AI/AN beneficiary to easily identify which plan includes his/her I/T/U pharmacy, avoiding the need for the individual to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. Of course, to ensure that I/T/U revenues do not decrease under this option, the wrap-around payment provision discussed above would be necessary. Designation of specific PDPs would also facilitate development of specific I/T/U contract terms.

If CMS is unable to secure private plans to offer the benefit, then it could either subsidize the benefit or provide a "fall back" plan as authorized by Section 1860D-2(b) of the MMA. The Part D proposed regulations depend on the private market to drive the benefit; however, because of the unique characteristics of Indian health programs, private plans may not have incentive or interest in serving a predominately low-income population. Establishing specific PDPs and MA-PDs to serve the AI/AN population is entirely feasible since PDP and MA-PD regions have yet to be established.[18]

Option 4: Exemption of AI/AN Dual Eligible Individuals from Part D

We offer an alternative that would allow CMS to avoid the complicated issues of access in Section 423.120, revenue loss to I/T/Us and the "wrap around" mechanism discussed on page 11 of these comments -- **Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid**.

We believe that exempting AI/AN dual eligibles from mandatory enrollment is an efficient and effective alternative for the following reasons:

- Exemption of AI/AN dual eligibles from mandatory enrollment will prevent any loss of revenue to I/T/U pharmacies that will result if drug coverage for dual eligibles is switched from Medicare to Medicaid.

[18] In creating special endorsements for AI/AN CMS could establish:
- A pool of Indian-specific PDP/MA-PD who would serve regions that mirror IHS Areas, or
- Nationwide PDPs/MA-PDs to serve AI/AN in all fifty states

- Exemption of AI/AN dual eligibles will eliminate the barriers dual eligibles, as well as AI/AN basic beneficiaries, will face in accessing the Part D benefit. For example, the MMA strategy to use private plans as a vehicle to provide prescription drug benefits severely restricts access for many AI/ANs because tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks.
- Exemption of AI/AN dual eligibles from mandatory enrollment will eliminate the detrimental impact on reimbursement levels and the increase administrative costs that will occur when the I/T/U pharmacy does not know what PDP or MA-PD to bill. This is particularly true with regard to automatic enrollments because the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

It is important to recognize that exempting AI/AN dual eligibles from mandatory participation in Part D thereby allowing them to continue to receive prescription drug coverage through the State Medicaid Program will have **no budget impact.** This is so because prescription drug coverage costs will be paid by the federal government regardless of whether the benefit is provided under Medicaid at 100% FMAP or Medicare Part D subsidy for dual eligibles.

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)

Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems

Goal: *To ensure that I/T/U pharmacies that participate in PDP pharmacy networks continue to have the option of purchasing prescription drugs for AI/AN Medicare beneficiaries at Federal Supply Schedule (FSS) prices or at the discounts available under the 340B program.*

Terms and Conditions Issue, Page 46658: CMS notes that the proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network. CMS seeks comment on whether it should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.

Comment: As the Preamble recognizes, there are 201 I/T/U pharmacies serving 107,000 elderly and disabled AI/ANs in 27 states (page 46657). These pharmacies currently have access to Federal Supply Schedule (FSS) prices for the prescription drugs they dispense to AI/AN Medicare beneficiaries, or they are covered entities entitled to discounts under the 340B program, 42 U.S.C. 256b, or both. These discounted prices reflect the purchasing leverage of the Federal government and have enabled I/T/U pharmacies to meet the needs of AI/AN beneficiaries, whether or not enrolled in Medicare, in a cost-efficient manner.

We are concerned that PDP sponsors and MA organizations offering an MA-PD plan may require participating pharmacies to purchase drugs through the PDP sponsor or MA organization. This could have the effect of forcing I/T/U pharmacies to choose between participating in Medicare Part D and retaining their current access to FSS prices or 340B discounts, or both. We do not believe Congress intended that I/T/U pharmacies be forced into this choice. We therefore propose that the final rule prohibit PDP sponsors or MA organizations from requiring I/T/U pharmacies to purchase drugs through mechanisms other than FSS or the 340B program. This would not preclude an I/T/U pharmacy that wished to do so from purchasing its drugs through the PDP or MA-PD plan. The option, however, would be that of the I/T/U pharmacy, not the PDP or MA-PD plan.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans should be revised to read as follows (modifications are *italicized*):

"(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;
(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; *and*
(iii) May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b. "

FORMULARY

Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements.

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule.

Goal: *I/T/*Us *should be exempt from formulary requirements and therefore able to utilize permissible substitutes. This exemption is needed to both accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries and to allow I/T/Us to include in their formulary of drugs for which reimbursement will be paid those drugs available through FSS or 340b.*

Comment: Section 423.120(b)(1) permits PDP and MA-PD plans to develop formularies so long as they meet the requirements of this section. We are concerned that plans that develop such formularies will make stocking the drugs in the formulary a requirement of its contracts with participating pharmacies. Many I/T/U pharmacies are small and cannot stock a full range of drugs, particularly if the condition the drug is used to treat is one beyond the scope of the I/T/U clinic and its providers. When establishing their formularies, I/T/U hospital and clinic pharmacies also consider aspects of treatment that may not be generally important, such as the extent of monitoring of the patient that may be required. Since many patients live far from the I/T/U pharmacy, this is an important therapeutic factor. Another factor in whether the I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principle sources of drugs purchased by I/T/U pharmacies. *See* "I/T/U Pharmacies and Federal Supply Schedule (FSS)."

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans in Section 423.120(a)(4) should be further revised to add a new paragraph (iv) to read as follows (new language is *italicized*):

  (v) May not require an I/T/U pharmacy to provide all the drugs in any formulary that may have been adopted by the PDP or MA-PD.

  AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U pharmacies are often the only pharmacy providers (page 46657). It is unfair to the AI/AN beneficiaries and to I/T/U providers to limit reimbursement or increase co-pays when a beneficiary is prescribed a drug that is not on the PDP or MA-PD formulary when that may be the only drug available from the I/T/U pharmacy that provides the same therapeutic effect as the formulary drug. In such cases, the PDP or MA-PD should be required to reimburse the I/T/U as if the drug were on its formulary in an amount equal to that the PDP or MA-PD would have paid for an equivalent drug on its formulary. In this way, neither the PDP or MA-PD or the I/T/U pharmacy is disadvantaged financially, and the patients are able to maintain access and continuity of care.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (v) to read as follows (new language is *italicized*):

  (vi) Must provide for reimbursement to I/T/U pharmacies for all covered Part D drugs whether or not they are on the PDP's or MA-PD's formulary at an amount not lower than the reimbursement that would have been made for an equivalent drug on the formulary.

BENEFITS AND BENEFICIARY PROTECTIONS
Comments on Section 423.100: DEFINITIONS
"Insurance or otherwise" for purposes of "Incurred costs"

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *To ensure that expenditures by I/T/Us on AI/AN beneficiaries (who do not qualify for the cost-sharing subsidy for low-income individuals) on prescription drugs count toward the annual out-of-pocket threshold ($3,600 in 2006).*

Incurred Cost Issue, Pages 46649-46651: CMS notes that, under the proposed rule, AI/AN Medicare beneficiaries who are not eligible for low-income cost-sharing subsidies may receive drug coverage directly from I/T/U pharmacies or under CHS referrals. While these payments will count toward the AI/AN beneficiary's annual deductible, they will not count as incurred cost toward meeting the out-of-pocket threshold ($3,600 in 2006). The reason, in brief, is that "incurred costs" are defined by section 1860D-2(b)(4)(C)(ii) of the Social Security Act to exclude payments by "insurance or otherwise." But this statutory provision does not expressly include the I/T/U programs in this term. Rather, it is CMS, not the law that has defined what is encompassed by the term "insurance or otherwise". The agency has chosen to include I/T/U health programs as "insurance or otherwise," -- but has not explained the basis for that decision, nor

analyzed the impacts of it on the IHS-funded system and affected Indian Medicare beneficiaries, nor acknowledged that failing to count I/T/U pharmacy contributions toward "incurred costs" would be a windfall to the PDP in which an affected Indian is enrolled. Perhaps CMS recognized that this matter requires additional thought, as it asks for comments on "how … IHS beneficiaries will achieve maximized participation in Part D benefits."

Comment: The effect of CMS's decision to treat I/T/U programs as "insurance or otherwise" is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, "most IHS beneficiaries would almost never incur costs above the out-of-pocket limit." (69 FR at 46657). And, as CMS further recognizes, this policy "would likely provide plans with additional cost-savings." (69 FR at 46657). We do not believe that Congress intended Part D to be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as "incurred costs." By using the phrase "not reimbursed by insurance or otherwise," Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not "reimbursed" by their IHS or tribal health care providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. "fulfills the Secretary's unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes." In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

The proposed rule, however, does not recognize this "unique" legal relationship. Instead, the proposed rule would require those AI/ANs who are Medicare beneficiaries but who are not eligible for the low-income subsidy program to pay substantial amounts out of pocket for their Medicare prescription drug coverage in order to meet the out-of-pocket threshold. In this way, the proposed rule violates the federal trust responsibility, under which AI/ANs are entitled to needed health care services, including prescription drugs, at the federal government's expense.

Section 1860D-2(b)(4)(C)(ii) specifies that costs shall be treated as incurred if they are paid "by another person, *such as* a family member, on behalf of the individual." (*emphasis added*). In the "unique relationship" between the federal government and AI/ANs, the I/T/Us are the functional equivalent of a "family member." Their mission, on behalf of the federal government, is to pay for prescription drugs and other health care services needed by AI/ANs. In terms of paying for prescription drugs, there is no functional difference between I/T/Us fulfilling their obligations to AI/ANs and family members fulfilling their obligations to one other. Again, there is nothing in the concept of family members paying incurred costs to suggest that Congress somehow intended that payments by I/T/Us on behalf of AI/ANs not be treated as incurred costs.

In the preamble, CMS explains that contributions made by charities would be considered "incurred costs" and describes in detail the reasons for a desirable objectives achieved by this decision. Many of the considerations recited there apply to the I/T/U system, particularly the outcome that Medicare beneficiaries who are not eligible for the low-income subsidy would be able to qualify sooner for the catastrophic coverage level. In other words, these beneficiaries would have a better opportunity to fully utilize their Part D benefit.

The outcome is just the reverse with regard to an Indian not eligible for subsidy who is served by an I/T/U pharmacy. That Medicare beneficiary would have to pay the same premium for Part D coverage (or have it paid on his behalf by the I/T/U program as CMS suggests at p. 46651), but the benefit received for that premium would be only slightly more than $1000 -- far lower than that of a non-Indian beneficiary. This is so because this Indian patient would never get out of the "donut hole" and thus would never be able to utilize the catastrophic coverage feature of the Part D benefit.

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

Section 423.100-"Insurance or otherwise" for purposes of "Incurred Costs"

The definition of "insurance or otherwise" used to define "incurred costs" for purposes of meeting the out-of-pocket threshold should be revised to read as follows (modifications are *italicized*):

"Insurance or otherwise" means a plan (other than a group health plan) or program *(other than a health program operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act , 25 U.S.C. 1603)*, that provides, or pays the cost of, medical care…, including any of the following: …(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals *(other than American Indians or Alaska Natives or urban Indians as those terms are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603)*."

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL
Comments regarding Section 423.286 Rules regarding premiums.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Tribes/Tribal Health Programs should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.*

Comment: We urge CMS to include I/T/U and/or tribes as permissible payment options and to remove barriers tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules. Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, would elect to pay premiums themselves.

AI/ANs served in an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the IHS based on the Federal Government's obligation to federally recognized Tribes. CMS recognizes this in the Preamble, page 46651, by stating that "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits". It is unlikely that AI/ANs, who are entitled to health care without cost sharing, would elect to pay premiums themselves, therefore, we request that language be included in the regulations recognizing the ability of I/T/Us to pay premiums if they so choose.

WAIVER OF COST SHARING
Comments on Background at 46651 and Section 423.120(a)(4)

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule and Formulary.

Goal. *Assure that I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B (b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.*

Comment: As discussed in the Preamble, the AI/AN beneficiaries receive health services under a unique government-to-government relationship between the United States and Tribes (page 46651). Under this relationship most care is provided directly by or through contract health services administered by I/T/U providers who provide the care without cost to the AI/AN beneficiary. The benefit plans provided under Medicare Part D contemplate patients sharing in the cost of the care they are provided. This is antithetical to the relationship between AI/AN beneficiaries and their I/T/U pharmacies.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (vi) to read as follows (new language is *italicized*):

(vii) *Must authorize I/T/U pharmacies to waive all cost sharing obligations of AI/AN beneficiaries.*

CREDITABLE COVERAGE
Comments Regarding Section 423.56: Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *IHS coverage should be deemed "credible coverage" therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.*

Comment: The CMS TTAG strongly supports the decision of CMS to include in the definition of Creditable Prescription Drug Coverage a "medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U)" in the Medicare Prescription Drug Benefit Proposed Rule at § 423.56(a)(9). The Indian Health Service, Tribe or Tribal organizations, or Urban Indian organizations currently provide pharmaceuticals to AI/AN beneficiaries, either through direct care services or IHS Contract Health Services (CHS), at no cost to the beneficiary. For purposes of not being subject to late

enrollment penalties, this Proposed Rule will protect those AI/AN beneficiaries who might not initially enroll in Medicare Part D because, for example, they receive their pharmaceuticals from an I/T/U pharmacy but later relocate off reservation and therefore need prescription drug coverage under Medicare Part D.

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

EXCLUDE CERTAIN INDIAN-SPECIFIC INCOME AND RESOURCES FOR CONSIDERATION OF ELIGIBILITY OF AMERICAN INDIANS AND ALASKA NATIVES FOR LOW-INCOME SUBSIDIES

Comments regarding Section 423.772: Premiums and Cost Sharing Subsidies for Low-Income Individuals-Definitions

Goal*:* To exclude from the income and resources tests for determination of an American Indian or Alaska Native (AI/AN) Medicare beneficiary's eligibility for a low-income subsidy under Part D certain income and assets that are excluded from consideration when determining eligibility for Medicaid.

Comment. CMS has recognized that certain Indian-specific income and assets are to be excluded when determining the eligibility of an AI/AN for Medicaid. *See, e.g.,* CMS State Medicaid Manual Part 3 -- Eligibility, §3810. These same exclusions should apply to the determination of whether an AI/AN qualifies for a low-income subsidy under Part D. Since all dual eligibles will be moved from Medicaid to Part D for prescription drug coverage, it is appropriate that the same federally-established exclusions should apply to the affected AI/AN dual eligibles.

In **Sec. 423.772,** the definitions of "income" and "resources" should be revised to exclude income that derives from tribal lands and other resources currently held in trust status, from judgment funds awarded by the Indian Claims Commission and the U.S. Claims Court, and from other property held in a protected status, as specified in the Medicaid Manual. In addition, cultural objects, as specified in the Medicaid Manual, should also be exempted from the definitions of these terms.

ELIGIBILITY AND ENROLLMENT

Comments regarding Section 423.48: Information about Part D.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.*

Comment: Without outreach, education and enrollment assistance from Indian health programs, AI/AN are unlikely to enroll in Medicare Part D or Part C. AI/AN are entitled to receive free health care at I/T/Us and

through Contract Health Services, thus they have no incentive to enroll in programs requiring premiums and cost sharing. I/T/Us know who may be eligible for new Medicare programs and how to contact them. AI/ANs trust I/T/U health workers. Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to I/T/U at no cost. As CMS states on Page 46642 of the Preamble, "we would undertake special outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate." In implementing this provision CMS must reach out to AI/AN beneficiaries.

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Plan" or Plan Sponsor") and _____ (herein "Provider") for administration of Transitional Assistance under the Prescription Drug Discount Card program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 at pharmacies and dispensaries of Provider. To the extent that any provision of the Special Endorsed Plan Master Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Special Endorsed plan Master Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Plan Sponsor" means _____ which operates the Prescription Drug Discount Card Plan defined in subsection (b).

(b) The terms "Prescription Drug Discount Card Plan" and "Plan" means a Prescription Drug Discount Card Plan operated by Plan Sponsor that is approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and holds a special endorsement from CMS to administer the Transitional Assistance feature of the Prescription Drug Discount Card program at pharmacies or dispensaries operated by the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations (hereafter "I/T/U endorsement").

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Co-pays, deductibles.

The parties agree that the Provider may waive any co-payments for any Indian who is enrolled in the Plan when such Indian receives services pursuant to the Plan at any pharmacy or dispensary of Provider.

5. Persons eligible for services of Provider.

(a)The parties agree that the persons eligible for services of the Provider under the Special Endorsed Plan Master Agreement and all addenda thereto shall be governed by the following authorities:

(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations
(2) Sec. 813 of the Indian Health Care Improvement Act, 25 USC §1680c
(3) Part 136 of Title 42, Code of Federal Regulations
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Special Endorsed Plan Master Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.;*
(2) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

Provider is a non-taxable entity and as such shall not be required by Plan or Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. A Provider which is an urban Indian organization which holds designation as a Federally Qualified Health Center shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify Plan or Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located, and shall be deemed qualified to provide services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided that such employee is currently licensed to practice pharmacy in any State. To the extent that any State exempts from state regulation a direct employee of Provider, such employee shall be deemed qualified to perform services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements pursuant to 42 CFR §431.110, the Provider shall not be required to hold a State license to receive any payments under the Special Endorsed Plan Master Agreement and any addendum thereto.

11. Re-Enrollment Period.

The Centers for Medicare and Medicaid Services has established as a matter of policy that an enrollee eligible for services from an I/T/U pharmacy shall be permitted to disenroll from a prescription drug discount card plan that does not hold a special I/T/U endorsement and to re-enroll in a plan that has received such endorsement at any time during the life of the Medicare Drug Discount Drug Card Program. Nothing in the Special Endorsed Plan Master Agreement or any other addendum thereto shall be interpreted to impede this right of re-enrollment.

12. Dispute Resolution.

Any dispute arising under the Special Endorsed Plan Master Agreement or any other addendum thereto shall be resolved through negotiation rather than arbitration. The parties agree to meet and confer in good faith to resolve any such disputes.

13. Governing Law.

The Special Endorsed Plan Master Agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between the Special Endorsed Plan Master Agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

14. Pharmacy/Dispensary Participation.

The Special Endorsed Plan Master Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum.

15. Acquisition of Pharmaceuticals.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in the Special Endorsed Plan Master Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

16. Formulary.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's formulary. The Provider is exempt from any provision of the Special Endorsed Plan Master Agreement and all addenda thereto requiring compliance or cooperation with the Plan Sponsor's or Plan's formulary, drug utilization review, generic equivalent substitution, and notification of price differentials.

17. Transitional Assistance Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim. When the toll-free number is used for non-electronic claims, Plan will verify the balance of an enrollee's Transitional Assistance subsidy remaining as of that time and obligate funds from that subsidy for payment of the Provider's claim at the point of sale. Instructions for filing and adjudicating non-electronic claims are attached as Schedule C.

18. Payment Rate.

Claims from the Provider for Transitional Assistance benefits shall be paid at the same rates as the State Medicaid program fee-for-service in the State where the Provider's pharmacy or dispensary is located, pursuant to Schedule A of this Addendum.

19. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Plan shall be supplied by Plan to Provider in paper and electronic format at no cost to the Provider. Provider shall have the right to convert such materials as it deems necessary for language or cultural appropriateness.

20. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Plan, Provider shall provide written notification of its hours of service to the Plan.

CMS-4068-P-1058

Submitter : Mr. John Chappuis **Date & Time:** 10/04/2004 06:10:12

Organization : Montana Dept. of Public Health and Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Attached please find a Word document containing Montana's comments regarding regarding the proposed Medicare Prescription Drug Benefit Regulations, published in Federal Register Vol. 69, No. 148, on August 3, 2004. File code CMS-4068-P.

CMS-4068-P-1058-Attach-1.doc

DEPARTMENT OF
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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: Proposed Rule With Comment Period, Medicare Program: Medicare Prescription Drug Benefit (CMS-4068-P)

Dear Dr. McClellan:

The State of Montana respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in Federal Register Vol. 69, No. 148, on August 3, 2004. We appreciate the opportunity to comment on these proposed regulations that implement The Medicare Modernization Act (MMA), especially as it relates to the new subsidy program for low-income Medicare beneficiaries. We estimate the new subsidy program will impact over 17,000 low-income beneficiaries that are currently full benefit dual eligibles in the Montana Medicaid program and will benefit another 900 plus low-income beneficiaries eligible under the Qualified Medicare Beneficiary (QMB), specified low-income Medicare beneficiaries (SLMB), and certain qualifying individuals (QI).

Montana has participated in numerous conference calls with CMS and discussed various issues regarding MMA. As you are aware, many of these issues raised by the Proposed Rule are highly technical in nature. Montana applauds CMS and the Social Security

Administration (SSA) for establishing an open dialog with representatives from the states to address the myriad of issues.

B. Eligibility and Enrollment – 2. Part D Enrollment Process and 3. Part D Enrollment Periods (§ 423.36)

In accordance with section 1860D-1(b)(1)(C) of the Act, CMS would establish a process to automatically enroll a full benefit dual-eligible individual (as defined under section 1935(c)(6) of the Act) who has failed to enroll in a PDP or MA-PD plan by either the end of the individual's initial enrollment period or upon becoming dual eligible after his/her initial enrollment period. For full benefit dual eligibles, this timeframe runs from 11/15/05 to 5/15/06. Section 1860D–1(b)(1)(c) of the Act also directs CMS to enroll full benefit dual eligible individuals who fail to elect a PDP or MA–PD plan on a random basis if more than one PDP within an area has a monthly beneficiary premium equal to or below the low-income benchmark premium.

Montana believes that the auto-enrollment process, for those who do not select a plan during their designated enrollment period, will present difficulties. It is our understanding that eligibility and enrollment in PART D for Medicare beneficiaries is essentially a two-step process: 1) the client voluntarily enrolls in Part D, and 2) the client must pick a PDP plan. The individual must first meet the eligibility criteria in order to obtain prescription drug coverage. In accordance with section 1860D–1(a)(3) of the Act, a ''Part D eligible individual'' is defined as an individual who is entitled to or enrolled in Medicare benefits under Part A or enrolled in Part B. The Part D eligible individual must then enroll in a PDP plan. Montana will automatically enroll all full benefit dual eligible and other low-income beneficiaries under QMB, SLMB and QI in Part D with the Social Security Administration (SSA) and CMS. However, we believe the decision of which PDP plan to choose is up to the individual and cannot be determined by the State without clear guidance and authorization by CMS. This part of the process concerns us greatly considering the low-income population consists of our most vulnerable individuals in nursing facilities, elderly, disabled, and individuals with HIV-AIDS, mental health conditions, cancer, and other conditions.

As written, it could be interpreted that a full benefit dual eligible individual who does not actively enroll in a plan will only be automatically enrolled after May 15, 2006. In this case, such full benefit dual eligibles who have not enrolled prior to Jan 1, 2006 would not receive Part D coverage until they are either automatically enrolled in May or they actively enroll in

a plan. Not only will full benefit dual eligibles not qualify for Part D benefits if unenrolled in a plan, but also federal matching funds are no longer available to State Medicaid agencies as of January 1, 2006 to pay for drugs for these full benefit duals. If we choose to cover and pay for their drugs, then the State will be, using 100 percent state general fund, for the cost of these dual eligibles during this 4 ½ month period of time. This is a cost that Montana is unable to absorb. It is likely that beneficiaries who do not select a plan will be without drug coverage until they pick a plan. Montana is willing to work with CMS to educate Montanan's of the importance to select a plan to ensure this does not happen.

In implementing any automatic enrollment process for full benefit dual eligible individuals, CMS is 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. Montana would prefer that this function be performed by CMS or a contracted entity on their behalf. We do not have the resources available to make this determination but feel that CMS is better situated to coordinate this activity directly with beneficiaries via the infrastructure that has been established with the 1-800-MEDICARE call line and the web site http://www.medicare.gov. In addition, we believe the automatic enrollment process for full benefit dual eligible individuals that qualify for the low income subsidy must be completed by CMS prior to January 1, 2006 and not extended to May 15, 2006 as identified in the proposed regulations. This would help ensure that full benefit dual eligibles would not lose drug coverage for any period of time.

B. Eligibility and Enrollment - 3. Part D Enrollment Periods (§ 423.36)

In the proposed rule CMS establishes special enrollment periods (SEPs). Special enrollment periods allow an individual to disenroll from one PDP and enroll in another PDP. Special enrollment periods are identified to be available for individuals with Medicaid coverage.

We intrepret tis to mean that any beneficiary that is a full-benefit dual eligible individual will be able to enroll and disenroll in perpetuity. CMS needs to clarify for States how often beneficiaries may change PDPs within special enrollment periods. Specifically, if an eligible individual has enrolled in another PDP based on one of the enumerated circumstances, may that individual continue to enroll and disenroll indefinitely? Montana encourages CMS to limit the number of times per annum that a full-benefit dual eligible may change PDPs due to the administrative burden of benefit coordination that would result.

B. Eligibility and Enrollment – 6. Disenrollment by the PDP (§ 423.44)

Section 1860D–1(b)(1)(B) of the Act generally directs CMS to use disenrollment rules similar to those established under section 1851 of the Act. In addition to providing requirements for disenrollments that are required by the PDP, CMS also outlined a proposed rule that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. We believe there are important beneficiary implications for those PDPs who disenroll individuals for these reasons. The provision regarding failure to pay the monthly PDP premiums will not necessarily impact low-income subsidy eligible beneficiaries. However, the proposed rule-allowing disenrollment for disruptive behavior can impact low-income beneficiaries and may potentially impact state programs if the individual is not permitted to enroll in another PDP. Especially, if the individual generally will not be able to enroll in either a PDP or an MA–PD until the next annual coordinated election period. We believe that a full benefit dual eligible that is disenrolled for disruptive behavior will seek coverage under state programs in either Medicaid or under a State Pharmacy Assistance Program. This will only result in a cost shift to the state at 100% general fund. This is especially concerning considering we will be paying CMS for these beneficiaries under the clawback provisions.

We believe that CMS needs to implement special provisions that prohibit a PDP plan from disenrolling subsidy eligible full benefit duals whose behavior is disruptive. The PDP plan should be subject to the same requirements as Medicaid programs that prohibit states from disenrolling clients from the Medicaid program or eliminating coverage for drugs. The PDP plan should be required to manage the care under restrictions (as adopted by CMS) to ensure that the beneficiary has access to prescription drugs in an efficient and economical manner.

B. Eligibility and Enrollment – 8. Part D Information that CMS Provides to Beneficiaries (§ 423.48)

In the interest of broadly disseminating information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees, CMS proposes to extend the price comparison requirements to PDP sponsors and MA organizations offering MA–PD plans and making comparative information about Part D plans' negotiated prices available to beneficiaries through *http:// www.medicare.gov*.

CMS states that their drug card experience shows that providing drug price information can significantly reduce prices and believes that information about negotiated drug prices will assist beneficiaries in deciding which Part D plan will offer them the greatest financial advantage. CMS proposes building on this experience in implementing the drug discount card price comparison Web site and develop requirements for the Part D price comparison Web site.

Montana recognizes that this tool is very useful to provide beneficiaries with information to assist in their decision-making on which Part D plan to enroll. However, we believe that this tool and the 1-800-MEDICARE call line cannot be relied upon to reach the low-income beneficiaries, especially those eligible for the subsidy benefit. Many clients often do not have the resources available to them to access the Internet as an information source. We believe that a variety of resources need to be made available to reach the low-income beneficiary so they can make an informed decision. Montana is committed to work with CMS to reach and educate this vulnerable population to ensure everyone who has access to prescription medications under Medicaid will have coverage under a Part D plan. We recognize this will be a significant administrative impact on the State and appreciate CMS's commitment to providing federal Medicaid administrative match for this effort. We believe that this is one of many administrative burdens placed on the state that will offset the recognized Medicaid benefit savings as a result of Medicare assuming the liability for the prescription drug benefit for full benefit duals.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections – 4. Access to covered Part D Drugs (§ 423.120) a. Pharmacy Access Standards

As required by section 1860D–4(b)(1)(C) of the Act, prescription drug plans and MA–PD plans would be required to secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by plan enrollees. The proposed rule would require that prescription drug plans and MA–PD plans establish pharmacy networks in urban areas, suburban areas, and rural areas.

Montana would like CMS to add language that defines "frontier" service areas as well, and address how beneficiary populations, like those in Montana, can expect service delivery. We would expect to see that anywhere in the proposed rules that utilize these (3) service area

definitions also address “frontier” services areas. The term "Rural" doesn't really do justice for places like Lame Deer and Two Dot.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections – a. Covered Part D Drug / 4. Access to Covered Part D Drugs (§ 423.120) b. Formulary Requirements

The definition of a covered Part D drug in § 423.100 of the proposed rule closely follows the statutory definition in section 1860D–2(e) of the Act. According to this definition, 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 specified 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).’’ CMS proposes to define those medical supplies to include syringes, needles, alcohol swabs, and gauze. 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. In accordance with section 1927(d)(2) of the Act, 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 seeks 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.

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. In addition, Section 1860D–4(b)(3)(C) of the Act and § 423.120(b)(2) require the inclusion of ‘‘drugs’’ in each therapeutic category and class of covered Part D drugs in a plan’s formulary, although not necessarily all drugs within such categories and classes. CMS interprets this requirement to

mean that a PDP sponsor or MA organization's formulary would 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 (unless there is only one drug in a particular therapeutic class or category, in which case the inclusion of only one drug would be required). Section 423.120(b)(2) of the 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 this is feasible. CMS believes that the inclusion of at least two drugs in each therapeutic class or category (except for those classes or categories that include only one drug) strikes an appropriate balance between providing plans with the necessary leverage to negotiate with manufacturers for significant discounts on covered Part D drugs and ensuring sufficient drug choice for beneficiaries. CMS notes however, that it is their expectation that plans' formularies will provide Part D enrollees a comprehensive benefit—one that covers an amount and variety of drugs sufficient to treat all disease states.

Montana also has the same expectation that a PDP plan formulary must provide Part D enrollees a comprehensive benefit, especially for the low-income full benefit dual eligible beneficiary. Under this proposed regulation Medicare is assuming the prescription drug benefit from the Medicaid program for full benefit dual eligibles. A State Medicaid program that chooses to provide optional pharmacy benefits under their state plan are required to cover drugs in accordance with section 1927 of the Act. Except for the excluded drugs mentioned above, we are required to cover drugs where CMS has a drug rebate agreement with manufacturers. State's are allowed to establish prior authorization programs to require authorization prior to dispensing covered outpatient drugs to Medicaid clients and may also implement supplemental rebate programs. In addition, CMS has allowed States to participate in purchasing pools to leverage our purchasing power to acquire prescription drugs for our Medicaid populations.

The Medicaid program provides a comprehensive benefit for our Medicaid population and with the Medicare assumption of the full benefit dual eligible, we expect Part D and the PDP plans to provide the same benefit to these eligibles. Especially since Montana is paying for this full benefit via the mandated clawback provision. Montana has the same expectation of the Medicare Part D benefit for full benefit dual eligibles as CMS does of the Medicaid program, as outlined in the SMDL #04-006 dated September 9, 2004. We believe that CMS must consider, and demonstrate to States that it will ensure that care and services be provided

in a manner consistent with simplicity of administration and the best interests of the client. To that end, we would expect that any PDP plan would continue to ensure that appropriate medically necessary drugs would be available to full benefit dual eligible individuals. We would expect a PDP's formulary be based on several factors, including the needs of the state's low-income Medicare beneficiaries. We further would expect a PDP plan to address the needs of beneficiaries with special and complex medical conditions. Especially to consider including in their formulary drugs that are needed by some of our most vulnerable populations, such as individuals with HIV/AIDS, mental health conditions, cancer, and other conditions for which clinical effectiveness or individual tolerance and responsiveness to drugs frequently vary. In addition, when approving a PDP formulary, we urge CMS to be mindful of full benefit dual eligible patients who are stabilized on previously prescribed, non-preferred medications. We urge CMS to consider the impact on beneficiaries of sudden changes in therapy as a result of formulary limitations. Such a sudden change could, in some instances, result in higher costs due to a patient's failure of therapy on limited formulary drugs.

We understand that enrollees who require a covered Part D drug that is not on their prescription drug plan or MA-PD plan's formulary would be required to use the coverage determination process described in § 423.566 of CMS's proposed rule. In the absence of a comprehensive benefit for full benefit dual eligibles we anticipate a significant administrative burden to the state of Montana to address the complaints and appeals from beneficiaries regarding their pharmacy coverage. Beneficiaries will turn to the state Medicaid programs requesting coverage of drugs, which will likely be denied due to general coverage under Part D as described above. We will be forced to redirect the beneficiary to CMS or the PDP plan for an appeal. This will result in the beneficiary being caught between two bureaucracies regarding coverage of drugs they may need to survive.

We believe that CMS needs to treat all dual eligible individuals as a "special needs population". Certain specialized plans can limit enrollment to special needs subgroups of the Medicare population in order to focus on ensuring that their needs are met as effectively and efficiently as possible. This provision will encourage greater access to Medicare PDP or MA-PD plans for special needs subgroups. We believe that the establishment of such special needs plan for low-income dual eligible beneficiaries would allow for their unique health care needs to be better addressed.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections – c. Long-Term Care Facility

CMS requested comments regarding the definition of the term long-term care facility in § 423.100 of the proposed rule, which 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. CMS expressed particular interest in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in § 440.150 of the proposed rule, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. CMS stated that it understands that there are 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. The CMS proposed definition limits the definition to skilled nursing and nursing facilities because it is their 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, according to the preamble, 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, CMS would consider modifying this definition.

Montana believes that CMS should modify this definition to include intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), and other types of facilities in this definition, such as to include intermediate care facility services for individuals age 65 or older in institutions for mental diseases as described in § 440.140. The proper determination of beneficiaries in Long-Term care Facilities will have an impact on the determination of cost sharing obligations. CMS should assure that full benefit dual eligibles in institutional services under Medicaid will have access to Part D benefits and will be exempt from cost sharing under the Act.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections – 4. Access to Covered Part D Drugs (§ 423.120) – a. Pharmacy Access Standards

Section 1860D–4(b)(1)(D) of the Act would require PDP sponsors and MA organizations offering an MA–PD plan to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. Such benefits could include an extended supply (for example, 45-day, 60-day, 90- day supply) of covered Part D

drugs that is typically available only through a network mail-order pharmacy. However, because mail-order pharmacies are often able to provide lower prices to individuals than retail pharmacies, it is possible that the negotiated price for an extended supply (for example, a 90-day supply) of a covered Part D drug would be more costly at a network retail pharmacy than through the network mail-order pharmacy assigned to the enrollee by their prescription drug plan or MA–PD plan. 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. Since any such differential costs would be associated with benefits covered under a Part D plan, CMS is seeking comments on their proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold consistent with the definition of ''incurred cost'' in § 423.100.

Montana understands the rational for the proposed rule regarding the differential and that a covered Part D drug would be more costly at a network retail pharmacy than through the network mail-order pharmacy. However, we believe that the proposed rule could have negative impacts resulting in cost shifting for low-income beneficiaries and may impact the financial viability of rural and frontier pharmacies. We do not believe that this requirement should be applied to individuals that qualify for the low-income subsidy benefit, especially those full benefit dual eligible individuals. These beneficiaries should be exempt from this requirement to pay the differential because this constitutes a cost shift to the beneficiary that chooses to do business with his local pharmacy, rather than a mail order pharmacy. This is especially important in a frontier state like Montana where support of their pharmacy is critical for access to pharmaceuticals. We cannot expect our frontier pharmacies to be there for acute needs only. If beneficiaries are forced to utilize a mail order pharmacy this could negatively impact the financial viability of the local pharmacy. The local pharmacist is often the one that ultimately is consulted by the beneficiary regarding questions and problems with mail order prescriptions. The local pharmacist provides this service to the community and if a significant amount of their business is diverted to mail order pharmacies, they may be forced to close, which will impact access for all members of the community.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections – 4. Access to Covered Part D Drugs (§ 423.120) – c. Use of Standardized Technology

In the proposed rule CMS requested public comments regarding their definition of usual and customary price (U&C). Under the proposed rule in § 423.124(b)(2), the enrollee would be responsible for any difference in price between the out-of-network pharmacies usual and customary (U&C) price and the plan allowance for that covered Part D drug. CMS proposed to define the term ‘‘usual and customary price’’ as the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage.

Montana believes the term should be defined in a broader sense than just the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage. The definition should reflect the charges the pharmacy usually and customarily charges to all customers and payors regardless of a determination of whether they have drug coverage or not. This would prevent a pharmacy from maintaining a charge structure that is different for customers with prescription drug coverage and those without any form of prescription drug coverage.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage – a. Coordination with SPAPs

The statute envisions a closer coordination of benefits between state pharmacy assistance programs (SPAPs) and Medicare drug plans. CMS believes that SPAPs have filled a significant gap in prescription drug coverage for many Medicare beneficiaries in the absence of a Medicare drug benefit. CMS believes that many beneficiaries have relationships with these programs, and it will be important to ensure that coordination between Medicare Part D and SPAPs occurs as efficiently and effectively as possible. However, section 1860D–23(c)(5) of the Act provides that nothing in the statute should be construed to require that a State Pharmaceutical Assistance Program coordinate or provide financial assistance with respect to any Part D plan. MMA allows states to use state-only SPAP funds to assist beneficiaries with out-of-pocket expenditures. Medicare Part D plans may coordinate with SPAPs in a number of ways including accepting premiums for basic Part D or enhanced alternative coverage; accepting a lump sum per capita payment from the State for enrollee coverage through Part D plans; and coordinating on a claim-specific basis when Part D plan pays first and the SPAP is the secondary payor. CMS does not know how SPAPs will actually choose to coordinate with Medicare drug plans, and they welcome comment in this regard—particularly from States. CMS 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. CMS’s goal is to

make the coordination of benefits process as functional for the beneficiary, pharmacy, and States as possible.

Montana does have a state funded prescription drug plan for mental health services that is considered a SPAP. We recognize the benefits of such coordination with Medicare Part D for beneficiaries and the possible savings for our SPAP program. We have not decided on a plan regarding premium assistance for Part D or coordinating benefits as a wrap around on a claim-specific basis. However, both options are likely to ensure our clients maintain access to needed mental health medications. Montana, has not considered enhanced alternative coverage or making lump sum per capita payment for enrollee coverage through Part D plans. We do believe however, that if we choose to provide a wrap around benefit that there will be significant costs associated with systems changes and administrative costs that will need to be absorbed by the state.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage – b. Coordination With Other Prescription Drug Coverage

In the proposed rule CMS believes there is a relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs under the statute. The drugs that must be excluded from Medicare coverage are, with limited exception, drugs that may also be excluded from Medicaid coverage under section 1927(d)(2) of the Act. CMS anticipates that there may be situations involving State Medicaid programs that may choose to continue coverage of a drug that is excluded from Medicare Part D coverage. For example, States may wish to continue coverage for barbiturates, benzodiazepines, or prescription vitamins. In these situations, a Part D plan providing primary coverage would need to coordinate this coverage with a State on behalf of a dually eligible beneficiary. CMS is requesting public comment on other situations that may involve benefit coordination between States and Part D plans (other than situations where the State is acting as an employer). In general, CMS invites comment on the other administrative processes and requirements that we might identify in order to help coordination between Part D of Medicare and other prescription drug plans.

Montana believes that the coordination of benefits between Part D and Medicaid will be a significant issue and CMS is understating the impact on beneficiaries and the administrative impact on States. Effective January 1, 2006 the pharmacy benefit for full benefit dual eligible clients will be assumed by CMS. Based upon the proposed rule, a full benefit dual

eligible needs to pick a plan or have been auto enrolled in a plan by 5/15/06. If a full benefit dual eligible has not picked a plan by 1/1/06, they will not have prescription drug coverage because State Medicaid programs will eliminate coverage under Medicaid effective 1/1/06. Medicaid programs are going to eliminate coverage for full benefit duals because any prescription drugs that are paid by Medicaid, that are included in the Part D benefit, are not be eligible for federal financial participation (thus funded at 100% general fund). In addition, effective 1/1/06, States will be paying the mandated clawback provision for these covered drugs. Montana can ill afford to pay claims for full benefit duals and risk liability at 100% general fund while we are also paying for these benefits via the clawback payment.

CMS mentions in this proposed rule that there are drugs that must be excluded from Medicare coverage and with limited exception these are the same drugs that may also be excluded from Medicaid coverage under section 1927(d)(2) of the Act. CMS anticipates that there may be situations involving State Medicaid programs that may choose to continue coverage of a drug that is excluded from Medicare Part D coverage. For example, States may wish to continue coverage for barbiturates, benzodiazepines or prescription vitamins. Many States have already made decisions regarding coverage of these drugs as well as over the counter drugs for coverage under their Medicaid program for a variety of reasons. We will continue to follow our coverage decisions for the general Medicaid eligible population but our coverage decisions on these drugs will change for full benefit dual eligible clients. For the full benefit dual eligible we will deny coverage of prescription drugs because of the availability of the Part D benefit. We will then check to see if the specific drug dispensed is on a list of excluded Part D drugs to make a decision regarding coverage. <u>The problem is that CMS has not specifically defined this list (other than the generic criteria under section 1927(d)(2) of the Act). Without specific identification by NDC of the excluded drugs under Part D, we will be unable to make informed decisions to provide coverage for these drugs.</u> It is our understanding that CMS has generated a list of excluded drugs for the calculation of the clawback payment. A specific list of covered and non-covered drugs by NDC was generated because the calculation could not be completed using the generic criteria under section 1927(d)(2) of the Act. We believe that the drug coverage under Part D cannot be a static process. New pharmaceuticals are developed and approved by FDA on an ongoing basis, and drug labels are bought and sold by manufacturers constantly.

In addition, MMA excludes from the definition of a Part D covered drug any drug for which Medicare Part A or Part B would pay. The regulations stipulate that coverage will be excluded for individuals who have only either Part A or Part B and, for whatever reason, have chosen not to enroll in both parts. Thus, beneficaries will be left without any drug coverage when hospitalized or in a Part A covered SNF stay or receiving hospice care, since Medicaid will no longer cover the cost of medications. The proposed regulations may have adverse consequences for some of the poorest Medicare beneficiaries, unless CMS identifies these excluded drugs for States.

States will not be able to guess what new drugs are covered and not covered by Medicare Part D, and what drugs are excluded for which Medicare Part A or Part B would pay. We believe that CMS needs to maintain a list of excluded drugs and communicate that list to states on a continual basis. This will allow States to make informed decisions regarding coverage of excluded Part D drugs so that we do not risk a payback of federal funds to CMS for drugs they considered to be included in the Part D benefit.

Another administrative burden imposed upon the States will be the requirement to coordinate benefits with a Part D plan. In the proposed rule CMS identifies an example where States may wish to continue coverage for barbiturates, benzodiazepines or prescription vitamins (drugs excluded under the Part D benefit). In this situation, a Part D plan providing primary coverage would need to coordinate this coverage with a State on behalf of a dually eligible beneficiary. In order to provide this coordination of benefits with PDP plans, States will need specific information from CMS regarding the plans that beneficiaries are enrolled with, and information regarding each plan. We believe this requirement will set up a significant administrative burden on States and CMS necessitating the need for data exchanges regarding eligibility and plan assignments between the States and CMS. In addition, CMS will need to create a demographic file of all the PDP and MA-PD plans serving full benefit duals. States will need this information so that we can accurately conduct a coordination of benefits between the State and the plan for the beneficiary. If a pharmacy bills Medicaid primary for a full benefit dual eligible, we will deny the claim and notify the pharmacy the correct plan to bill. In addition, if we are billed as the secondary payor we will make sure the claim was paid or denied by the correct plan before we consider it for coverage under Medicaid. This will require significant MMIS and eligibility systems changes to account for this new information to facilitate a coordination of benefits activity.

In the proposed rule CMS states that it envisions a system of information sharing between Medicare, Part D plans, SPAPs, group health plans, insurers, and other third-party arrangements. If CMS is expecting a coordinated system for providing Part D benefits, this system of information sharing needs to include state Medicaid programs.

P. Premiums and Cost-sharing Subsidies for Low-Income Individuals – 1. Eligibility for the Low-Income Subsidy (§ 423.773)

Section 1860D–14(a)(3)(B)(v)(I) of the Act requires that full-benefit dual eligibles (as defined under section 1935(c)(6) of the Act) and individual receiving benefits under the SSI program be treated as full subsidy eligible individuals. Under Medicaid, the term ‘‘dual eligibles’’ generally refers to low-income Medicare beneficiaries who qualify for some level of medical assistance. Those entitled to full benefits under Medicaid generally have most of their health care expenses, including prescription drugs, paid for by a combination of Medicare and Medicaid. For purposes of the low-income subsidy under Part D, CMS proposes to define the term ‘‘full benefit dual eligible individual’’ as an individual who for any month has coverage under a PDP or MA–PD and is determined eligible by the State for medical assistance for full benefits under Title XIX for the month under any eligibility category covered under the State plan. In addition, as indicated in the proposed regulations CMS proposes to exercise authority under Section 1860D–14(a)(3)(B)(v)(II) of the Act to treat qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and certain qualifying individuals (QIs) as being eligible for full subsidy assistance. This decision is based on the fact that nearly all QMBs, SLMBs, and QIs, by definition, will likely meet the requirements to be considered a full subsidy individual. Generally, QMB, SLMB, and QI individuals have income below 135 percent of the FPL and resources that do not exceed twice the SSI limit.

Full benefit dual eligibles and QMBs, SLMBs, and QIs are provided premium assistance, and other benefits that include elimination of the deductible, continuation of coverage above the initial coverage limit, and elimination of cost sharing above the annual out-of-pocket threshold. Co-payment subsidies for these individuals will vary depending on their percent of poverty and whether the individual is in an institution.

Although it is not specifically stated in the proposed rule, States will be required to provide information to CMS to identify the individuals that are deemed to be eligible for Part D and

eligible for the low-income subsidy as defined above. In addition, states will be required to identify the percentage of poverty level and whether the individual is in an institution. This information is needed in order to provide the subsidy benefits as identified in the Act. This information sharing with CMS is another administrative burden put upon the State that has to be absorbed under existing resources. In addition, the timing of this information as it relates to identifying whether the individual is in an institution is a concern for Montana. In the proposed rule CMS often comments about pharmacy claims processing in a real time point of service adjudication. Identification of an individual's placement in an institution for purposes of overriding cost sharing will factor significantly in a pharmacy real time point of service adjudication. The regulations should address the issue of people going in and out of long-term care facilities. This will create a very difficult situation for clients if there are separate PDPs for LTC residents than for people in the community. Not only for coverage of drugs but for the application of the cost sharing. We believe that prompt identification of an individual's institutional status is needed in order to assure that a individual is not charged a co-payment upon entering a long-term care facility. If this is not communicated to the PDP plan they will attempt to collect co-payments from the individual that should be exempt under the Act. This is especially important for clients that enter the long-term care facility because generally under State law the client cannot take their prescriptions with them into the facility; all prescription must be refilled by the facility. The timing of this information should be considered by CMS to ensure that PDP plans receive this information. We believe that if this is not coordinated properly there will be complaints and appeals that will just create more administrative burdens for the State, CMS, PDP plans and pharmacy providers. Not to mention the distress experienced by the beneficiary.

P. Premiums and Cost-sharing Subsidies for Low-Income Individuals – 2. Eligibility Determinations, redeterminations and Applications (§ 423.774)

In accordance with section 1860D– 14(a)(3)(B)(i) of the Act, an application for subsidy assistance may be filed with either a State's Medicaid program office or SSA. Eligibility determinations would then be made by the State for applications filed with the State Medicaid agency or by the Commissioner of Social Security for those filed with SSA. It is CMS's goal to provide a single application and determination process for the low-income subsidy. The statute provides redeterminations and appeals of eligibility determinations are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. Similarly, the Commissioner will decide how to conduct redeterminations and appeals for those subsidy determinations made by

Social Security. CMS asks for comments on State Medicaid agency procedures that best implement the redetermination and appeal process that would best be accomplished if the two separate processes produce the same outcome.

States recently have had discussions with CMS regarding the MMA requirement that states and the SSA accept applications and determine eligibility for low-income subsidies. It is our understanding that SSA would very much like state Medicaid programs to act as application intake/assistance but to forward applications to SSA for actual processing of the eligibility determination. SSA would especially like states to decide to use the SSA application that is currently under development. It is our understanding that some states would like an option to fulfill this obligation to actually process applications through some sort of arrangement with SSA. However, Montana would prefer to accept an application and forward this to the SSA for determination of the low-income subsidy. We believe that this will be the most efficient method for us to coordinate efforts and encourage low-income consumers who are not deemed eligible for subsidies under Part D to make a timely application for financial assistance. Montana does not intend to develop our own subsidy application. We intend to use the SSA application currently under development.

We believe that clients who approach the State offices requesting assistance for the low-income subsidy will be offered a choice of application for determination under Medicaid and assistance under QMB, SLMB, and QI or, the SSA application for the low-income subsidy. If the client chooses to apply only for the low-income subsidy under Part D, we will forward that application to the SSA. If the client chooses to apply for benefits under Medicaid and our other low-income benefits, we will complete the determination, redetermination and appeal process. If the client is determined eligible, the client will be deemed to be eligible for Part D as authorized under the Act, and we will enroll them by notifying CMS and SSA. We believe this auto enrollment in Part D can occur in the same manner as the auto enrollment for our current full benefit dual eligibles, QMB, SLMB and QIs. We believe this process will best implement the determination, redetermination and appeal process that would produce the same outcome of providing subsidy assistance to low-income beneficiaries.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions – 1. Eligibility Determinations (§ 423.904)

The MMA added a new section 1935 to the Act, ‘‘Special Provisions Relating to Medicare Prescription Drug Benefit,’’ which specifies the requirements for States regarding low-income subsidies under the new part D benefit. In accordance with the statute, CMS proposed regulations at § 423.904(a) and (b) would require States to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic redeterminations consistent with the manner and frequency that redeterminations are conducted under Medicaid, and to notify us of eligibility determinations and redeterminations once they are made. In § 423.904(c), States would be directed to identify individuals who apply for the low-income subsidy who may also be eligible for programs under Medicaid that provide assistance with Medicare cost sharing and to offer enrollment in these programs. This requirement is consistent with existing obligations imposed on States when they make eligibility determinations for Medicaid. CMS also specifies that States notify deemed subsidy eligibles of their subsidy eligibility. In section § 423.904(d), CMS would require States to begin accepting application forms for the low-income subsidy no later than July 1, 2005. In section § 423.904(d), CMS would also require States to make available application forms, provide information on the nature of and requirements for the subsidy program, and provide assistance in completing subsidy applications. States also would be required to ensure that applicants or personal representatives attest to the accuracy of the information provided. In verifying application information, we would specify that States may require the submission of statements from financial institutions and may require that information on the application be subject to verification in a manner the State determines to be most cost effective and efficient. In addition, § 423.904(d) would direct States to provide CMS with necessary information to carry out implementation of the Part D program. This will include information such as income levels for other low-income subsidy eligible individuals under § 423.773 needed to permit PDPs and MA–PDs to determine the amount of cost sharing and sliding scale premium subsidy that a person will receive under § 423.780(b). CMS is considering a number of options to ease the burden on States and to ensure, to the degree permissible under the MMA, a consistent eligibility determination process. CMS invites comments from States on this issue.

Montana will work with CMS to ensure, to the degree permissible under the MMA, a consistent eligibility determination process. As mentioned in the previous comment we will offer an application process to coordinate with SSA the applications for the low-income

subsidy benefit and will provide CMS necessary information to carry out implementation of the Part D program. The requirements placed upon the State impose an additional administrative burden to develop the policies and procedures and data systems to carry out this effort. This is yet another area of increased costs to the State general fund that will offset any recognized savings identified under the clawback provision.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions - 2. General Payment Provisions (§ 423.906)

CMS specifies in § 423.906(a) that States could receive the regular Federal match for administrative costs in determining subsidy eligibility. Section 1935(d) of the Act contains provisions on Medicaid coordination with Medicare prescription drug benefits. The proposed regulations specify in § 423.906(b) that, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, medical assistance is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. In these cases Medicare is the primary payer. The provision of Part D covered drugs is no longer considered a benefit under the Medicaid program for full benefit dual eligibles, even if such individuals have not enrolled in a Part D plan. Therefore, no payment should be made under Medicaid for covered Part D prescription drugs for full benefit dual individuals. Also, in the proposed regulations in § 423.906(c), CMS specifies that for individuals enrolled in a drug plan under Part D or in an MA–PD, States may elect to cover under Medicaid outpatient drugs, other than Part D covered drugs (excluded Part D drugs), in a manner as otherwise provided in their State Plan for individuals who are not full-benefit dual eligible individuals or through arrangements with the PDP sponsor or MA–PD.

Montana understands the requirements outlined in the proposed regulation, and as stated before in previous comments, we have concerns regarding the administration of this Part D benefit for our full benefit dual eligibles. Specifically regarding the flexibility of the PDP formulary and the coordination of benefits option for States to cover excluded Part D drugs. We believe that on January 1, 2006, it is possible that clients will not have access to the same prescription drugs under PDP plans as they now have under Medicaid benefit. Especially if CMS allows a limited formulary and different formularies under each PDP plan for this low-income population. We believe that CMS should require PDP plans to provide the prescription drugs under the same requirements as the Medicaid programs for the full benefit duals eligibles. States are paying CMS this level of benefits in the clawback payments and anything less would be unacceptable to the State and the beneficiary. Changes in the clients'

prescriptions will have negative impacts on other state programs such as utilization review processes, disease management programs, and managed care programs. Changes and/or no access to needed drugs could also have a negative impact on other health care expenditures for Medicare Part A and Part B services and possibly state funded programs such as our state mental hospital. In addition, as mentioned in a previous comment, the coordination of benefits between Part D and Medicaid is a significant issue. Effective January 1, 2006, Medicare will assume the pharmacy benefit for full benefit dual eligible clients. Montana will eliminate coverage under the Medicaid program for full benefit duals that are included in the Part D benefit, because as noted in the proposed rule the state will not be eligible for federal financial participation for these expenditures. CMS also mentions in this proposed rule that there are excluded Part D drugs State Medicaid programs may choose to continue coverage. The problem with this coordination of benefits is that CMS has not specifically defined this list of excluded drugs (other than the generic criteria under section 1927(d)(2) of the Act). Without specific identification by NDC of the excluded drugs under Part D, we will be unable to make informed decisions regarding continued coverage for these drugs. We believe that CMS needs to maintain a list of excluded drugs by NDC and communicate that list to states on a regular basis. This will allow States to make informed decisions regarding coverage of excluded Part D drugs so that we do not risk a payback of federal funds to CMS for drugs they considered to be included in the Part D benefit. The alternative is for us to adopt a policy of no coverage under Medicaid for any drugs for a full benefit dual eligible. We believe that this will result in less access to pharmaceuticals for low-income beneficiaries and increase administrative burdens for both the State and CMS to handle appeals regarding coverage.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions - 4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908 through § 423.910)

Under the Proposed Rule, states would provide a phased down State contribution to Medicare Part D drug benefit costs. Often referred to as the clawback payment. Medicare will subsidize prescription drug costs for full-benefit dual eligible individuals. States and the District of Columbia will be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for these individuals. The proposed rules under § 423.908 through § 423.910, calculate the monthly State contributions, by determining the projected monthly per capita drug payment. This amount is based in part on a State's Medicaid per capita expenditures for covered Part D

drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003, which is equal to the weighted average of gross per capita Medicaid expenditures for prescription drugs for 2003 for Medicaid recipients not receiving drugs through a managed care plan and the estimated actuarial value of prescription drugs benefits provided under a capitated managed care plan for these individuals in 2003. This calculation will be based on data from the Medicaid Statistical Information System (MSIS) and other available data, as adjusted by an adjustment factor to account for drug rebates. The adjustment factor for a State would equal the ratio of the aggregate payments to the State in 2003 under rebate agreements under section 1927 of the Act to a State's 2003 gross expenditures for covered Part D drugs based on data contained in the CMS–64 Medicaid expenditure report. CMS propose to define 2003 as CY 2003 (January 1, 2003, through December 31, 2003).

This baseline amount will then be adjusted by a growth factor. During fiscal years 2004-2006, the growth factor, under the proposed rule, would be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure projections). For 2007 and beyond, the factor would equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs for Part D eligible individuals for the 12-month period ending July of the previous year.

We believe that this methodology is flawed because it does not take into account matching principles related to the timing of drug rebate collections, TPL collections for prescription drugs under a cost avoidance waiver and assumes a uniform cost of drugs nationwide. Drug rebate collections on the CMS-64 for a portion of calendar year 2003 reflect drug rebates for prescriptions dispensed in the last half of calendar year 2002. We believe that the adjustment factor based upon the ratio proposed by CMS understates the level of drug rebates collected in relation to the drug expenditures for calendar year 2003. CMS should apply generally accepted accounting matching principles that matches drug rebates to the related expenditures. In regard to TPL collections under cost avoidance waivers, CMS should allow an adjustment factor for states with approved cost avoidance waivers that effectively reduced our Medicaid drug expenditures in Calendar year 2003. We believe that failure to account for drug rebate and TPL collections will result in an overstated clawback payment to CMS. Lastly, the use of national data for inflating drug costs could cause disproportionately higher drug expenditures for many states. This would be punitive to our state if the rate of inflation

in our geographic region were considerably less than national data. Accordingly, we suggest a modification in this formula to include state specific data, which we believe would represent a more equitable approach to estimating drug expenditures and the total amounts due the federal government each month.

General comment - Medicaid drug rebates and the Medicare assumption of drug costs for full benefit duals.

In the proposed rules CMS will implement a rebate adjustment factor that takes into account drug rebates for a State. We have already commented on the calculation of this adjustment factor and would like to raise a related issue for consideration by CMS. CMS appears silent on the calculation of the unit rebate amounts for Medicaid when the best price negotiations between PDP plans and manufacturers are excluded from the rate calculations.

Montana is concerned that this exclusion from the best price calculation will negatively impact the unit rebate calculations under the Medicaid drug rebate program. In addition, we believe that manufactures will experience a significant windfall of savings if PDP plans cannot negotiate unit rebate amounts that equal to or better than that calculated under the Medicaid drug rebate program. If manufacturers do experience such a windfall savings on drugs rebates that would otherwise have paid, States and CMS should be able to share in this savings.

Montana greatly appreciates the opportunity to submit comments on the Proposed Rule. We welcome the opportunity to discuss the comments with you and your staff. Should you have any questions, please contact, Jeff Buska at (406) 444-4145.

Respectfully submitted,

John Chappuis, Deputy Director
Montana State Medicaid Director
Department of Public Health and Human Services

CMS-4068-P-1059

Submitter : **Date & Time:** **10/04/2004 06:10:10**

Organization : **Aetna**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached documents

CMS-4068-P-1059-Attach-2.doc

CMS-4068-P-1059-Attach-1.doc

Title I (Medicare Part D)
Aetna Comments to Proposed Rule

Subpart A – Definitions

- No Comments

Subpart B – Eligibility and Enrollment

- 423.34 Part D Enrollment Process

  Comment: As noted in the preamble pg. 46638, CMS will allow "automatic enrollment of an MA full benefit dual eligible into a MA-PD plan offered by the same MA organization offering his or her MA plan if the basic premium for such plan does not exceed the low-income benchmark premium amount."

  We support this direction and suggest that this automatic enrollment action occur at the beginning of the Annual Coordinated Election Period (ACEP), as opposed to the end of this period. CMS and/or the MA organization may facilitate this action by providing advance notice to the applicable beneficiaries. Similar to passive elections, such a notice could inform full benefit dual eligible individuals that they need not take any action for this to occur, however could also inform the individual how to opt-out of this action. The benefit of performing this action at the beginning of the ACEP would be the reduced likelihood that some individuals would be without Part D coverage as of January 1, 2006.

  Regardless of whether the basic premium for the MA-PD plan(s) offered by the MA organization exceeds the low-income benchmark premium amount, such beneficiaries should be afforded the same right to seamless continuation of their benefits through their current organization through automatic enrollment into any MA-PD plan offered by the MA organization. This ensures that such individuals will at least have some coverage under Part D, while still enabling the beneficiary to continue as an enrollee of an organization they have come to trust. Further, as noted in the preamble, these individuals would always have the opportunity to decline the enrollment or make another selection via the SEP afforded to them.

  Comment: To promote consistent and effective administration, we recommend that CMS assume the responsibility for coordination of the automatic enrollment process and suggest the possibility of including such auto assignment transactions within the existing Monthly Transaction Reply process (for MA-PDs). To the extent that plans will be required to support the automatic enrollment process for full benefit dual eligible individuals currently enrolled in a MA plan, or will need to verify the current status of a particular dual eligible individual for other purposes, we would request that CMS develop a standard process for obtaining information on the applicable status of dual eligible individuals.

- 423.36 – Part D enrollment periods

  The proposed regulations at §422.62 of Title II of the MMA state that beginning in 2006, beneficiaries may elect a MA/MA-PD plan, or return to Original Medicare, only

once during the first six month of the year. Beginning in 2007, beneficiaries may make only one change during the first three months of the year. With regards to Title I, since there is no corresponding enrollment period that would allow an individual the opportunity to elect a PDP plan under Part D, CMS proposes creation of a SEP to correspond to these open enrollment periods. As noted in our comments to Title II, we strongly encourage CMS to remove the enrollment lock-in requirements from the Title II regulations and allow beneficiaries freedom to choose the health plan that best suits their health plan needs. Assuming the removal of these lock-in requirements, we would recommend that CMS revise the SEP, described in the preamble to §423.36, to allow for election of a PDP by beneficiaries disenrolling from a MA-PD at any time during the calendar year.

- 423.42 Coordination of enrollment and disenrollment through PDPs

Comment: The enrollment mechanisms permissible under Part C should also be available mechanisms for enrollment in PDPs, including electronic enrollment and web-based enrollment mechanisms for individuals. Additionally, the final regulations should clearly prohibit pharmacist from encouraging/soliciting/accepting enrollment in specific PDP plans.

Employer groups (Preamble p. 46876)

Within the corresponding section on coordination of enrollment and disenrollment in the Title II proposed regulations (§422.66), CMS states that the Agency must carefully consider the impact of a default enrollment process on individuals enrolled in employer groups.

-- CMS raises concerns about a potential conflict with incentives under the MMA for employers to maintain creditable coverage and the possibility that such a provision could negatively impact married individuals enrolled in employer group plans under certain circumstances.
-- However CMS also states that:

> "On the other hand, we may learn from system processes we are establishing under the new Medicare-approved discount drug plan, such as data sharing with the States and other agencies. We could consider offering MA plans the option to establish a process with its employers to automatically enroll individuals, with an option for individuals to decline before enrollment. We recognize that any strategies to streamline and improve enrollment could lead to an overall reduction in costs. These are all important issues that must be carefully considered."

Comment: As we noted in our comments for Title II, to help ensure maximum employer sponsor flexibility and innovation, we recommend that CMS allow each employer to determine if they want to auto enroll their Medicare eligibles into a Medicare Advantage plan, or allow their Medicare eligibles to remain in alternative retiree health plans.

- 423.44 Disenrollment by the PDP

Comment: For PDPs with network pharmacies in other regions, or nationwide, we agree that PDP members could still effectively access their Part D benefits and, as a result, should not be subject to involuntary disenrollment because they no longer reside in the area where they had originally enrolled. As done under the MA program with regard to traveler/visitor programs, PDPs should have the ability to limit this option to enrollees who travel to certain areas.

- 423.48 Information about Part D

  Comment: As with the Medicare Prescription Drug Discount Card, a general level of concern with the disclosure of negotiated prices continues to exist throughout the industry. This concern is elevated when this specific information is consolidated on one public website. Disclosure of detailed negotiated price information could inhibit competition by resulting in the development of standardized contract terms and pricing that stifle innovation and undermine the ability to negotiate tailored agreements to address specific needs. In addition, negotiated prices may be subject to confidentiality requirements, and the disclosure of such prices potentially could affect the efficient functioning of a network.

  Suggestions that may possibly mitigate these, and other, concerns include disclosure of estimates or averages of negotiated rates within a given area (*e.g.,* county) and publication of such approximations only on the specific PDP or MA-PD website. However, to the extent that cost sharing under a particular plan design is represented as coinsurance (and not a co-payment, where the negotiated price would be irrelevant), estimated price information could be made available to current and prospective enrollees through direct contact with the plan.

- 423.50 Approval of marketing materials and enrollment forms

  Comment: Within the preamble for this section, CMS indicates it is considering allowing pharmacies and pharmacists to accept enrollment forms. Aside from the uneven playing field this would seemingly create between the marketing activities of PDPs in comparison to the permissible activities of MA-PDs, allowing acceptance of enrollment forms at pharmacies would also appear to create the same possibility for influence in plan selection that was of concern in the MA context. To avoid the potential for inadvertent influence which could affect the beneficiary's freedom of informed choice, we recommend that CMS apply the MA rule to PDPs and pharmacy providers. Similarly, sales presentations should be prohibited in areas or locations where beneficiaries intend to receive their Part D benefits. For the foregoing reasons and consistent with MA program requirements, pharmacy providers should not be permitted to accept applications

- Additionally, 423.50 states that the provisions of the MA regulations (422.80) applicable to MA marketing materials and activities are generally applicable to PDP MA marketing materials and activities.

  Comment: Under the current MA regulations, health plans must ensure that their portfolio of products and the marketing materials (including enrollment forms) associated with those products are not contained within the same packet. In order to ensure maximum beneficiary awareness and education, and at the same time reduce administrative cost, sponsors should be able to fully disclose their portfolio of

Medicare product offerings available to Medicare beneficiaries in each market within the same packet, including enrollment forms.

- 423.56 Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

  Comment: For those beneficiaries eligible for Part D prior to November 15, 2005, disclosure of whether the coverage they currently have is creditable should be provided prior to November 15, 2005, so these individuals would be afforded the maximum opportunity to exercise their decision to enroll. Development of model language by CMS for this notice will facilitate this process and add consistency to the message. However, to reduce the administrative burden associated with this important yet time-sensitive communication, we would recommend that sponsors be permitted to provide this notice within their own materials and through the same medium currently employed for other plan-related communications to retirees, including notification through electronic means.

  Upon termination or disenrollment from a plan offering creditable coverage, individuals may need evidence that their prior coverage was in fact creditable, to avoid late enrollment penalties. Given that evidence of prior creditable coverage may need to be provided to other entities, and that such individuals should be informed of the availability of a Special Election Period and other relevant instruction, there is a compelling reason to create a standardized notice for this communication.

  Part D eligible individuals would also need to be informed of changes in the creditable status of their current coverage prior to the effective date of that change. As this would, in effect, constitute a "termination" of their current creditable coverage, we would also recommend that a standard notice be issued by sponsors in these scenarios. Ideally, this communication would be provided at least 30 days prior to a change in the creditable status of coverage, and like the above, would include information on the availability of a Special Election Period and other relevant information.

  For all communications related to the loss of creditable coverage, whether due to termination, disenrollment or loss of creditable status, retirees should also be advised of other Part D coverage options that may be available to them, including specific information on where such individuals may obtain information related to availability of PDPs and MA-PDs in their area.

  Comment: With regard to additional information that may be required in disclosures, CMS requests comment on the potential administrative burden associated with providing an indication of the value of beneficiaries' drug benefit, the total amount of the annual premium for their drug benefit, and the amount of the annual drug benefit. First, in the context of these disclosures, the most important message to the beneficiary is whether the coverage is considered creditable or not. Communicating that information alone would appear to satisfy the disclosure needs in the most efficient manner. Further, to the extent that employers delegate responsibility for issuing such notices and disclosures to insurers or third party administrators, requiring this additional language could present these administrators with numerous variations in the content of disclosure notices, and in turn create a significant financial and operational burden.

Subpart C – Benefits and Beneficiary Protections

- 423.100 – Covered Part D Drug (Preamble 46646)

- Excluded from coverage under Part D are drugs for which payment would be available under Parts A and B.

  Comment: CMS needs to develop consistent national guidance clarifying which drugs will be covered under part B and which drugs will be covered under Part D. CMS should not allow this to vary based upon the local carrier's decision (as it does today under Part B). If CMS does not develop a uniform national list, some drugs may be available under Part B in one area of the county but not others. National employer plans will dictate pharmacy plan designs that are consistent for all retirees without regard to the state or region where such retirees may reside. As such, if a drug is not available under Part B in one area of the country, the drug would be covered under Part D in that area of the county.

  In addition, we believe CMS should clarify how drugs that may be covered under Part B or Part D in certain circumstances should be covered under Part D. For example, there are drugs that are administered in physician offices that also may be self-administered by beneficiaries in their homes. PDP plans and MA-PD plans will further information to clarify whether drugs must be covered in both of these situations.

  We also recommend that CMS exclude from coverage those drug which have non-prescription drug alternatives available (same drug, same strength); *e.g.,* when rantitidine 150 mg is available without a prescription, then the 150 mg prescription version should not be covered.

  CMS should carefully consider its exclusion of benzodiazepines and barbiturates. Since the drugs can also be used for seizure control, muscle relaxants, etc., CMS may want to reconsider a blanket exclusion for those drugs that may have multiple uses.

  Additionally, CMS should clearly exclude those drugs which are typically considered "lifestyle" drugs such as Viagra and Cialis.

- Identification of drugs that need specific guidance with regard to their coverage under Part D.

  Comment: In the preamble (Page 46647), CMS provides the example of the coverage of immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare. CMS indicates that Part D could pay for these drugs since Part B is prohibited by statue from paying for them

  In the case of transplants, payment of drugs associated with those transplants should be incurred by the primary payor (*e.g.,* employer group health plan). Coordination of benefits between the primary payor and Part D should be no different than it is today under Part A and Part B. If there are "gaps" between Part B

and Part D coverage, the PDP should be able to offer enhanced coverage to fill in those gaps and price accordingly.

In addition, we note that CMS has requested comments on whether HSA's, FSA's, HRA's and MSA's should be treated as "incurred costs". We believe this is necessary given the introduction of consumer-driven health plans. HSA and FSA funds, in particular, are directed by the employee and should be included as "incurred costs".

Dispensing Fees--Definition (Preamble p. 46647). CMS is inviting comments with regard to three options for defining the term, "dispensing fee."
-- negotiated prices shall include dispensing fees,
-- risk corridors are based on allowable costs, including dispensing fees, and
-- the costs used in calculating the retiree drug subsidies includes dispensing fees.

- **Comment:** We believe Option I**,** in which the dispensing fee would include only those activities related to the dispensing and transfer of possession of the covered Part D drug from the pharmacy to the beneficiary (including charges associated with mixing drugs, delivery, and overhead), is the preferred option of the three proposed by CMS. First, we believe that Option I reflects the standard practice in the industry. Second, we do not believe that the dispensing fee should include payment for any services or products that may be provided beyond the point of sale (for example, any activities such as home infusion services) that are performed by entities other than the pharmacy dispensing the Part D drug.

  Finally, we also do not believe the Part D program should be expanded to fill in the gaps in coverage between Parts B and D as implied within the dispensing fee definition options II and III. If PDP sponsors want to offer enhanced coverage to fill in those gaps, they should be able to do so and price accordingly.

- 423.104 (preamble 46649) Requirements Related to Qualified Prescription Drug Coverage

  Comment: As part of the CMS description of standard prescription drug coverage, CMS provides a definition of incurred costs. This definition is important because an individual's catastrophic coverage begins only after the beneficiary has incurred $3,600 true out of pocket expenditures. Tracking of those incurred costs, as outlined in the proposed regulation, appears to be extremely burdensome.

- Preamble 46642 – Actuarially equivalent standard coverage

  Comment: We appreciate the flexibility that the proposed regulations have outlined with regards to plans' ability to substitute cost-sharing requirements (including tiered structures tied to formularies and use of preferred pharmacies) for cost above the annual deductible and up to the initial coverage limit.

- Preamble 46652 – Enhanced alternative coverage

  Comment: We appreciate the flexibility that CMS has presented in its proposed rule with regard to the provision of benefits that are considered enhancements to the

standard part D benefit; *e.g.,* reductions in cost-sharing, and coverage of drugs that are specifically excluded as covered Part D drugs.

- Preamble 46656 – Pharmacy Access Standards (Long-Term Care Pharmacies)

  Comment: CMS raises a number of issues with regard to relationships between PDP sponsors and long-term care pharmacies. We do not feel that CMS should require plans to contract with long-term care and other types of pharmacies. Generally, we believe that CMS's access standards and the Part D any willing pharmacy requirements ensure that beneficiaries will have appropriate access to pharmacies. However, we are supportive of the option that would "encourage" plans to negotiate in good faith with long-term care pharmacies on the same terms as it does with other pharmacies within the region.

- Preamble 46656 – Pharmacy Access Standards (Home Infusion pharmacies)

  Comment: We believe CMS should develop less stringent access requirements when developing standards for all specialty pharmacy services, not just home infusion. Many retail pharmacies do not stock or dispense specialty pharmaceuticals. As such, there is a lack of competition in the retail pharmacy market for these services and the few retail pharmacies that do dispense specialty pharmaceuticals often are unwilling to negotiate acceptable prices. In order to develop rates/benefits/premiums that do not disincentivize use, PDPs should be able to fulfill beneficiaries' specialty pharmacy needs and meet the pharmacy access requirements through their mail order pharmacy and specialty pharmacy network arrangements.

  Comment/Question: Is this measured at the individual beneficiary or aggregate level? What criteria will CMS use to determine whether preferred network structure is not likely to discourage enrollment.

- 423.112 Establishment of Prescription Drug Plan Service Area

  Section 1860D-11(a)(2) of the Act provides CMS with the authority to establish PDP regions in a manner consistent with the establishment of regions under 42 CFR 4222.445 of the proposed rule.

  Comment: As noted in our Title II comments, Aetna is in favor of fewer, larger regions as opposed to many smaller regions. Multi-state regions would increase competition and give Americans greater choice in selecting a PDP or MA PD plan. In addition, larger regions would provide an adequate number of beneficiaries in each region, creating a more stable program.

- Preamble p. 46660 - CMS is seeking comments on the USP draft Guidelines.

  Comment: While we believe that the Draft Model Guidelines are in some respects too detailed or "granular", we generally are encouraged by the USP's and Expert Committee's efforts to strike an appropriate balance between assuring beneficiaries access to medication therapy and preserving the Medicare Modernization Act's goal of affording plan sponsors sufficient flexibility to maximize the value of the dollars spent under the Part D benefit.

In reviewing public comments and developing the Final Draft Guidelines, we believe it is vital that USP avoid granularity in the definition of classes and categories, and improve upon the balancing of access and flexibility reflected in the Draft Model Guidelines. A more detailed model formulary structure could unduly restrict the opportunities for plans to negotiate lower prices with manufacturers for prescription drugs. For example, if a drug class is defined in such a way that it includes only two drugs, plans would, under the proposed regulations, be required to include both drugs on the formulary. In such circumstances, plans would have little ability to negotiate lower prices with manufacturers since the market forces that typically drive such discounts – i.e., competition among manufacturers for inclusion on a plan's formulary – would be absent.

In improving the balance between access and flexibility, reflected in the Draft Model Guidelines, we believe USP appropriately should take into consideration the many additional protections built into the framework of the Medicare Modernization Act and the proposed regulations that further assure beneficiaries will have access to necessary medications. For example, the proposed regulations (Section 423.120(b)) would establish detailed requirements related to the composition and operation of the P&T Committees engaged in the development of formularies. Moreover, while it may be too restrictive when applied to a limited number of the proposed classes and categories, the proposed rule would require formularies utilized by Medicare prescription drug benefit plan sponsors to include at least two (2) drugs in each category and class (Draft Model Guidelines, p. 7). Similarly, the Medicare Modernization Act (Sections 1860D-4(f)-(h)) and the proposed regulations (Sections 423.560-423.638) set forth extensive appeal and exception requirements which not only assure that beneficiaries will have access to medically necessary drugs that are not included on a plan's formulary, but afford beneficiaries even greater protections by requiring coverage of non-preferred drugs at preferred drug cost-sharing levels in a broad range of circumstances.

As the examples above demonstrate, the Final Model Guidelines will fit within a larger framework to form a system of checks and balances that assures beneficiaries broader access to prescription drugs. To accomplish the goals of the Medicare Modernization Act, we believe it is essential that the Final Model Guidelines build upon the foundation laid by the Draft Model Guidelines. This will help ensure that sponsors of Medicare Part D plans have a flexible model formulary structure to enable the Medicare Part D program to provide the same type of quality, affordable prescription drug benefits as those that already meet the needs of millions of Americans in the commercial marketplace.

- CMS requested comments on how to further define "plan allowance"

  Comment: We generally support CMS' proposed rule requiring plans to pay their plan allowance less any beneficiary cost-sharing obligation for drugs purchased at out-of-network pharmacies. While CMS' proposed definition of plan allowance may be consistent with the current practice of some in the industry, there are plans whose current practices differ and others whose practices in the future may require CMS' to adopt a definition with greater flexibility. Rather than adopt a specific definition that could be overly proscriptive and could limit innovationwould limit PDPs and MA-PDs and may not be consistent with existing or future network contractual arrangements, CMS should adopt a definition that generally defines the plan allowance as the

amount that the plan would have paid for Part D drugs obtained at a network pharmacy, which typically will be the negotiated charge with the network pharmacy less any cost sharing obligation. A more general definition capturing what PDPs or MA-PDs would have paid to network pharmacies will preserve flexibility.

- CMS requested comments on how to further define “usual and customary”

  Comment: We do not believe that plans should need to pay more than what they would have paid had the member used a network pharmacy, since this could expose PDPs and MA-PDs to undue financial risk. Importantly, concerns regarding member exposure to uncontrolled out-of-network pharmacy prices should be tempered by the broad access members will have to network pharmacies as a result of the access requirements in the rule.

- 423.128 Dissemination of Plan Information (preamble 46664)

  Although most requirements are reflective of those under the Medicare Advantage program, CMS is proposing to require the PDP organization to maintain a toll-free customer call center, an internet web site, and provide responses in writing upon beneficiary request. CMS is encouraging, but not requiring a 24-hour call center. (CMS is inviting comments on the 24 hour call center issue.)

  Comment: CMS should not require PDP organizations to operate 24 hour call centers. Our experience clearly demonstrates that health plan organizations receive few calls after regular business hours. In lieu of a 24 hour call center. PDP organizations may want to consider the development of web site and/or IVR systems that will allow the beneficiary to access their accounts to determine TrOOP balances.

- Claims Information (Explanation of Benefits Notices) (preamble 46664)

  Comment: We encourage CMS to allow greater flexibility in how the EOB information is provided to beneficiaries. Rather than mail an EOB each month there is activity, PDP organizations should have the ability to provide access to the required information on the internet, or by telephone/IVR, with an option for beneficiaries to request a copy by mail. One concern with EOB's provided by mail is that the information quickly would be "stale" - potentially by the time the member receives it whereas the internet or telephone could provide access to more current information.

Subpart D Cost Control & Quality Improvement

- 423.153 Cost Effective Utilization Management

  CMS is proposing that the step therapy, precertification and other similar functions operate under the direction of the P&T committee. PDPs must have a Quality Improvement program to evaluate medication errors, ADR’s and improving medication use.

  Comment: We believe that the proposed rule appropriately describes the important role that drug utilization review and quality assurance programs can play in providing access to quality Part D drug benefits. We note that many of these programs are

operated at the pharmacy level and not the PDP sponsor level. CMS should make every effort to create regulations around existing programs to avoid duplicative services and unduly burdensome requirements.

While PDPs have systems and programs in place to promote improved quality and cost-effective pharmacy services, PDPs themselves do not prescribe or dispense drugs and therefore should not be responsible for dispensing errors. Consequently, it may be appropriate for PDPs to be evaluated based on the drug utilization, quality management and medication therapy management programs they have in place, but they should not be considered responsible for the results that are measured through such programs.

- Fraud, Abuse & Waste

  Comment: One area of concern for CMS is the inappropriate switching of prescriptions by PDPs without the consent of the prescribing physician. This section should include the ability of a physician to institute a protocol for substitution in collaboration with the pharmacist.

- Preamble 46668 Medical Therapy Management Programs (MTMP)

  Comment: We are generally supportive of the Medicare Therapy Management Program (MTMP) as outlined in the proposed regulations. The proposed rules however, appear to assume that physicians and pharmacists will provide the MTMP services. Assuming the PDP organization could develop and administer programs within its organization to meet all the requirements of the MTMP, CMS should build flexibility into the regulations that would allow the PDP organization to provide these services using internal resources or contracted external parties such as physicians and pharmacists, as appropriate.

Subpart F – Submission of Bids and Monthly Beneficiary Premiums

- Tests for Alternative Coverage (Preamble p. 46676)

  To qualify a plan as an alternative coverage to Part D, this section describes five tests that need to be met:
  - Test for Assuring at Least Equivalent Value of Total Coverage
  - Test for Assuring Equivalent Unsubsidized Value of Coverage
  - Test for Assuring Standard Payment for Costs at Initial Coverage Limit
  - Test for Assuring the Deductible Does not Exceed the Standard Deductible
  - Test for Assuring the Same Protection Against High Out-of-Pocket Costs

  Comment: Aetna believes that these tests in the proposed regulations may impose constraints on plan design that are more restrictive than required by statute. This will limit the plan design flexibility that Part D Plans and employers can use to effectively control costs. This will also limit flexibility in maintaining or enhancing existing prescription drug coverage and provide less choice to Medicare beneficiaries.

  Aetna believes the tests should not impose constraints any more restrictive than required by statute, and that they should be focused primarily on the proportion of

costs borne by the beneficiary. For example, we believe that the test with regard to coverage up to the initial coverage limit ($2,250) should focus on whether the deductible is not greater than $250 and that the average expected PMPM payout is equal to that under the standard plan. As written, the tests would not allow a copay-based plan to cover less than 75% of costs between $250 and $2,250, forcing the plan to either (i) introduce a deductible (if goal is to maintain PMPM payout equal to standard plan) or (ii) offer a plan with PMPM payout greater than standard plan.

Comment: Aetna would like to clarify that the regulations allow for the value of any enhanced benefit design to reflect both the potential impact of utilization changes and mix shifts to less expensive drugs. Also, any test of benefit value should also take into account the impact of utilization management programs. For example, reduced generic copays combined with UM that encourages generic use has the potential to increase utilization but have a favorable impact to total costs. Decreasing the beneficiary payment share should not be viewed on a stand alone basis from other initiatives.

- Rebate Reallocation for MA-PD Plans (Preamble p. 46680)

  Comment: Aetna would like to clarify that MA-PD plans with pharmacy coverage equivalent to their Part D Plan are able to charge a lower premium if sufficient savings are generated from other sources within the MA plan. Said differently, Aetna wants to make sure a MA-PD plan can avoid the situation of a member's premium being artificially inflated simply to match the premium for a comparable Part D plan.

  Comment: Aetna also believes that MA plans currently able to offer non-standard pharmacy coverage should not be precluded from doing so going forward. For example, we believe that we should be able to continue offering generic only drug coverage (as in existing MA plans) without any subsidy from the Part D program.

  Comment: Aetna would also like to clarify the degree of flexibility CMS intends to grant MA plans to waive small supplemental premiums emerging from the bidding process. For example, if otherwise required premiums are less than $10, Aetna would prefer the flexibility to waive the supplemental premium and/or make benefit changes.

- Adjustments for Regional Price Variation in Drugs (Preamble p. 46683-4)

  CMS proposes to adjust the national average monthly bid amount if there are significant differences in prices for covered Part D drugs across the regions. CMS further states that it may not implement a geographic adjustment for the first few years until sufficient information is compiled.

  Comment: Aetna believes that adjusting the national average monthly bid amount only for unit cost price differences will leverage utilization differences onto the beneficiary premium and result in significant premium variations across the regions. Aetna therefore believes that both unit cost and utilization differences ought to be taken into account.

  Comment: Aetna also believes that it is likely that there will be significant unit cost and/or utilization differences among local markets within a region, and would

therefore urge CMS to implement these adjustments in a manner that accounts for local unit cost and utilization differences.

Comment: Aetna also believes that these adjustments should be implemented as soon as possible, and therefore requests that CMS clarify when such cost differences will be studied and when these adjustments will be implemented.

- Collection of monthly beneficiary premiums and late enrollment penalties (Preamble p. 46684-5)

  Comment: CMS indicates that beneficiary premiums can be paid directly to the PDP sponsor or MA organization, as they can be under Part C. However, unlike Part C plan premiums, these Part D premiums may also include payment of relevant enrollment penalties on a monthly basis. As a result of the penalty amount varying based upon individual circumstances, PDPs and MA-PDs will likely encounter scenarios where members of the same prescription drug plan have widely varying premium payments.

  This variance would substantially increase the administrative burden for such organizations, both in terms of collection of premiums and application of payments. In addition, collection of penalties by the PDP or MA-PD may add complexity to the description of relevant premiums in marketing materials and the non-payment of premium process. As enrollment penalty payments made directly to the MA-PD or PDP would be deducted from CMS' payment to the organization, the burden associated with the prior examples would be further compounded by the need for added reconciliation activities. As a result, our recommendation is that CMS should deduct any applicable enrollment penalty directly from the beneficiary's social security benefit check, in the same fashion as Part B penalties are deducted today.

Subpart G: Payments to PDP Sponsors and MA Organizations Offering MA-PD for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

- Risk Adjustment (Preamble p. 46688)

  Comment: Aetna would like clarification of the methodology CMS intends to use to risk adjust payment rates. Aetna would also like clarification on whether risk-adjusted payment rates will be fully implemented in 2006, or whether they will be phased-in at a reduced amount (e.g. 75%).

- Adjustments to Reflect the True Out-of-Pocket Threshold (Preamble p. 46690)

  This section discusses the fact that only certain costs can be considered in determining whether the True Out-of-Pocket Threshold (TROOP) where reinsurance payments are triggered. In particular, claims covered under supplemental coverage do not count towards the TROOP and the existence of supplemental coverage therefore reduces the amount of reinsurance recoveries.

  Comment: Aetna believes that reinsurance payments should be triggered at the point that each enrollee hits $5,100 for the year rather than $3,600 out-of-pocket. We believe this because without a change in this provision there is a strong disincentive to not offer plans with enhanced coverage because the member will pay

for both the cost of the enhanced benefits and the reinsurance recoveries that will be eliminated because of a higher than $5,100 trigger point.

- Low Income Subsidy Payments (Preamble p. 46690)

  Comment: In order to simplify the administrative process of reimbursing plans for lower cost-sharing available to low-income beneficiaries, Aetna believes that CMS should prospectively calculate and pay an equivalent PMPM amount. Such a reimbursement process would be equivalent financially, yet significantly reduce administrative processes and costs. We believe that this is conceptually similar to what CMS does for the working aged population.

- Risk Sharing Payments or Recoveries (Preamble p. 46691)

  Comment: CMS notes that an adjustment will need to be made for excess utilization induced on standard coverage by virtue of offering richer than standard cost-sharing. Aetna would like CMS to clarify how they will ensure that such adjustments will be objective and consistently applied across all plans.

  Comment: Aetna also believes that aggregate risk-sharing targets should be established for all plans offered by an MA-PD or PDP in a region.

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

- 423.420 Solvency standards for non-licensed entities

  Comment: 423.420 appears to create an un-level playing field for risk bearing PDPs that are not a state licensed insurer. First, they can be waived from licensing requirements which reduce their administrative and compliance costs and second, if the state's solvency requirements are waived (and these state requirements are greater than the federal standards) then the PDP gets the federal standards. Unfortunately, licensed insurers are still held to licensing requirements and the higher solvency standards. State licensing standards and state solvency standards should serve as the basis of regulation for all PDPs.

- 423.440 Preemption of State Laws

  Federal Preemption of State Laws: In the preamble to the proposed rules, CMS explains that Section 1860D-12(g) of the Social Security Act (the "Act") incorporates section 1856(b)(3) of the Act. See preamble to August 2004 proposed rule, 69 FR at p. 46696. Section 1856(b)(3) of the Act states that: "The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." 42 U.S.C. § 1395w-26(b)(3). With regard to this preemption standard, in the preamble, CMS states:

  > We do not believe, however, that the language in 1856(b)(3) means that each and every State requirement applying to PDP sponsors would now become null and void. In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted.

> For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws.

See preamble to August 2004 proposed rule, 69 FR at p. 46696.

Comment: CMS's narrow interpretation of the statutory preemption is contrary to the clear and broad language of Section 1856(b)(3) and subverts Congressional intent.

There is no support in the text of Section 1856(b)(3) for the position that Congress intended that any State laws, except for State licensing and solvency laws, would apply to MA plans, or prescription drug plans offered by PDP sponsors or MA prescription drug plans offered by MA organizations (collectively referred to as "Part D plans"). The clear language of Section 1856(b)(3) indicates that the standards established under the Act shall "supercede **any** state law or regulation" and the only exception to this rule is State licensing and solvency laws (emphasis added). If Congress intended to exclude any additional State laws from this preemption standard, such as State contract or tort laws, Congress would have done so explicitly in Section 1856(b)(3), as it did with State licensing and solvency laws.

In fact, Congress intended to clarify in Section 1856(b)(3) that MA plans and Part D plans are offered under federal programs that are, therefore, subject solely to federal rules, with limited exception. The Conference Agreement explains the basis for this broad preemption authority, stating that:

> The conference agreement clarifies that the MA program is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases.

See Conference Agreement, Joint Explanatory Statement at p. 121, November 21, 2003. The Conference Agreement makes clear that Congress intended to draft a clear and broad federal preemption standard that would address the "confusion" evidenced in case law, thereby easing the administrative burden associated with the ambiguity in the former Section 422.402 of the Medicare+Choice regulations. CMS acknowledged this Congressional intent in the Instructions for the 2005 Contract Year distributed to MA organizations, stating that: "The reason for such a broad preemption authority is that Congress intended that, with the exception of licensing and solvency requirements, the MA program to operate solely under Federal rules." See CMS "Instructions for the 2005 Contract Year", dated June 22, 2004, on p. 2.

Nonetheless, rather than promote clarity and reduce administrative burden, CMS proposes a preemption analysis that creates even more ambiguity and potential for confusion than the former Medicare+Choice preemption standard. In particular, to determine whether a particular State law is preempted with respect to Part D plans, CMS proposes that PDP sponsors and MA organizations determine whether CMS has the "expertise" and "authority" to regulate in a particular area. If CMS has no expertise or authority to regulate in a particular area, CMS indicates that State laws related to this area would not be superseded or preempted. CMS provides no

specific, objective standards to guide this analysis, and does not cite to any support for this analysis in either the text or legislative history of Section 1856(b)(3) of the Act.

For all of the reasons set forth above, we believe that CMS's proposed interpretation of Section 1856(b)(3) of the Act plainly contradicts the clear language and Congressional intent of this provision. With regard to Section 1856(b)(3), it was the clear and manifest purpose of Congress that, with the exception of State licensing and solvency laws, only federal laws, rules and regulations should apply to MA and Part D plans. Accordingly, we request that CMS consider these comments and make clear that **all** State laws and regulations (with the exception of State licensing and solvency laws) are preempted with respect to MA and Part D plans.

In addition, although the proposed regulation contains broad federal preemption language, the final rules should clarify in a manner consistent with section 1860D-12(g) that State laws are preempted by federal standards with respect to Part D actuarially equivalent "qualified retiree prescription drug plans".

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

- 423.458 Application of Part D rules to MA-PD plans on and after January 1, 2006 (Employer group waivers)

  As noted in the preamble pg. 46697 of the proposed rule, CMS intends to use its broad waiver authority to facilitate employers and unions offering retirees their current high quality drug benefits under the CMS waiver authority.

  Comment: Within the CMS Employer Open Door Forum Discussion Paper titled "Retiree Drug Coverage under the MMA: *Issues for Public Comment to Maximize Enhancement in Drug Coverage and Reductions in Drug Cost for Retirees",* CMS provides an example of a possible CMS waiver allowing insurers to offer retiree drug coverage anywhere in the nation, under the following circumstances;

  - Participating as a Medicare PDP in at least one region of the country and having a nationwide pharmacy network;
  - Having a nationwide pharmacy network; and
  - Obtaining an enrollment waiver that allows the PDP to serve just the employer or union's retiree group, and to serve them nationally.

  We are supportive of the waiver example outlined in the open door forum discussion paper; however, we suggest further clarifying that waiver to indicate that the employer does not have to be headquartered in the approved PDP region service area, i.e., as long as the employer has a location or retirees residing in the PDP approved region, the PDP sponsor may offer PDP benefits in any of the employer's locations on a nationwide basis, if necessary.

  Comment: Additionally, under section 423.894, the preamble indicates that nothing in section 1860D-22 of the Act must be interpreted as preventing…..

- Sponsors from providing for flexibility in benefit design and pharmacy provisions, without regard to the requirements for based Medicare Part D drug coverage, as long as the actuarial equivalence requirement is met.

Nothing in the regulation is intended to prevent employers from having flexibility in plan design and pharmacy access provisions, as long as the plan is actuarially equivalent. As such, CMS needs to create a specific waiver allowing employers/sponsors to create actuarially equivalent plans that are not subject to the P&T guidelines or access, formulary and appeals requirements.

Comment: We believe the regulations should clarify and confirm that employer based insured group policies are permissible (in addition to self-insured plans typically offered by large national employers). We feel the regulations should clarify and confirm that an employer may be issued an actuarially equivalent Part D stand alone or integrated (with medical) group insurance policy. Such insured actuarially equivalent policies would serve as the employer's qualified retiree prescription drug plan for purposes of certifying coverage for the employer's 28% tax free subsidy.

Many employers today offer RX products that are not actuarially equivalent to Part D or designed to function as a supplemental wrap-around. Going forward we would expect employers to wrap-around or supplement Part D coverage.

In addition, we do not feel the statute prevents employers from offering stand-alone or integrated (with medical) insured group policies or self insured arrangements that are not actuarially equivalent. For instance, many employers may offer generic only benefits to their employees and although we understand the employer would not qualify for the tax free subsidy, their retirees could avail themselves of the benefits/services to which they and their employer have been historically been accustomed. As long as the employer clearly communicates that this coverage is not considered "creditable" and explains the impact of non-creditable coverage, we do not feel CMS has the authority to prevent employers from offering stand-alone products that are not considered actuarially equivalent to Part D. (We do not feel the statute prevents employers from offering stand-alone insured group policies.)

- 423.464 Coordination Of Benefits With Other Providers Of Prescription Drug Coverage

Comment: Procedures and requirements related to the coordination of benefits between Part D plans, SPAPs and other prescription drug plans will be published before July 1, 2005. Given the complexity of these requirements, plans will have an extremely limited period of time to develop and implement the extensive system enhancements and modifications that will be necessary for Part D plans in connection with these requirements. In addition, since some COB requirements will be applicable at the point-of-sale, systems and processes to support these requirements essentially need to be available as of January 1, 2006. Because of the abbreviated lead time, it will be extremely important for all potential plans to be extensively involved in the development of these requirements.

Comment: Part D plans will be required to coordinate benefits with other Part D plans when a beneficiary disenrolls from one plan and enrolls in another during the same year. Although such occurrences in the PDP context are likely to be limited to

plans changes during a SEP, such changes may be more common for enrollees in MA-PD plans, who may join a new MA-PD or PDP during the applicable OEP, as well as any SEP.

To help ensure smooth transfers between the two plans, the "receiving plan" would ideally receive information regarding OOP expenditures prior to the beneficiary's effective date under the new plan. However, depending upon when the election of the new plan occurs, it's possible that the "transferring plan" will not be aware of the need to release such information until several days, possibly weeks, after the plan change has actually occurred. Pending appeals, outstanding claims and cancelled prescriptions will further complicate the transfer of accurate information from one plan to another. We would suggest that CMS create a standardized process for reporting this information between plans, as well as instructions to handle scenarios where information is unavailable or inaccurate.

Comment: As noted within the preamble for this section and for Subpart C, the dispensing, method of administration and setting can affect whether a drug will be covered under Part B. In addition, as a result of LCDs and variances in the determination of drugs that are usually self-administered, coverage of a particular drug under Part B may vary from region to region. Although in many instances drugs denied coverage under Part B, for example, would be covered under Part D, this could still potentially impact the plan and/or beneficiary through application of cost-sharing that might not otherwise be applicable for the given scenario. To reduce the likelihood of such occurrences and increase the consistency by which drugs are appropriately covered under Part B or Part D, plans would need complete and accurate information regarding coverage variations from region to regions.

- Operationalizing the Data Exchange related to Part D Coordination of Benefits

Comment: We believe that Option 2 under the two options related to tracking TrOOP costs would be the most beneficial of the options. Given the above-mentioned issues, a CMS contractor entity would be a reasonable solution to help coordinate between Parts D and B for all areas related to this provision in the statute.

Subpart K: Application Procedures and Contracts with PDP Sponsors

- 423.504 General Provision

Comment: Full-risk PDP bidders will develop and submit bids assuming that the plan access requirements (at least two PDPs in a region or one PDP and one MA-PD) are met. If plan access requirements are not met and there is only one PDP bidder, that bidder should be able to negotiate directly with CMS for the delivery of PDP services to that region. If unable to reach agreement, the PDP bidder should be able to withdraw its application.

- 423.504(b)(4)(vi)(G), General Provisions (Compliance Plan Requirements)

Comment: CMS indicates in the preamble (p. 46709) that it will apply to PDP sponsors the same compliance plan requirements that apply to MA organizations. CMS notes in the preamble (p. 46709) that it has proposed to revise the compliance program requirements applicable to MA plans set forth at 422.501(b)(3)(vi)(G) to require that MA organizations conduct a timely, reasonable inquiry if the organization

discovers "from any source" evidence of misconduct related to payment or delivery of health benefits under its MA contract. If, after reasonable inquiry, the MA organization determines that the misconduct may violate criminal, civil, or administrative law, the MA organization must report the misconduct to the appropriate government agency within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. CMS adopted these compliance program requirements in § 423.504(b)(4)(vi)(G).

More specifically, § 423.504(b)(4)(vi)(G) provides that PDP sponsors must have a compliance plan that consists of "[p]rocedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's contract as a PDP sponsor." In the preamble to the proposed MA regulations (69 FR 46908), CMS explains that it proposes to change the compliance program requirements to require mandatory reporting of potential fraud, because of "corporate fraud scandals that have occurred over the past several years." In addition, CMS believes that the mandatory reporting requirement is "in keeping with" the Sarbanes-Oxley Act of 2002. Id. However, the proposed revisions to the compliance program requirements appear to be inconsistent with the standards set forth in Federal Sentencing Guidelines.

According to CMS, the original Medicare+Choice compliance program requirements set forth in § 422.501(b)(3)(vi) were developed based on the seven elements of an effective compliance and ethics programs set forth in Section 8B2.1 of Chapter Eight of the Federal Sentencing Guidelines. Chapter Eight of the Federal Sentencing Guidelines was recently amended, and, in the synopsis to the amendment, the United States Sentencing Commission ("USSC") explains that:

> This amendment is the culmination of a multi-year review of the organizational guidelines, implements several recommendation issued on October 7, 2003, by the Commission's Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (Advisory Group), and responds to the Sarbanes-Oxley Act ("the Act"), Pub. L. 107-204, which in Section 805 directed the Commission to review and amend the organizational guidelines and related policy statements to ensure that they are sufficient to deter and punish organizational misconduct.

See United States Sentencing Commission, Amendments to the Sentencing Guidelines at p. 109 (May 10. 2004); Federal Register Volume 69, Number 97, pp. 28993-29028, at p. 29022 (May 19, 2004). Most notably, after this thorough analysis, which, as noted above, included consideration of the Sarbanes-Oxley Act, the USSC did not amend the Federal Sentencing Guidelines to require that compliance programs include mandatory self-reporting of "potential" violations of law. Rather, the USSC recognizes that self-reporting is one indicator of an effective compliance program and should be considered in determining an organization's ultimate culpability with regard to an actual offense.

Specifically, in determining a base fine associated with a violation of law, Section 8C2.5(f) of the amended Federal Sentencing Guidelines requires that courts calculate a "culpability score" which includes an evaluation of whether the organization had an effective compliance and ethics program in place at the time the offense occurred, and whether, "after becoming aware of the offense, the

organization unreasonably delayed reporting the offense to appropriate government authorities." See United States Sentencing Commission, Amendments to the Sentencing Guidelines at p. 123 (May 10, 2004). The USSC explains that Section 8.C(f) "contemplates that the organization will be allowed a reasonable period of time to conduct an internal investigation," and indicates that no reporting is required under the Federal Sentencing Guidelines "if the organization reasonably concluded, based on information then available, that no offense had been committed." Id. at p. 124.

As stated above, the proposed § 423.504(b)(4)(vi)(G) is inconsistent with the Federal Sentencing Guidelines. First, as explained above, the Federal Sentencing Guidelines do not mandate that organizations report potential or actual violations of law as part of an effective compliance program. Second, while the USSC recognizes that one of the factors of an effective compliance program is investigating and reporting actual offenses to government authorities, the USSC does not mandate that the organization: (1) conduct an internal investigation within a particular period of time, or (2) report "suspected" or "potential" violations of law. CMS, on the other hand, is proposing that PDP sponsors be required to report potential violations of law to government authorities, and that this report be made within "not more than 60 days after the determination that a violation may have occurred." Thus, PDP sponsors would be required to make a report within 60 days after determining that misconduct may violate criminal, civil or administrative law, even if the organization is not yet able to draw a firm conclusion that a violation has actually occurred. This self-reporting would, in turn, potentially expose the PDP sponsor to a premature, formal government inquiry when, in fact, the conclusion may ultimately be reached that no violation occurred at all. This approach appears to present an unreasonable waste of administrative resources for both PDP sponsors and the government.

In conclusion, not only is the proposed §422.501(b)(3)(vi)(G) inconsistent with the amended Federal Sentencing Guidelines, but they do not appear to be based on requirements in any law and conflict with the USSC analysis of the Sarbanes-Oxley Act. Consistent with the amended Federal Sentencing Guidelines, the current MA compliance plan requirements recognize that "self-reporting" of actual violations of law is an integral component of an "effective" corporate compliance program, but they do not require an organization to report misconduct to the government. Therefore, we recommend that CMS revise § 422.501(b)(3)(vi)(G) to make it consistent with the current compliance plan requirements set forth in § 422.501(b)(3)(vi)(G) of the MA regulation.

- 423.514(b), Reporting Requirements & 423.501, Definitions

In proposed § 423.514(b), CMS would require that PDP sponsors report significant business transactions to CMS annually, within 120 days of the end of the PDP sponsor's fiscal year (unless for good cause shown, CMS authorizes an extension of time). The information provided to CMS would have to contain a description of the significant business transactions (as defined in proposed 42 CFR § 423.501) between the PDP sponsor and a party in interest. In the preamble, CMS specifically seeks comments to the type of business transactions which should be reported to CMS. 69 FR 46708.

CMS explains in the preamble that proposed sections 423.501 and 423.514 are based on current definitions and reporting requirements set forth in the

Medicare+Choice regulations, because CMS believes that the proposed MA and PDP programs are quite similar. 69 FR 46708. CMS indicates in the preamble that, in some instances, the Medicare+Choice requirements were revised to accommodate for differences between MA and PDP sponsors. Id. There is one notable difference between the old M+C program and the PDP program that was overlooked by CMS.

The proposed § 423.514(b) presumes that the Part D plan is the only line of business offered by the PDP sponsor. The proposed § 423.514(b) does not contemplate PDP sponsors that are national companies with multi-state operations and multiple lines of business engaging in numerous business transactions that may be wholly unrelated and immaterial to the Part D plans they offer. Application of the proposed reporting requirements set forth in § 423.514(b) would prove very burdensome to these types of national PDP sponsors. To illustrate, a director of a PDP sponsor may also be the executive of a company that supplies goods to the PDP sponsor, and the purchase of these goods may be solely related to a separate line of business offered by the PDP sponsor that is in no way associated with the Part D plan. If the PDP sponsor paid $25,000 or more for these goods, the proposed § 423.514(b) appears to require that the transaction be reported to CMS, even though the transaction may be immaterial and wholly-unrelated to the Part D plan offered by the PDP sponsor. In addition, the definition of a "business transaction" set forth in § 423.501 would appear to be overly broad and could include routine and immaterial business transactions, such as the provision of bona fide health and welfare benefits to a PDP sponsor's employees, directors, officers and partners, and their dependents, as well as compensation paid to directors for services performed in the normal course of their membership on the board of the PDP sponsor. We do not believe that CMS intended to require that PDP sponsors report such inconsequential information to CMS, because there is no direct correlation between such information and the offering of the Part D plan or the fiscal soundness or prudent management of the PDP sponsor. It is unclear what "protection" is afforded CMS in having this information reported and tracked by the PDP sponsor, particularly in light of the low dollar threshold.

Accordingly, we recommend that CMS consider the significant burdens associated with this reporting requirement for national PDP sponsors, and revise subsection (3) of the definition of "business transaction" set forth in proposed § 423.501 as follows:

> *Business transaction* means any of the following kinds of transactions:
>
> * * * * * *
>
> (3) Good, services, or facilities furnished for a monetary consideration, including management services, but not including –
>
> (i) Salaries, bonus or other compensation paid to employees for services performed in the normal course of their employment; or
> (ii) Health services furnished to the PDP sponsor's enrollees by pharmacies and other providers, by PDP sponsor staff, medical groups, or independent practice associations, or by any combination of those entities**; or**
> **(iii) Compensation paid to directors for services performed in the normal course of their board membership; or**

(iv) Bona fide health and welfare benefits provided to employees, directors, officers, or partners, and their dependents.

(Proposed revision to § 423.501 is **bolded**.)

In addition, we recommend that the definition of "significant business transactions" set forth in proposed § 423.501 be revised as follows:

> *Significant business transaction* means any business transaction or series of transactions of the kind specified in the above definition of business transactions that **is directly related to the Part D plan and,** during any fiscal year of the PDP sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

(Proposed revision to § 423.501 is **bolded**.)

We believe that with these revisions to § 423.501 CMS achieves the intended goal of limiting the reporting requirement set forth in § 423.514(b) to those types of significant business transactions that bear directly on the offering of the Part D plan, and the fiscal soundness and prudent management of the PDP sponsor.

Subpart L: Change of Ownership

- 423.552 Novation Agreement

Comment: CMS should clarify in its final regulations that a stock purchase or similar change in stock ownership does not constitute a change in ownership that requires a novation agreement. It should only require a name change agreement**.** This is particularly important when the stock ownership changes between affiliated companies with a common parent company.

Subpart M: Grievances, Coverage Reconsiderations, and Appeals

- Preamble pg. 46723 - Federal Preemption of Grievances and Appeals

CMS regulations do not currently mandate a grievance process. As such, many health plans default to state grievance guidelines and processes. Section 232 (a) of the MMA states that the standards established under the MA program supersede law or regulation with respect to MA plans. CMS is seeking comments on whether they should adopt a grievance provision that would supersede state laws.

Comment: We favor CMS adopting one specific set of grievance provisions for notification and time frames for responses. We should not be subject to multiple and conflicting state laws governing the processing of grievances. The clear language of Section 1856(b)(3) indicates that the standards established under the Act shall "supercede **any** state law or regulation" and the only exception to this rule is State licensing and solvency laws (emphasis added). If Congress intended to exclude any additional State laws from this preemption standard, such as State grievance laws, Congress would have done so explicitly in Section 1856(b)(3), as it did with State licensing and solvency laws.

- Preamble pg. 46723 - Employer Sponsored Prescription Drug Programs and Appeals

  CMS notes that Medicare beneficiaries may receive integrated prescription drug benefits, i.e., Part D benefits through an MA-PD or PDP and supplemental benefits through an ERISA-covered plan. CMS states that, if the enrollee had a dispute about Part D coverage, they could file an appeal with the PDP sponsor. However, if the enrollee's dispute involved only the amount of cost sharing paid by the employer-sponsored plan, the enrollee would file an appeal through the process established for the ERISA based plan. CMS solicits comments on these parallel procedures.

  Comment: We favor CMS adopting the single process, under Subpart M of Title I, to apply to all benefits offered by an MA-PD or PDP to an employer group, including benefits separately negotiated between the MA-PD or PDP and the EGHP. We do not believe that it is necessary for MA plans to be subject to the requirements for the DOL/ERISA claims rule for employer based plans.

  There are comparable protections are under the DOL/ERISA claims rule and the Subpart M appeals process. The differences in the requirements make it difficult to educate beneficiaries about their rights under both processes. Employer-negotiated benefits are not separately designated in marketing and membership materials, and, in many cases, most benefits fall under the CMS-approved benefit package (including all Medicare-covered benefits). To determine which appeals arise from employer-negotiated benefits and ensuring that different notices of appeal rights are issued and that a different process is followed for these appeals is administratively and financially onerous. Moreover, it is confusing for an enrollee who must navigate through both of these separate processes for, possibly, a coverage determination on the same issue. A single, uniform appeals procedure for all benefits, such as the appeals process under Subpart M, (which includes access to independent review), will make it easier for MA-PD or PDP enrollees to understand and pursue their rights. Further, it will eliminate the duplication which exists in the parallel appeal tracks.

- 423.562 General Procedures

  When a complaint is received, the PDP must promptly determine and inform the enrollee whether the complaint is subject to the appeal procedures or to the grievance procedures.

  Comment: Can this be accomplished verbally or does it need to be in writing? And does this only need to happen in those instances when the enrollee may be confused as to which process they are entering?

- 423.564 Grievance Procedures

  When a complaint is received, the PDP must promptly determine and inform the enrollee whether the complaint is subject to the appeal procedures or to the grievance procedures.

  Comment: Can this be accomplished verbally or does it need to be in writing? And does this only need to happen in those instances when the enrollee may be

confused as to which process they are entering? CMS needs to clarify and specify these requirements.

- 422.566 Coverage Determinations

  Enrollee can appeal a decision on the amount of the cost sharing for a drug

  Comment: Cost sharing and/or Co-payment amounts do not represent a denial. As such, complaints about cost sharing/co-payments should not be subject to the appeals process.

- 423.578 Exceptions Process

  PDP sponsor that provides prescription drugs in a tiered formulary must establish and maintain an exceptions process for the following circumstances:
  1) If enrollee is using a drug and cost-sharing structure changes mid-year
  2) If enrollee is using a drug and cost-sharing structure changes at the beginning of a new plan year
  3) Enrollee has no pre-existing use of the drug.

  Comment: Tiered Cost Sharing should be limited to the instance only where a member is on a drug, which is moved to a higher tier mid-year. (Not as the preamble suggests: 1. when they have not been on the drug at all, 2. where the enrollee is on the drug and cost tiering changes for the **new** plan year).

- If sponsor does not make a timely decision, the enrollee is entitled to have coverage for up to a 1-month supply of the requested drug and the PDP sponsor must make their determination before the enrollee completes the supply. If no decision is issued by this time, the enrollee is provided coverage until PDP sponsor makes a decision.

  Comment: If the member is given the 1 month supply of the requested drug due to a delay in the decision and then receives a denial, we are concerned that there are certain experimental/investigational medications that may require a course of treatment longer than 30 days and, if interrupted, may be detrimental to the patient.

- When an exceptions request is approved the PDP Sponsor can not require enrollee to request a new approval for a refill or new prescription to continue using the drug after the refills for the initial prescription are exhausted, as long as the enrollee's prescribing physician continues to prescribe the drug and the drug continues to be safe for the treating the enrollee's condition.

  Comment: Once the plan grants the exception for coverage of a non formulary drug or coverage of a non-preferred drug at a preferred cost sharing tier, the proposed rule would require the plan to continue coverage as long as the prescribing physician prescribes the drug and the drug is considered safe for the treatment of the beneficiary's disease or condition. We believe that the proposal to require continued coverage unless a drug is no longer considered safe for treatment of a beneficiary's condition is too restrictive.

First, the proposed requirement to continue coverage should be limited only to medications used on an ongoing basis to treat chronic conditions. Medications taken to treat acute conditions (e.g., antibiotics taken for an acute bacterial infection) should be excluded from this requirement.

Second, this exception to continuation of coverage should be expanded to allow plans to implement new coverage requirements designed to maintain access to clinically appropriate, cost-effective medications. For example, plans should be allowed to impose a new step-therapy requirement that requires a member who received an exception for coverage of a nonformulary brand-name drug to first try a generic drug considered by the FDA to be safe, effective and interchangeable with that brand name drug. CMS' proposal to require continued coverage except in circumstances where a drug is no longer considered safe will significantly diminish plans' ability to develop new programs which reflect new drugs that become available and new clinical information regarding drug therapies as it evolves. Such flexibility is essential if the MMA is to achieve its goal of providing beneficiaries with access to quality, affordable prescription drug benefits.

- 423.578 Request for a standard redetermination

  Allows a party to request a standard redetermination orally or in writing.

  Comment: The acceptance of oral requests for redeterminations will be burdensome. If oral requests are permitted from appellants other than the beneficiary, we will need CMS to clearly define the process of how the sponsors will handle oral requests. If a provider is appealing on behalf of the member, there should be some type of confirmation by the physician submitting the request they have been authorized to do so by the member. Would representative statements still be a requirement? If so, how will the sponsor respond in the event that they can not obtain signatures from the appellant?

- 423.578 Expediting certain redeterminations

  An enrollee or a physician on behalf of an enrollee may request that a PDP sponsor expedite a coverage redetermination.

  Comment: Would representative statements still be a requirement? If so, how will the sponsor respond in the event that they can not obtain signatures from the appellant?

Subpart N Medicare Contract Determinations and Appeals

- No comments

Subpart O Intermediate Sanctions

- No comments

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

- 423.772 Definitions

  Institutionalized individual is defined as a full benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month.

  Comment: Aetna would like additional information regarding how CMS will determine that an individual meets this definition. MA organizations will no longer be required to report institutionalized members since that special status payment category is being phased out. Our assumption is that CMS plans to use the Medicare Beneficiary Database or some similar system for verifying institutional status. However, based on our experience, Aetna is not confident that the data from these sources is accurate and reliable. Aetna encourages CMS to consider the reliability of the database that will be used for this determination.

- 423.774 Eligibility Determinations, Redeterminations and Applications

  CMS is proposing to define personal representative as an individual who is authorized to act on behalf of the applicant, an individual acting responsibly on behalf of an applicant who is incapacitated or incompetent, or an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

  Comment: Aetna favors this broad definition of authorized representative. We would also encourage CMS to permit a beneficiary to appoint an organization (not just an individual) to act as an authorized representative. This is currently permissible in other situations (such as the dual eligible outreach and assistance process).

- Effective Date of Initial Eligibility Determinations

  Eligibility determinations are effective beginning with the first day of the month in which the individual applies.

  Comment: Aetna is strongly opposed to allowing retroactive effective dates for eligibility determinations. Our experience in working with various states on the dual eligible process has shown that states often take up to 4-6 months to approve applications. Even in an ideal situation where an application is approved by the state or SSA within 30 days, there will still be a 1-2 month period of retroactivity, requiring adjustments on premiums and copayments paid during this period. This is a burdensome process for MA organizations and would potentially cause confusion for beneficiaries.

- 423.780 Administration of Subsidy Program

  CMS will reimburse sponsors and MA organizations for reductions in premiums and cost sharing on either a per member basis or a capitated basis. In turn, the PDP or MA-PD must reimburse low-income subsidy eligible individuals any out of pocket costs related to excess premiums and cost sharing paid before the date the individual is notified of the subsidy eligibility and after the date that subsidy eligibility is effective.

Comment: As noted above, retroactive eligibility determinations and adjustments for previously paid premiums and copayments is a challenge for MA organizations to administer. Aetna does not have a system in place to refund premium amounts or make copayment adjustments due to retroactive eligibility determinations. These adjustments would therefore need to be made manually, creating a time consuming and burdensome process for Aetna. In addition, such manual processes would increase the opportunity for human error, potentially resulting in lower quality results. Finally, refunding premium and copayment amounts to beneficiaries may be difficult for beneficiaries to understand, resulting in increased calls to Customer Service.

Comment: Additionally, we recommend that CMS hire a contractor to assist in the management of the cost-sharing subsidies associated with low-income beneficiaries.

Subpart Q – Fallback Plans

- No comment

Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans

Options for Sponsors of Retiree Prescription Drug Plans (Preamble p. 46736)

Option I – Qualified Retiree Health Plan (Actuarially equivalent to Part D)

Comment:

- Neither the law nor the regulation make a distinction whether the actuarially equivalent qualified retiree prescription drug plan can be offered by an employer on a self insured basis or fully insured basis. We believe either approach as determined by the employer is authorized. We seek CMS' confirmation.
- In addition, although the proposed regulation contains broad federal preemption language, the final rules should clarify in a manner consistent with section 1860D-12(g) that State laws are preempted by federal standards with respect to Part D actuarially equivalent "qualified retiree prescription drug plans".

Option II – Employer may contract with a PDP plan or a MA-PD that provides part D coverage.

No comments.

Option III – Employer could apply to become a PDP sponsor or MA organization and offer a PDP or MA-PD plan to its retirees.

- **Comment:** This would require employer to meet not only state licensure requirements, and/or alternative waivers meeting solvency requirements,. but also, employers must have the ability to perform all other functions as required under the Part D program; *i.e.,* enrollment, access, quality programs, appeals, etc.

Option IV – Non-Part D plans that "wrap around" or supplement PDP benefits

Comment: This type of coverage could delay the payment by the government and its obligation to the PDP or MA-PD plan since payments made by the ER's wrap plan are not counted as True Out Of Pocket costs (TROOP)

Question: An employer or union offers a wrap around plan for its retirees, with coverage designed to "fill in the gaps" of the standard Part D benefit. In this scenario, the PDP pays 75% of the drug costs between $250 and $2,250, the wrap around coverage pays 20%, and the retiree pays 5%. As noted within the preamble, the 20% paid by the employer wrap around coverage will not be counted as TrOOP and, as a result, it will take the retiree a higher volume of gross expenditures to reach the $3,600 OOP cost level. However, prior to achieving that level, the PDP offering the standard benefit would have already paid up to $2,250 in total expenditures (via their 75% plan contribution). Would the donut hole apply based upon the 75% paid by plan ($1500 paid), even though the retiree hasn't met that corresponding level (TrOOP) of $750 (as a direct result of the wrap around/supplemental payments made by the employer wrap around coverage).

- **Payment Methodology preamble pg 46746**

    - CMS proposes monthly reconciliations to determine the amount of the subsidy payment, i.e., Single subsidy payment at the end of the year
    - Interim payments throughout the year, based on an estimate of per capita settlement at the end of the plan or calendar year
    - Lagged payments based on actual experience with a year end settlement reconciling these estimates with rebates received.

Comment: To help ensure maximum participation, CMS should allow insurers, plan administrators and employers the opportunity to choose the option that works best with-in their system.

423.884

- *CMS asking for comments on the most effective methods of conducting outreach as well as prospective venues for conducting the outreach*

Comment: Many administrators and insurers, like Aetna, have committees or councils comprised of select large national accounts (employers); *e.g.,* ACAG. Presentation and discussion of this information in this type of forum would benefit employers as well as plan administrators.

- Attestation of Actuarial Value

Comment: We do not feel this requirement would pose an undue burden. The beneficiary needs as much notice as possible to make an appropriate choice in benefits without the risk of incurring the late penalty.

However, employers are required to make the initial and annual attestation of actuarial equivalence. CMS appears to permit (in this area and numerous other administrative areas) this attestation to be made by a plan administrator designated by the employer.

The delegation of the employer's plan attestation could cause potential unintended liability for administrators. This could be problematic since the actuarial equivalence attestation creates potential false statement, false claim and perjury implications for the declaring. Union groups are also requesting CMS to permit third party actions against employers with false certifications and to review their actuarial equivalence determinations. This attestation is also a basis for the employers' tax subsidy request, the creditable coverage determination, and is also used by CMS to assure that the employers' contribution strategy does not result in a financial windfall to the employers. These are areas outside the scope of any insurance risk/administrative risk that 3rd parties take on. The ultimate responsibility for the attestation function should rest with the employers who have contracted directly with CMS.

- Establishing Actuarial Equivalency:

CMS proposes to take the position that all health benefits provided by a sponsor are presumed to be under a single plan thus applying the actuarial equivalence test to each group health plan as a whole so that if the test is met with the average of the plans offered, they would meet the subsidy requirement. CMS indicates this approach is less burdensome for plan sponsors.

Comment: We feel while this would make the administration of the process easier on plan sponsors; however, beneficiaries could enroll in a sponsor plan that, by itself, not actuarially equivalent to standard Part D and when necessary, switch to a more robust plan without incurring a penalty.

- Requirements for qualified retiree prescription drug plans (Creditable coverage and notification)

  Comment: For those beneficiaries eligible for Part D prior to November 15, 2005, disclosure of whether the coverage they currently have is creditable should be provided prior to November 15, 2005, so these individuals would be afforded the maximum opportunity to exercise their decision to enroll. Development of model language by CMS for this notice will facilitate this process and add consistency to the message. However, to reduce the administrative burden associated with this important yet time-sensitive communication, we would recommend that sponsors be permitted to provide this notice within their own materials and through the same medium currently employed for other plan-related communications to retirees, including notification through electronic means.

  Upon termination or disenrollment from a plan offering creditable coverage, individuals may need evidence that their prior coverage was in fact creditable, to avoid late enrollment penalties. Given that evidence of prior creditable coverage may need to be provided to other entities, and that such individuals should be informed of the availability of a Special Election Period and other relevant instruction, there is a compelling reason to create a standardized notice for this communication.

  Part D eligible individuals would also need to be informed of changes in the creditable status of their current coverage prior to the effective date of that change. As this would, in effect, constitute a "termination" of their current creditable coverage, we would also recommend that a standard notice be issued by sponsors in these

scenarios. Ideally, this communication would be provided at least 30 days prior to a change in the creditable status of coverage, and like the above, would include information on the availability of a Special Election Period and other relevant information.

For all communications related to the loss of creditable coverage, whether due to termination, disenrollment or loss of creditable status, retirees should also be advised of other Part D coverage options that may be available to them, including specific information on where such individuals may obtain information related to availability of PDPs and MA-PDs in their area.

- 423.886 Retiree Drug Subsidy Amounts

Comment: With regard to the calculation of the subsidy for a fully insured plan, the 28% tax free subsidy for an employer/sponsor offering a fully insured actuarially equivalent qualified retiree prescription drug plan should be based upon the insurance premium paid for the plan and not the actual incurred drug costs for each retiree between $250 and $5000.

- 423.888 Payment Methods, Including Provision of Necessary Information

  - Gross Retiree Costs and the Definition of "Coverage Year"

The CMS preamble defines gross covered retiree plan-related costs as specified costs incurred during a covered year. CMS defines "covered year" as a calendar year.

Comment: Since many employer plans begin at other times than 1/1 of each year, we recommend clarifying "coverage year" as plan year…in lieu of calendar year. We understand this presents unique issues for those plans that may end, for example, on June 30 of 2006 and only six months of the plan year accrued after January 1, 2006. The preamble describes three options to address this problem. We encourage CMS to allow all three options to remain in the final rule, so employers may choose the option that best conforms to the accounting system of the employers. However, if CMS, in its final rules, presents only one of the options, we prefer Option 2 as described on page 46746 of the preamble.

> *To determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire "plan year" and then to prorate this amount based on the number of "plan years" months that fall in 2006*.

  - Data Collection

The proposed rule requires employers to submit data to CMS to support their application for the employer subsidy.

Comment: We are pleased to see that CMS has ruled out requiring plans to submit actual claims data on each qualifying covered retiree. However, the three options that CMS has provided still have the potential to be of substantial burden to the sponsor. Of the three options presented, we are in favor of the provision that would

allow sponsors the ability to submit the aggregate total of all allowable drug costs for all qualifying covered retirees in the plan for the applicable time period.

- 423.894 Construction

The preamble pg. 46751 indicates that nothing in section 1860 D – 22 of the Act must be interpreted as preventing…..

- Sponsors from providing for flexibility in benefit design and pharmacy provisions, without regard to the requirements for based Medicare Part D drug coverage, as long as the actuarial equivalence requirement is met.

Comment: Nothing in the regulation is intended to prevent employers from having flexibility in plan design and pharmacy access provisions, as long as the plan is actuarially equivalent. As such, CMS needs to create a specific waiver allowing employers/sponsors to create actuarially equivalent plans that are not subject to the P&T, access formulary and appeals requirements.

Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

- 423.902 Eligibility Determinations for Low-Income Subsidies

This section outlines the process for screening applications for eligibility and making eligibility determinations.

Comment: Aetna is requesting that CMS institute a time requirement for States to review and approve an application for a low-income subsidy. Our experience in working with states on the dual eligible process has shown that States often take 4-6 months to approve an application for the Medicare Savings Programs. Aetna is suggesting that states be required to review and approve or deny an application for a low-income subsidy within 30 days of the date the application is submitted.

Subpart T - Part D Provisions Affecting Physician Self-Referral, Cost-Based HMOs, PACE, Medigap, and Medicaid Requirements

Comment: Section 403.205(c)(4) contains a newly proposed definition of the Medicare Supplement Policy ("Medicare Supplement" or "Medigap"). The Preamble (P.40758) states that effective January 1, 2006 the definition of Medicare Supplement is revised "to include any insurance policies that contain a prescription drug benefit, and that are primarily designed for or are primarily marketed and sold to Medicare beneficiaries…Moreover, any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy, will meet that definition as of January 1, 2006, when the prescription drug benefit takes effect, and any new sales would be prohibited after that date."

We strongly urge CMS to reconsider this proposal and that the proposed revision contained in 403.205(c)(4) be removed. CMS notes that there was "some ambiguity" in the past" about whether stand-alone drug policies met the definition of a Medigap policy (see Preamble 46758). We are not aware of any such ambiguity as such plan

policies have been regulated by the states as limited benefit plans. This determination was recently reinforced by the NAIC Senior Issues Task Force that specifically rejected the position CMS now proposes. These products were developed by companies at considerable cost and effort and filed with various states and approved by state regulators. They serve as important product offerings and choice to Medigap eligible individuals. Beneficiaries continue to be protected by the existing state regulation.

We question the legal basis for this change. Section 104 of the MMA contains the "Medigap Amendments." There is no statutory authority or other language in this provision (Section 1882(v)) that prescribes stand-alone drug policies as Medigap policies. Nor is there any language either in this Section or the Conference Report (See Page 79) to support the product's elimination on 1-1-2006 as proposed by CMS. Finally, the MMA did not revise or otherwise amend the statutory definition of a Medigap policy (except for standardized "true" Medigap Plans H, I, J) and Congress did not direct CMS to prohibit new sales of stand-alone individual drug policies. (See Section 1882(g)(i)).

There are additional, adverse and significant business implications for this proposal with regard to those beneficiaries who do not enroll in Part D and wish to retain their stand-alone drug coverage. By regulation, CMS would "convert" a limited benefit plan into a Medigap Plan and thereby expose insurers to additional plan risk and operational costs not contemplated by the insurer nor Congress in enacting MMA. (Unlike "true" Medigap insurers that sold standardized plans H, I, J and understood the legislative proposal and changes specified in MMA.) For example, the stand-alone Rx coverage would newly become a regulated Medicare Supplement policy and be subject to new and different Medicare Supplement rating and loss ratio requirements. It would also "convert" the Plan to a form of guaranteed renewable (GR) coverage which not only has rating implications but exposes the insurer to an added line of GR business that was not considered or required as part of its regulation as a limited benefit plan.

Finally, the Medicare Supplement notices of "creditable coverage" under Section 104 of the Act cannot be used for these stand-alone drug plans because they are unrelated to existing Medigap Supplement requirements and technically do not become (under CMS's proposed rule) a Medicare Supplement policy until after the date in which the notices are required to be distributed. This proposed change would only serve to further confuse and complicate the Medigap changes Congress intended to apply to standardized Medigap plans H, I, J.

We urge CMS to address these concerns and issue a final regulation that is consistent only with the specific Medigap changes authorized by Congress under the MMA and thereby remove the proposed revision under Section 403.205(c)(4) with respect to the "stand-alone" drug policies.

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Sir/Madam,

As a leader in the Medicare managed care industry and as a provider of prescription drug benefits for over 8.1 million members currently, Aetna* welcomes the opportunity to comment on CMS's Medicare Program: Medicare Prescription Drug Benefit proposed rule dated August 3, 2004 (CMS-4068-P). Aetna has been a provider of prescription drug benefits to Americans for over 20 years with extensive experience meeting the challenge of promoting quality, cost-effective care.

We are excited about the opportunities presented under the Medicare Part D program and want to help ensure the regulations crafted to support the Part D legislation are developed in such a way that 1) Maximizes the number of Medicare beneficiaries enrolled in prescription drug programs affording greater access to coverage for the medications they need, 2) Prescription Drug Benefit Program sponsors maintain the ability to do what they have been successfully doing for years for the commercial population (managing pharmacy benefits and programs) without the burden of overregulation and, 3) employers sustain the ability to offer flexible, innovative, comprehensive pharmacy benefits to the Medicare population without incurring unnecessary costs and overly prescriptive regulatory requirements.

Although we are excited about the prescription drug benefit opportunities afforded to Medicare beneficiaries, there are three areas of the proposed regulations that raise significant concern for our organization.

1) **Protecting viable Rx options**:

   Under the current statute, no MA plans may be offered which include drug coverage that is more limited in scope than standard Part D coverage. Currently we have approximately 90% of our membership enrolled in Medicare Advantage plans that have an Unlimited Generic drug benefit - many at a $0 premium. Under the proposed statute, we will be forced to move these beneficiaries into a MA plan with Part D coverage – requiring a substantial increase in premium. We are concerned that many beneficiaries, who do not want or need the standard Part D benefit, will no longer have access to those pharmacy programs and benefits that have met their needs thus far. Many beneficiaries are pleased with their Medicare Advantage Unlimited Generic, or limited brand benefit plans under the current statute. In the future, such programs will be unavailable and thereby force the beneficiary to enroll in a plan that may far exceed their needs and premium affordability. We see no issue of adverse selection against the

*Aetna is the brand name for products and services provided by one or more of the Aetna group of subsidiary companies. These companies include Aetna Life Company ("ALIC") and the various state licensed HMO legal entities (that include but are not limited to those HMO Managed Care Organizations that currently contract with CMS to provide Medicare Advantage coverage. These latter entities are generally known as "Aetna Health™").

new Part D benefit as many carriers today offer MA plans with and without prescription drug coverage in the Individual market.

2) **Actuarial equivalence**:

The concept of actuarial equivalence as applied to actuarially equivalent standard coverage appears to limit the flexibility that employers and Part D plans can employ when designing an equivalent plan. We believe that the test with regard to coverage up to the initial coverage limit should not focus separately on costs between the deductible ($250) and initial coverage limit ($2,250), but rather on (i) whether the deductible is not greater than $250 and (ii) whether the average expected PMPM payout below the initial coverage limit ($2,250) is at least that under the standard plan.

For example, a plan that requires copays or coinsurance equal to 1/3 of costs requires no deductible and covers $1,500 for a member incurring claims equal to the initial coverage limit ($2,250). This is identical to Part D, which covers none of the first $250 and 75% of costs between $250 and $2,250. Yet this plan would fail the test that requires 75% coverage between the deductible ($250) and initial coverage limit ($2,250). To comply and not increase expected claim costs, this plan would need to:

- Introduce a $250 deductible.
- Reduce copays / coinsurance to 25% above the deductible.

3) Timing of Final Regulations:

Understanding that final regulations and regional alignment have yet to be announced, the current compressed time frames for the application process and bid submission make broad participation in the program extremely difficult. PDP sponsors will need to re-contract with their pharmacy networks, redesign their Pharmacy and Therapeutic committees, develop formularies to meet CMS requirements, and create an operational infrastructure to support the Medicare Part D product (*i.e.*, COB, tracking of incurred costs, EOB language requirements, 24x7 customer service, etc.). Given the timing to complete such tasks, broad geographic participation will have to be limited.

Additionally, bids are estimated to be awarded by September 2005. Most large national employers will have already made their benefit determinations and commitments for 2006 and will be significantly limited in their ability to integrate in or offer the Part D benefit to their Medicare population.

Attached to this letter, you will find Aetna's questions and comments on the Title I Part D proposed rule based upon our experience in Medicare managed care for more than a decade. We have organized our questions and comments according to the various subparts of 42 CFR Part 423. To the extent CMS believes it is precluded from adopting any comment because of statutory or other regulatory limitations--we would appreciate your identification of such limitations so that we may work together in achieving our mutual goals for a sustainable Medicare program.

As stated earlier, we do appreciate the opportunity to provide our comments to the proposed regulations and welcome the occasion to further discuss our comments with

CMS. Should you have any questions regarding our comments, please contact Kim McDonnell at 215.775.4020.

Sincerely,

Frank McCauley
Vice President
Consumer Markets, Medicare

CMS-4068-P-1060

Submitter : Ms. Beth Waldman **Date & Time:** 10/04/2004 06:10:09

Organization : Executive Office of Health and Human Services, MA

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1060-Attach-1.doc

October 4, 2004

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

Re: Comments on Medicare Part D Proposed Regulations from the Massachusetts Office of Medicaid

Dear Dr. McClellan:

The Commonwealth of Massachusetts appreciates this opportunity to submit the following comments on the Medicare Prescription Drug Benefit proposed rule (CMS-4068-P), published in the Federal Register on August 3, 2004. The creation of the Medicare Part D benefit is one of the most sweeping changes to the Medicare program since its inception. We applaud the federal government's achievement in adding an outpatient prescription drug benefit to Medicare drug coverage. We are concerned, however, about several provisions in the law and regulations that have a direct and significant impact on state Medicaid programs.

Administration of the Low-income Subsidy

On pages 46751 and 46862, the proposed regulation outlines significant requirements for the state Medicaid program in making eligibility determinations (including information dissemination, application assistance, notifications, appeals, and redeterminations) for the Part D benefit's low-income subsidy. As you are likely aware, the statute[1] conditions receipt of federal financial assistance for the Medicaid program on the requirement to administer the subsidy program. While dual eligibles are deemed eligible for the subsidy and will not have to apply, states are required to make eligibility determinations for Medicare beneficiaries who previously have had no contact with the Medicaid system. The requirement to administer this program is essentially in an unfunded mandate on the state and would generate significant administrative costs, which will be difficult to absorb as the state continues to face budgetary constraints. While the rule proposes applying the state's regular federal medical assistance percentage (FMAP) for administrative expenditures resulting from these requirements (in Massachusetts, this is 50% FMAP), we believe any costs generated from administering the low-income subsidy program should be reimbursed at 100% FMAP.

[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (PL-108-173).

The proposed regulations also state that CMS is considering several options to ease the burden of this requirement on states and to ensure consistency in determinations across the country. Recent guidance from CMS indicates that it is working with the Social Security Administration (SSA), which is also charged with administering the low-income subsidy program, to develop a single, simplified application for the subsidy. CMS indicates that it plans to establish a process whereby SSA will handle the bulk of the eligibility determinations and Medicaid will simply serve an application intake and referral function. For example, CMS indicated that if a Medicare beneficiary applies for the subsidy at a Medicaid office, the state will only need to accept the application and refer it to SSA for eligibility determination, appeals and redetermination. We would support this option or a similar one that mitigates the state's role and costs in this area. Otherwise, the state could be required to make substantial systems changes and significantly increase staff resources to meet the demands of this requirement. Having SSA process the applications and conduct the eligibility determinations for this national program would also help ensure consistency in the process across the country.

Finally, we are concerned that very important policy remains undeveloped, especially when states are required by the proposed regulations to be able to begin accepting applications for the subsidy by July 1, 2005. As noted, the eligibility determination process itself is undefined. It is also unclear whether states will need to screen applicants for eligibility for the Medicare Buy-In programs, as required by the statute and regulations, if states ultimately only accepts and refers applications to SSA. We encourage CMS to consider these concerns as it finalizes the Part D regulations. We request that CMS memorialize the final low-income eligibility determination process in the final regulations and affirmatively acknowledge that the Medicaid intake and referral process will satisfy the states' statutory obligations in this area.

Phased-down State Contribution

On page 46752, the proposed regulations outline the calculation for the phased-down state contribution to the Medicare Part D drug expenditures for dual eligibles. The state's primary concern in this area is that the actual payments the state will make to CMS, particularly in the first few years of the program, will not accurately reflect what the state would have spent on outpatient drug expenditures for dual eligibles in the absence of the Part D benefit. It is likely that Massachusetts will pay *more* in the first year of the program (at least) than it would have spent without Part D. This is primarily due to the application of a national pharmacy expenditure growth rate to the state's base year CY 2003 drug expenditures for dual eligibles, rather than a rate that is more in line with what the state's actual projected growth rates for drug spending for this population would have been.

The regulations in this area state that the growth factor for 2004, 2005 and 2006 that will be applied to the base year expenditures will be the average percent change from the previous year of the per capita amount of prescription drug expenditures (*determined using the most recent National Health Expenditure projections)* (emphasis added). We

believe this language provides flexibility to allow CMS to use the National Health Expenditures to develop a more equitable growth rate. According to our analysis, the underlying data used to develop the NHE projections is available at the state level. Alternately, CMS could work with states to develop state-specific adjustment factors that could be applied to the national growth rate. In this way, states, such as Massachusetts, that have implemented numerous cost containment tools that have successfully controlled the growth in pharmacy spending in their Medicaid programs would not be penalized for their efforts by having to apply a national, and higher, growth rate to the base year spending. Massachusetts' urges that the phased-down State contribution formula take into account a state's actual experience and tie the payment to the lower of the state's actual experience or the national average.

Also of concern is that in 2007 and thereafter, the growth factor that will be applied to state's base year per capita expenditures to determine a state's contribution amount is based on actual per capita expenditures in the Part D program, which is completely outside the control of the state Medicaid program. Massachusetts has been very successful in limiting growth of its pharmaceutical expenditures, and requests a growth factor that acknowledges its efforts. We propose that the growth factor be linked to a state's actual pharmaceutical service experience, perhaps to its remaining Medicaid populations, SPAP, or the Part D program.

Finally, the phased-down state contributions are based on state Medicaid drug spending for dual eligibles, but will be used to subsidize coverage for duals that likely will be much less comprehensive than Medicaid drug coverage. Massachusetts, for example, has a very comprehensive outpatient prescription drug benefit for its members, including dual eligibles. Medicare Part D plans, however, can implement restrictive formularies that can limit drug coverage to two drugs in each therapeutic class. In essence, states will be paying a disproportionate share of less comprehensive coverage. This leaves states in the uncomfortable position of potentially paying more in phased-down contribution for reduced services, while receiving pressure at the state level to continue to cover drugs not included in the formularies at state-only cost.

Autoenrollment of Dual Eligibles into Part D Plans

Page 46638 describes the autoenrollment process for dual eligibles who do not select a Part D plan on their own. Dual eligibles who do not select a plan will be randomly assigned to a low-cost drug plan. We recommend that the autoassignment process not be random, but that it take into account the special health conditions of this population, who by definition are poor, elderly (often frail elderly) and/or disabled. We are concerned that dual eligibles could be enrolled in a plan with significantly less comprehensive drug coverage than they had in Medicaid. We urge CMS to consider developing a process whereby dual eligibles would only be autoenrolled into Part D plans with comprehensive drug coverage and expertise in serving vulnerable populations to ensure access to the prescription drugs that meet their needs.

The proposed regulations specifically invite comment on which entity should administer the autoenrollment and random assignment process for dual eligibles - CMS or the states. While we are concerned that the autoenrollment process for duals is thoughtful and, again, that duals are not randomly assigned, we believe that CMS or SSA would be the most appropriate entity to administer this function. If CMS determines that states should fulfill this role, we urge CMS to provide 100% FMAP or fully reimburse states for the costs of assuming this responsibility.

Finally, we are concerned about the timing of the autoassignment process. The initial enrollment period for the Part D benefit is from November 15, 2005 through May 15, 2006. However, prescription drug plans cannot start marketing to beneficiaries until October 2005 and Medicaid drug coverage for dual eligibles ends on January 1, 2006. If dual eligibles are not fully informed about their drug plan options and do not select a Part D plan by January 1, the individual could go without drug coverage until May 15 when he or she would be autoenrolled. This could leave an unacceptable gap in coverage. We request that CMS consider this situation and facilitate earlier autoenrollment or some other option to protect this vulnerable population.

Prescription Drug Coverage for Vulnerable Dual Eligibles

CMS must take steps to make sure that formularies are broad enough to ensure access to the medications meet the needs of dual eligibles. Many of these individuals have chronic conditions or diseases (e.g., mental health conditions and HIV/AIDS) that require specific medications that may not be on an individual's plan formulary. Our review of the US Pharmacopoeia model guidelines and suggested therapeutic classes of drugs leaves us concerned as to the comprehensiveness of the Part D coverage for dual eligibles. We are concerned that the model guidelines did not cover many of the drugs that our members currently use. Will a member have access to alternative drugs, when a formulary drug is demonstrably medically inappropriate? We support CMS' indications that it will apply stricter standards than the guidelines suggest.

In addition, these individuals may be stabilized on their prescription drugs for a long period of time and any change could have catastrophic effects on their health and the utilization and cost of their other services, including hospital care. Such stabilized members who can safely switch to an alternative medication regimen will need to have the opportunity to do so over a reasonable period of time. While an individual can go through the appeals process, the process must have the capability to ensure expedited appeals in such cases, and access to drugs pending appeal. Alternately, perhaps CMS could specifically require Part D plans with formularies to include more than two drugs in each therapeutic class to expand the choice of drugs available to high-risk populations.

Impact on PACE and Massachusetts' Senior Care Options (SCO) Options

Pages 46697-8 and 46753-7 of the proposed regulations discuss the coordination between Programs of All-Inclusive Care for the Elderly (PACE) and Medicare Part D. While the statute provides that the Part D provisions apply to PACE organizations and that PACE

organizations may be deemed to be a Medicare Advantage-Prescription Drug plan (MA-PD), the proposed regulations minimize the burden on PACE organizations of having to go through the Part D plan bidding process. The regulations propose a waiver process whereby PACE organizations could seek waivers from the various provisions of Part D that conflict or contradict the intended purpose of the PACE program, while continuing to treat PACE organizations as MA-PDs for Part D payment purposes. In essence, the regulations propose a special rule for PACE that would automatically apply the waivers granted in the final rule without a plan-specific application process. We fully support this effort. In addition, we propose that all integrated Medicare-Medicaid plans, including organizations that participate in Massachusetts' Senior Care Options (SCO) program, should not have to bid to become drug plans in order to continue to provide pharmacy services to their enrollees.

Data Sharing
States currently have access to members' pharmaceutical history and usage which permits states to have programs to improve the health of Medicaid members. For example, a state may use such data to notify a provider if a member is receiving multiple drugs to treat the same illness, thus prompting a provider-review of the patient's regimen. States can also review the drug treatment of member's with particular diseases, to assist members in better managing symptoms, or to notify a provider that the member might benefit from alternative disease management. Massachusetts requests that states be able to easily obtain pharmacy-related data concerning our dual eligible members to help us continue with disease management, and other programs, to improve the health of our members.

Thank you for considering our comments and concerns. We look forward to receiving the final regulations and working with CMS to ensure a successful implementation of the Medicare Part D program.

Sincerely,

Beth Waldman
Medicaid Director, Massachusetts

CMS-4068-P-1061

Submitter : Mary Kennedy **Date & Time:** 10/04/2004 06:10:38

Organization : Minnesota Department of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The attached Word file contains comments on the proposed regulations governing the Medicare prescription drug benefit from Mary Kennedy, the Medicaid Director in Minnesota, on behalf of the Minnesota Department of Human Services

CMS-4068-P-1061-Attach-1.doc

Minnesota Department of **Human Services**

October 4, 2004

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

Re: File Code CMS-4068-P

To Whom it May Concern:

Thank you for the opportunity to comment on the proposed regulations governing the new Medicare prescription drug benefit. The Minnesota Department of Human Services is the single state agency responsible for administering the Medicaid Program in the State of Minnesota. In addition, the Department is the State Health Insurance Program (SHIP) and administers a number of state-funded health programs, including a state pharmacy assistance program. Accordingly, we have an interest in ensuring that Medicaid enrollees experience a smooth transition from Medicaid coverage for their medications to the new Medicare Part D Program; that Medicaid recipients receive timely and meaningful assistance to ensure that they make informed choices; that low-income Minnesotans, especially those with high prescription drug needs, have full access to pharmacy services and the medications their doctors prescribe; that the state is compensated for the increased administrative cost of assisting with this new Medicare benefit; and that the state financial contribution for this benefit is calculated and allocated fairly across all states.

We recognize that the implementation of Part D and the other changes to the Medicare Program brought about by the Medicare Modernization Act (MMA), represent a massive undertaking on the part of CMS, as it does for the states. We also recognize that many of the complexities and difficulties with this new benefit are a reflection of the design of the program as enacted by Congress. We appreciate the format of this proposed regulation, which in many places, lays out more than one alternative and requests comment on the benefits and drawbacks of each.

Our specific comments fall into several general categories: eligibility; enrollment and disenrollment; drug coverage issues; the bid process; and administration and cost issues.

ELIGIBILITY

Eligibility process for the low-income subsidy. Reference: pp. 46727, 46855, §423.774(a).

The MMA requires that state Medicaid programs or the Social Security Administration (SSA) shall determine eligibility for subsidy assistance. CMS has advised states that even though the SSA is developing a uniform application, states will be required to process an application for individuals who apply at the state level, including those who are not eligible for or do not wish to apply for Medicaid. This plan requires all state Medicaid programs to develop an application and redetermination process and the systems capacity to determine eligibility for Part D subsidy assistance, to mirror the system under development by the SSA. This seems unnecessary, both from the perspective of administrative cost and effort, and in terms of giving applicants a clear and streamlined route to Part D coverage. We support a hybrid process in which states can forward to the SSA those applications that are unrelated to Medicaid and in which the determinations for those applications are completed by the federal agency.

Low-income subsidy, institutionalized individuals. Reference: p. 46725,46784, §423.772

We strongly recommend that CMS include individuals residing in intermediate care facilities (ICFs/MR) as institutionalized for purposes of the cost-sharing requirements. The reasoning for not requiring cost-sharing for people in nursing facilities is the same for people in ICFs/MR and is consistent with the exclusion from copayments in the Medicaid regulations. Individuals residing in ICFs/MR are required to spend all but a small amount of their income on their cost of care.

In addition, as we understand it, many ICF/s MR serve large numbers of dual eligibles and have responsibilities similar to nursing facilities for storing, safeguarding, administering and overseeing medications under extensive state and federal regulations. Many typically have exclusive relationships or special arrangements with one or two pharmacies. There are similar issues with other group living arrangements such as foster homes and residential living facilities in which providers have responsibility for medication administration and safeguards.

Eligiblity for Medicare Savings Plan enrollees and other low-income subsidy. Reference: pp. 46726-46727, 46854, §423.773

We support CMS' proposed inclusion of QMBs, SLMBs, and QIs as deemed to be full subsidy eligible individuals. Since many Medicare Savings Plan enrollees move on and off Medicaid medically needy eligibility, and many eventually become eligible for long term care (creating stable Medicaid eligibility), it makes sense to avoid the administrative costs of making a case-by-case determination.

CMS is allowed by the statute to permit a state to make subsidy determinations using the same resource methodologies that it uses to determine Medicaid eligibility for Medicare Savings Plan enrollees. The commentary indicates that CMS is proposing not to exercise

this option, so that all states will use the same resource methodologies to determine eligibility for all other low-income subsidy eligibles across the country.

As we commented earlier, we think the SSA should process applications for low-income subsidies that are unrelated to Medicaid. However, if the final regulation requires states to conduct eligibility determinations for applicants and recipients who are not Medicaid or Medicare Savings Plan eligibles, then the regulation should allow states to use their income and asset methodologies in use for their Medicaid Savings Plan group. If uniformity in the application process is truly a desired goal, there should be a single entity performing this function. This provision would require that most states create a new unique track to determine Medicare subsidy eligibility for low-income, non-dual eligibles that is different from the way determine income and assets. The commentary states that the alternative process would involve complexity and administrative burden. The proposed process provides the same amount of complexity and administrative burden—the difference is that the burden is on states rather than CMS or the SSA.

If one purpose of having states determine subsidy eligibility is to capitalize on the similarities between the Medicare subsidy determination and the Medicaid determination, this requirement falls short of that purpose. In addition, since states' offer Medicaid coverage to varying optional populations at different income and resource standards, a Medicare beneficiary might be full subsidy dual eligible if a resident of one state while subject to a sliding fee scale Medicare Part D premium in a neighboring state.

Medicare Part D subsidy eligibility will not be uniform. It is reasonable, that the benefits or detriments that apply to beneficiaries residing in a specific state should apply uniformly to all residents of that state, not just those who are dual eligibles.

CMS should allow states to use the resource methodologies of their Medicare Savings Programs for determining low-income subsidy eligibility for individuals who choose to apply at the state agency. Individuals who choose to apply with SSA should be determined for subsidy eligibility in accordance with the federal resource methodology.

PLAN ENROLLMENT AND DISENROLLMENT, OUTREACH, MARKETING

Automatic enrollment. Reference: pp. 46638 and 46811, §423.34

CMS would establish a process to automatically enroll a full benefit dual eligible who fails to enroll in a PDP by either the end of the individual's initial enrollment period or upon becoming a dual eligible after his/her enrollment period.

For individuals dually eligible January 1, 2006, automatic enrollment would not occur until after the initial enrollment period for Part D ends on May 15, 2006. Therefore, dual eligibles that do not choose a plan will have neither a Medicaid nor Medicare drug benefit from January 1 through at least May 15, 2006.

We recommend that the automatic enrollment process for dual eligibles begin in November or December 2005, so that individuals do not have a gap in drug coverage if they fail to choose a plan.

Automatic enrollment into MA-PD plans. Reference: pp. 44638 and 46811. We agree with CMS' proposed interpretation that "prescription drug plan" means both PDP and MA-PD plans, thereby allowing automatic enrollment of full benefit dual eligibles enrolled in MA plans into an MA-PD plan offered by the same organization.

Medicare Savings Plan enrollees. Reference: pp. 46638, §423.34

We recommend that CMS consider requiring automatic enrollment of Medicare Savings Plan enrollees who do not choose a plan within the time allotted. The law and the proposed regulation deem Medicare Savings Plan enrollees to be full subsidy eligible. However, in contrast to full benefit dual eligibles, if MSP enrollees do not choose a Part D plan, they will go without coverage for prescription drug. The cost of that coverage could have otherwise been used to spend down to Medicaid and full benefit dual eligible status. The reasoning for automatic enrollment of full dual eligibles also supports automatic enrollment of the Medicare Savings Plan group.

Automatic enrollment function. Reference: pp. 46637, 46811, §423.34

CMS is considering what entity is best suited to perform the automatic and random enrollment function. CMS notes that states have experience with random assignments through their Medicaid programs and have more immediate access to changes in Medicaid eligibility. States would be compensated through administrative FFP for their efforts.

In Minnesota, we think the state is best suited to perform automatic assignment and enrollment for Medicare Part D, because most of the seniors who are dual eligibles are already enrolled in a managed care plan.. We are accustomed to the churning of Medicaid enrollment, and have first hand knowledge of individual fluctuations in Medicaid eligibility and the impact of such fluctuations on health plan enrollment, disenrollment and reenrollment. We recognize that other states may have the opposite opinion, and therefore recommend that CMS allow states the option of conducting the assignment function for their residents.

To assign and enroll dual eligibles, states would need significant data from CMS particularly to identify dual eligibles enrolled in MA plans, and individuals already enrolled in PDPs who become dually eligible over time.

Federal reimbursement at 50 percent of state costs is not adequate funding to administer Medicare drug plan assignment and enrollment. If CMS takes administrative responsibility or contracts out for this function, CMS will assume 100 percent of the cost.

If states are mandated or given the option to perform this function, it should be at 100 percent federal financial participation. In the alternative, CMS could contract with states to perform the enrollment broker function, if that is a better way to recognize the costs in implementing Part D.

Random assignment. Reference: p. 46638,46811, §423.34

When there is more than one PDP in a region, with a monthly premium at or below the subsidy premium amount, full benefit dual eligibles will be automatically enrolled on a random basis.

The proposed regulation would require random, unsystematic assignment for dual eligibles who do not enroll in a PDP. Random assignment would ignore previous relationships via Medicaid managed care or other criteria, such as drug formularies, for assignment purposes. A modified assignment process, in which states could utilize information about the enrollee to choose a default PDP would provide a more useful benefit for individual enrollees with special drug needs and would likely prevent the large scale shifting that would occur with fully random assignment. Dual eligible seniors enrolled in Medicaid managed care plans are likely to request enrollment in the PDPs offered by those plans.

We recommend that CMS modify the random assignment process to allow the enrolling entities to choose a default PDP for each full benefit dual eligible based on information known to the agency. If the individual fails to choose a PDP, he/she is enrolled in the default PDP.

We can also envision a situation in which there is no regional PDP available and only MA-PDs are available. In that case we would not support automatic assignment to MA-PDs in which dual eligibles are not already enrolled, unless it was being done in accordance with discussion in Part III of the proposed regulations at page 46932. In that discussion, CMS states that in certain circumstances a state may require the enrollment of dual eligibles in MA plans if, for example, the plan is also a Medicaid health plan and the state has a waiver permitting mandatory health plan enrollment for Medicaid beneficiaries.

Further, Minnesota requires that seniors (65+) enroll in Medicaid managed care plans statewide (with the exception of three rural counties.) Therefore, automatic assignment of duals should be closely coordinated with the state and with their Medicaid managed care plan. For example if a dually eligible beneficiary's Medicaid managed care plan was associated with a particular PDP sponsor, assignment to that PDP might be preferable than to a different PDP.

Because it is unlikely that CMS would have all of the information needed to coordinate Part D enrollment with Medicaid managed care and with cultural needs, it is imperative that states have a strong role in the auto assignment process.

Enrollment of individuals enrolled in MA plans. Reference: FR page 46637, FR page 46811, §423.34

CMS asks for comment regarding how to provide qualified drug coverage to full benefit dual eligibles who are in an MA-only plan where the premium for the MA-PD plan offered by the MA organization exceeds the low-income benchmark premium.

Individuals enrolled in MA plans may not enroll in a PDP (with some exceptions). CMS' explanation provides and then discounts several potential solutions for how to automatically enroll full benefit dual eligibles who are enrolled in an MA plan with no MA-PD plan within the benchmark premium.

We recommend that CMS allow individuals in MA only plans to enroll in PDPs if they are full benefit duals and for whom there are no MA-PD plans available at or below the low-income benchmark premium. In the alternative, we recommend that CMS require that all MA organizations offer at least one MA-PD plan at or below the benchmark premium, or provide services to the subsidy population at the benchmark premium.

Declining enrollment or disenrolling. Reference: pp. 46811 §423.34 (d)(3).

The proposed regulation provides that the automatic assignment of a full dual eligible who does not choose a plan during the initial enrollment period does not prevent the individual from affirmatively declining enrollment or disenrolling from the plan and selecting a new plan. We recognize that some individuals will elect not to participate in Part D, but we recommend that notices and information provided to full benefit dual eligibles make very clear that Medicaid is no longer available in that event.

Special enrollment periods. Reference: P. 46639-46640, 46811-12, 46640, 46811, §423.36.

The introductory phrase at §423.36(c) appears to contain a typographical error. We also recommend that a special enrollment period should apply at the time a full benefit dual loses Medicaid eligibility.

In addition, we recommend that CMS consider adding a special enrollment period for all subsidy eligible individuals, not just for full benefit dual eligibles. The MMA provides authority for the Secretary to establish additional special enrollment periods for individuals who meet certain exceptions. All low-income subsidy eligible individuals should have the opportunity to change plans when they move in and out of subsidy status. For example, an individual might choose to enroll in a lower cost plan based on

affordability. If he becomes subsidy eligible at a later date, a different plan might be more appropriate.

Also, we recommend that CMS consider additional circumstances under which a full benefit dual might require a special enrollment period. The discussion notes that dual eligibles may obtain a special election period when they become duals and may change plans when automatically assigned. However the actual regulation language references only PDP enrollment with regard to this special enrollment period. It is important to clarify that this special enrollment period should be continuously available to dual eligibles at any time and that it applies to both MA-PD plans and PDPs regardless of automatic assignment. This is also needed to clarify the ability of duals enrolled in traditional Medicare to choose an MA-PD, including a special needs plan, or a dual demonstration, at any time.

It is essential that dual eligibles are allowed to access special needs plans, SHMOs, dual demonstrations and other MA–PD plans when the need arises. They should be able to change plans when specialized options become available, when they become aware that such a plan would benefit them, and when they become frail. Otherwise, they will essentially be denied the benefits of those options when they most need them. The standard open enrollment periods will not likely coincide with the particular timelines in which the conditions of dual eligibles change and they hear about plans which specialize in their conditions. Furthermore, those special plan options will be unable to remain viable without the growth provided by new enrollees.

Minnesota is particularly concerned about the impact of this provision on our special Medicare payment demonstration for dually eligible seniors and persons with disabilities, MSHO/MnDHO. We are working with CMS to expand this full risk based Medicare demonstration to rural areas and to include Part D benefits in 2006. Few dual eligibles enroll in these plans upon becoming dual or during open enrollment periods currently provided under Medicaid. Instead, plans rely on traditional M+C marketing mechanisms, which includes extensive one to one contact and education about the special provisions involved in integrated Medicare/Medicaid benefits prior to enrollment of new members. If enrollment is no longer open at any time, dual eligibles will not be allowed to access these plans when they are provided information about them and/or when they most need them.

In addition, if enrollment periods are restricted, these plans will not have enough enrollment growth to remain viable. Death rates in plans that serve large numbers of frail elderly dual eligibles are high because average ages served are 80 and above. New enrollment must remain at least constant to maintain current enrollment levels. There are not enough people becoming dually eligible each month to provide needed growth to these plans. Most growth comes from enrollment of people who have been dually eligible for some time, but have now become aware of how they would benefit from enrollment

in a plan specializing in their needs. We recommend that the special enrollment period be clarified to assure enrollment in these plans at any time, similar to the institutionalized population.

We are also concerned about the differences between the continuous enrollment period for institutionalized people and this SEP for dual eligibles. It appears the provision around institutional populations provides more flexibility than the SEP for dual eligibles residing in the community. This provision could therefore impose new barriers to enrollment of community dwelling individuals, resulting in an institutional bias in enrollment patterns. CMS has encouraged Minnesota's demonstration to enroll more community members.

In addition, there are many frail elderly and dual eligibles with disabilities who meet criteria for institutions but have chosen to reside in the community and, depending on the interpretation of these provisions, they could essentially be discriminated against for making a more cost effective choice.

In addition, at a minimum, continuous open enrollment periods for institutional enrollees should clearly be defined to include beneficiaries residing in ICF/MR settings as these are considered institutions for other purposes. For all of these reasons, CMS should clarify that a continuous open enrollment period or SEP which allows enrollment at any time, is available for all duals.

Effective date of enrollment. Reference: p. 46641, 46812, 46725, 46854, §§423.38, 423.722

The proposed regulations provide that, for an individual already enrolled in Part A or Part B, the effective date of enrollment in Part D is the first day of the calendar month following the month in which enrollment in Part D is made. However, the individual will be ineligible for Medicaid coverage for prescription drugs in that month, since the individual meets the definition of a full benefit dual eligible. Furthermore, §423.774(b) provides that the effective date of eligibility for the subsidy is the first day of the month of application, which seems to create a situation in which a person could have subsidy eligibility but is not yet enrolled in Part D.

We recommend that CMS create an exception to the Part D effective date of coverage for full benefit duals, to ensure that people do not experience coverage gaps.

The enrollment process related to special populations. Reference: pp. 46638-46639, 46911-12, §423. 34.

We are concerned about how enrollees of Minnesota's dual eligible demonstration (Minnesota Senior Health Options (MSHO) and Minnesota Disability Health Options (MnDHO)) will be able to access their current health plan for drug benefits. These

demonstrations are operated under a Medicare Payment Demonstration and are similar to MA-PD special needs plans with some variances. They currently serve over 6,000 elderly and disabled Medicaid and dual eligibles in ten counties and are expanding their service areas to additional rural areas. Participating plans are required to provide drug coverage under Medicaid, and we have requested that these plans continue to provide drug coverage to enrollees under Part D.

The Part D bid process and the low income subsidy determination does not establish procedures for such demonstration projects, special needs plans or PACE programs to assure that they can continue to provide these integrated and comprehensive services including pharmacy benefits. Because the low-income benchmark premium for dual subsidies will not be known, it is impossible to determine whether there will be additional premium required for enrollment in these projects. There is concern that these plans will be particularly disadvantaged in the bid process since they are specialized and lack volume purchasing power. We also assume that duals eligibles will not be able to afford additional premiums and that states will not be able to afford to pay such premiums.

However, given the options discussed in this section, we would support the automatic assignment of dual eligibles into any MA-PD or dual demonstration that they are enrolled in at the time of the Part D enrollment process whether or not there is a residual premium. If these individuals were subjected to truly random assignment in a PDP it could disrupt their current care. If there is a residual premium that they are unable to pay, the dual eligible would still be able to change plans and choose a different option. In the mean time, we suggest that CMS pay that premium for a few months to allow the beneficiary to make a different choice.

Service area exclusion—incarceration. References: pp. 46636-38, 46810,46818, 46812.

CMS proposes to define "service area" by reference to the proposed definition for the Medicare Advantage regulations (§423.4 references §423.112, which states that PDP regions shall be consistent with the standards for MA regions in §422.455). In the discussion, CMS makes clear its intention to use this coordinated use of terms and provisions to preclude access to Part D for incarcerated individuals and to allow PDPs to disenroll incarcerated individuals.

CMS intends to treat all incarcerated individuals as residing outside the service area. Although CMS states that "incarcerated individuals should be ineligible to enroll in a PDP" and that "…we therefore provide in §423.4 of the proposed rule that a PDP's service area would exclude areas in which incarcerated individuals reside…," the definition section does not contain this exclusion. It is unclear how this exclusion would be accomplished or whether CMS is waiting for comments before inserting such language.

CMS maintains that individuals in jails or prisons: 1) would not have access to Part D services; 2) would not meet the coordinated care plan definition of service area; 3) that there is no reason for an individual to enroll in MA plan while incarcerated since services typically are covered by the jail or prison and the prisoner could always enroll in an MA plan without penalty upon being released; 4) and that incarcerated individuals would have to pay a penalty for not enrolling while in prison.

CMS also justifies the exclusion principles for a Part D service area by referencing the definition of a Part D eligible individual – one who is "is entitled to Medicare Part A or enrolled in Part B," and then equating the incarcerated individual to one who would be ineligible because he resides outside the United States.

The proposed regulations exclude incarcerated individuals from enrolling in Part D either through a PDP or an MA-PD, and mandate disenrollment upon incarceration. Under the proposed §423.42(b)(2), a PDP sponsor must disenroll a person no longer residing in the PDP's service area. Mandatory disenrollment from an M+C plan is currently authorized under §422.74(b)(2) for an individual who no longer resides in the M+C service area, and would presumably apply to MA-PDs.

There are a number of concerns with this approach. There is no provision in federal law that contains a blanket exclusion from Part D participation for incarcerated people. Medicare law on Parts A and B in fact provides for continued Medicare liability for a person in a correctional facility, and does not alter the individual's entitlement.

Medicare law contains a qualified prohibition to payment under Medicare Parts A and B under federal law; see §1862(a)(2) and (3) and regulations at 42 CFR §411.4 that deal with nonpayment when an individual receives health services with no legal obligation to pay and health services that are the responsibility of a governmental entity. We do not believe that CMS has authority under the MMA to be more restrictive with Part D enrollment than the existing Medicare payment provisions allow. The existing payment provision for a Medicare beneficiary in the custody of a corrections authority at 42 CFR §411.4(b) provides for conditions under which Medicare payment may continue.

Differences may exist in local and state laws on responsibility to pay medical services. Under the proposal, incarcerated individuals who may have access to services under Parts A or B would still be unable to access services under Part D.

The proposal uses the definition of service area and 'residing in a service area' to exclude incarcerated individuals. CMS maintains such authority exists by virtue of the directive to follow Part C residency rules. CMS states that it is directed to adopt residency requirements similar to Part C requirements under §1851(b)(1)(A), which require that a person reside in the plan's service area. This is not an adequate basis for creating a total bar to access to Part D. Individuals who are not eligible to enroll in a Part C plan because they reside outside of the plan's service area have a fall-back option to enroll in original

Medicare fee-for-service. There is no fee-for-service coverage under Part D, and it is inappropriate to use this as the justification for precluding all access to Part D for incarcerated individuals.

CMS maintains that the incarcerated individual is like someone residing outside the U.S. Much confusion will be generated in the concept of residency if it is used in this way. Using service area and residency principles to create a group exclusion from a Medicare benefit is contrary to the notion of entitlement and exceeds agency authority.

CMS also maintains that incarcerated individuals would not have access to drug benefits. Incarcerated individuals would have access in the same way that other individuals with barriers (such as nursing home residents, or incapacitated individuals) obtain access: they utilize authorized representatives, mail order and other types of assistance.

CMS claims that incarcerated individuals would be subject to a penalty for not enrolling if they were treated as residents of the services area. This is merely the result of the service area construct created by the proposed regulations. Incarcerated individuals for whom a Medicare payment prohibition takes effect should be treated the same in Part D as in Part B. There is no mandatory disenrollment from Part B for incarcerated individuals; if social security benefits are suspended thus ending the automatic deduction of Part B premiums, enrollees are given the option of directly remitting the Part B premiums under 42 CFR §408.46. Part D enrollees in PDPs should receive the same treatment.

If CMS views incarcerated individuals as an administrative burden for MA plans (regardless of the outcome under 42 CFR §411.4), the agency can establish a procedure for MA plan disenrollment without foreclosing benefits under Medicare fee-for-service for Parts A and B and PDP enrollment.

CMS can address the matter of incarcerated individuals in another manner that does not result in a penalty for absence of enrollment. The most logical method would be to treat incarcerated individuals who do not qualify for Medicare payment under 42 CFR §411.4 as having other creditable drug coverage. No penalty should result if in fact the state corrections authority is considered a full payer for health care under §1862 and 42 CFR §411.4(b).

In summary, we recommend that CMS address the treatment of incarcerated individuals differently than as proposed through the definition of service area. Any measures dealing with this subject should be consistent with Medicare principles in §1862 and the Medicare payment regulations.

Disenrollment for disruptive behavior**.** Reference: Pp. 46641, 46812-466813

PDPs are authorized by §423.44(b)(1) to disenroll individuals for nonpayment of monthly premiums, or if "…the individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section." Paragraph (d)(2) states that an "…individual may be deemed to engage in disruptive or threatening behavior if the individual exhibits any of the following:

(A) Behavior that jeopardizes his or her health or safety, or the health and safety of others;
(B) Behavior that impairs the PDP sponsor (or a network pharmacy's) ability to furnish services to either the individual or other individuals enrolled in the plan; or
(C) An individual with decision-making capacity who refuses to comply with the material terms of the enrollment agreement.

Paragraph (d)(2) also states that disruptive behavior may not be based upon noncompliance with medical advice. Similar provisions have been added to §422.74 for disenrollment by the MA organization.

The state disagrees with this proposal. First, the existence of authority in §1851 to disenroll from Part C plans for disruptive authority does not mean there is good reason for it to be exercised and applied to original Medicare Part A and B enrollees in PDPs. As CMS recognizes, Part C/MA enrollees disenrolled on this basis are always able to fall back to original Medicare. This result should include Part D under PDPs.

Second, the criteria are highly subjective and determinations would be capable of arbitrary and discriminatory outcomes. PDP administrators are not qualified to make adequate determinations on whether an individual's behavior is or is not based on noncompliance with medical advice.

Finally, because Medicaid is a safety net program, the dually eligible population includes a disproportionate number of people with highly unusual conditions, developmental disabilities, mental illnesses, brain injuries, dementia, and other cognitive impairments that may result in behaviors that could be misinterpreted by a Part D plan. Many of their typical behaviors may be considered disruptive but may be associated with an underlying mental or physical condition. Many of these people also do not have formal guardians authorized to take over their care and finances.

There are less drastic means available for dealing with disruptive behavior, such as allowing plans to restrict access to specialized providers. We recommend that CMS remove any authority for PDPs to disenroll for disruptive behavior. CMS should also remove references to expedited disenrollment related to disruptive behavior.

Disenrollment process. Reference: pp. 46641, 46813.

§423.44(c) allows a PDP to disenroll an individual for nonpayment of premiums, disruptive behavior, a move from the service area, or the termination of the PDP's contract. The process in the proposed regulation does not define "timely" notice, which appears to mean that a beneficiary could be notified with only one day's notice. Also, while the regulations provides for an effective date when the disenrollment is due to disruptive behavior, the regulation does not specify an effective date for other types of disenrollment.

We recommend that CMS require the notice of disenrollment be issued a reasonable number of days in advance of the proposed effective date of disenrollment, so that the enrollee can make other arrangements and avoid gaps in coverage if possible.

Also, §423.44(d)(2)(vii) and (d)(3)(ii) allow a PDP to refuse reenrollment of an individual who was disenrolled for disruptive behavior or for material representation of information, for a time period "specified by CMS." The regulations do not specify a time period for such a lock-out period, apparently leaving those decisions to CMS staff to be made on an individual basis. The regulations at least should specify a maximum time period for such lock-out periods, to avoid discriminatory and/or arbitrary decisions. The regulations should also be clear that an individual is entitled to a fair hearing on the determination of the lock-out period.

And finally, if a person who was disenrolled for failure to pay a premium is subsequently determined to be a full subsidy dual eligible, the lock-out period should not apply.

Creditable coverage and premium penalties. Reference: pp. 46644 and 46814

We agree with CMS' decision to add individual policies and coverage provided by the IHS and tribal organizations to the list of creditable coverage. We would also add that state and federal penal institutions should be added to the list of creditable coverage, so that incarcerated individuals "locked out" of Medicare when the conditions for continued payment under 42 CFR §411.4(b) have not been met. If an individual is "locked out" of Medicare by virtue of an incarceration, he/she should be able to re-enroll in Part D at the time of their release without being subject to a late enrollment penalty.

We also note that it will be important for CMS to ensure that people with other creditable coverage or considering purchasing private coverage have access to accurate information about that creditable coverage.

Outreach. Reference: pp: 46643, 46813

We appreciate that CMS intends to use its website to deliver information to beneficiaries about their choices under Part D. We encourage CMS to post a premium penalty calculator and a decision support tool for professionals such as SHIPs to use to counsel and assist clients.

We are concerned that the mechanisms discussed thus far for outreach and information to dual eligibles about plan choices may be inadequate to achieve large proportions of duals self selecting plans, and that therefore many dual eligibles may be subject to the automatic assignment process. It does not appear that there will be the staff, time and resources available to achieve the education needed for self-enrollment for populations with cognitive impairments, or those with cultural barriers.

Minnesota currently requires that materials and interpreter services for Medicaid managed care choices be available in nine different languages. All materials include a "language block" indicating how to obtain translations or interpreter services, usually through a 1-800 number for customer service. We serve a highly culturally diverse dual eligible population, including many immigrant groups who are unfamiliar with written languages and western health care systems. Under the MSHO/MnDHO programs, we have had past experience with materials required by CMS that do not consider the need for such "language blocks." We suggest that CMS require the use of such mechanisms in all beneficiary materials related to Part D coverage. This means that CMS and/or the PDP and MA-PD sponsors must be able to accept the 1-800 calls and have the capacity to respond with the necessary interpreter or translation services through purchase of access to "language lines" or multilingual staff.

In addition, it is not clear that all Part D plans will initially have equal capacity to deal with these diverse languages and cultures and to properly serve their needs. Will customer services be routinely available in all of these languages on an ongoing basis? One-to-one assistance is likely needed for making an initial informed choice of which plan may best address these cultural concerns, but also for ongoing access and communication with the sponsor.

Marketing. Reference: pp. 46644, 46813

CMS asks for comments on the advisability of allowing PDPs to provide additional products (such as financial services) to Medicare beneficiaries in conjunction with PDP services and the appropriate limitations on such activities.

Due to the inherent conflicts of interest, PDP plan sponsors should not be allowed to co-market financial products to beneficiaries in their PDP plans. Beneficiaries may fall victim to subtle coercion or other marketing techniques around these kinds of products that could sway them inappropriately to purchase products marketed by the PDP plan sponsor, when other more generous or appropriate products may be available in the market. CMS should encourage beneficiaries to explore their options rather than encourage PDP plans to bundle these services. Also, allowing PDP plans to co-market financial or other products would provide undue advantage to PDP sponsor organizations by unintentionally giving the appearance that certain products are endorsed by the federal government or otherwise more appropriate due to the organization's affiliation with the Medicare program.

While CMS acknowledges that allowing PDP sponsors to market additional products to beneficiaries would be a strong incentive for companies to sign up as a PDP plan sponsor, we question the appropriateness of this strategy. If organizations require that level of financial incentive to sign up as a PDP sponsor, perhaps they are not an appropriate provider of a Part D plan.

We recommend that marketing requirements for Part D be consistent with those now used under MA. CMS should not liberalize those rules for the purpose of Part D marketing. For example, CMS should not allow direct phone marketing or cold call marketing for Part D plans, but then prohibit these techniques for other MA-PD plans. We believe there should be special procedures involving release of information about dual eligibles and that any such information should be coordinated with the state since marketing by MA-PD plans to dual eligibles may cause disruption or conflicts with enrollment Medicaid managed care plans.

CMS should also consider how provision of information about enrollees in PACE, dual demonstrations and special needs plans will be handled. Providing information about these enrollees to other plans that do not offer the same level of services to allow them to market to people already enrolled in such programs may result in confusion and disruption for enrollees.

Marketing related to special products. Reference: P. 46655-46664, 46663, 46819, §423.128

We seek clarification of how information about dual demonstrations such as MSHO/MnDHO or special needs plans will be handled under this section. The rules indicate that information about Part D plan coverage will be handled in a manner similar to current information provided under MA. However, information about PACE, MSHO/MnDHO and other similar programs is currently excluded from mechanisms such as Medicare Compare, used for distribution of MA materials to the general Medicare population.

Information on these programs is usually excluded because the additional Medicaid benefits included in these demonstrations and the fact that the state pays the premiums may be confusing to the general public. The extensive coverage provided under MSHO/MnDHO at no extra cost would highly attractive to many beneficiaries, who are not aware of the specifics of Medicaid eligibility and do not understand that they are not eligible. CMS and the states have determined that inclusion of the information would generate many time-consuming and frustrating calls resulting in disappointed beneficiaries.

On the other hand, we are concerned that those who are eligible for such special programs are informed of all choices available for Part D including PACE programs, dual

demonstrations and special needs plans. Information provided to dual eligibles should indicate the differences between obtaining services from a PDP, MA-PD or a fully integrated program such as PACE or the dual demonstrations. If a SNP is also covering Medicaid benefits it is important to explain that as well. There are also additional products for other special populations where this may be relevant (e.g. there are some products targeted toward QMB/SLMB only dual eligibles). Since duals cannot choose both a PDP and an integrated demonstration or MA-PD, it is also important to explain what differences there may be when they disenroll from an integrated program or MA-PD to obtain benefits from a PDP.

We understand that CMS is considering special options for PACE programs to address these issues. We would like to work with CMS on how to develop appropriate materials and distribution mechanisms targeted toward all dual eligibles to inform them of choices with appropriate explanations of the differences between all of the different products available to them.

Premium Payment. Reference: p. 46674, 46826

§423.293(a) provides for premium payment options that include Social Security withholding, direct payment to the plan by electronic bank transfer, payment by employer or retiree health plan, or other options according to CMS guidelines. We recommend that CMS add an option for direct payment by state-funded programs that provide cost-sharing assistance.

COVERAGE

Definition of PDP and MA-PD. Reference: Page 46810.

§423.4 defines an MA-PD plan as one that provides qualified prescription drug coverage. It defines a PDP as coverage that is offered under an approved plan and through contract with CMS. Both types of plans are required to offer qualified plans. The two definitions should be parallel—either both should refer to qualified coverage, or both refer to meeting the requirements of Part D.

Exclusion for Part A and B covered drugs. Reference: pp. 46646- 47, 46815

CMS proposes to exclude from Part D coverage any drug covered by Parts A or B to an individual who is eligible to enroll in Parts A or B. This has the effect of requiring those individuals who are not entitled to premium-free Part A coverage to pay the premium and enroll in order to obtain coverage for those drugs available under Parts A and B. We believe this is inconsistent with the meaning of the statute and the intent of Congress in enacting §1860D-2(e)(2)(B). That provision prohibits Part D coverage of a drug if payment for such drug "…is available … under Part A or B for that individual." In the explanation, CMS interprets the phrase "available to that individual" to mean that Part A or B coverage is available if the individual *could* enroll, regardless of the cost.

The exclusion forces a group of individuals to pay the Part A premium at great expense. Many individuals who are eligible to enroll in Part A but not premium-free are at income levels just above the poverty line, and are unlikely to be able to pay the premium. They will not longer have those medications available to them. We recommend that CMS interpret the term "available" to mean entitled to Part A at no cost.

Adequacy of Part D coverage. Reference: Pp. 46646-46649, §423.100.

We are concerned about the adequacy of the covered drugs for dual eligibles. Some of the excluded drugs are used frequently and appropriately for dually eligible populations. Dually eligible populations are likely to include disproportionate numbers of people with unusual disabilities and conditions that require unusual treatments and uses of medications.

Medicaid may also have employed different coverage criteria for certain drugs and supplies that exceeded Medicare coverage criteria. It appears that Medicaid will now be prohibited from obtaining FFP for those items under those circumstances. It is not clear how dual eligibles will continue to access these needed benefits if they are not eligible under new coverage criteria. We are also concerned about the affect of inadequate coverage both for enrollees whose medical conditions can deteriorate as a result, and the effect on program expenditures in both Medicare and Medicaid, especially emergency room use and inpatient hospital care.

Access to formularies. Reference: §423.120(b)(5)

We also have many questions and concerns about access for dual eligibles to the most appropriate formularies due to the limitations to the low income subsidy. Will they be relegated only to the most basic formularies, with the more flexible arrangements only available to those with means to pay additional premiums or cost sharing?

Various financial incentives tied to use of preferred pharmacies, access to out-of-network pharmacies, access to optional drugs, tiered cost sharing arrangements, and using mail order and extended supply arrangements seem to be designed only for non-dual eligibles. Will dual eligibles be excluded from these arrangements due to limits on the low-income benchmark premium and inability to pay for additional premiums. If it is difficult for them to access optional drugs and preferred pharmacies, etc, won't they be unfairly disadvantaged?

Dual eligibles may also be disadvantaged by formulary change notification requirements. CMS is requiring plans to notify enrollees about formulary changes. However since utilization and needs are so much higher for dual eligibles, they may require a new drug that they believe is on the formulary only to find that it is no longer available in their plan. Internet web sites are not well utilized by most dual eligibles and should not be relied upon to reach them with this information. Most lack access to a computer, or are

too disabled or frail to use one or to travel to a library or public source. Many also lack the language and other skills needed to access this information and would be dependent on third parties to assist with access to this information. It is not clear who will provide this kind of direct assistance and it is not likely to be uniformly available.

Also, for certain changes in drug coverage, 30 days notice is not sufficient. CMS should consider requiring plans to have exceptions or create a longer process for people who require certain types of medications that cannot be changed or substituted within the standard time frame.

Formulary exceptions process. Reference Pp. 46719, 46840, §423.578.

We continue to be concerned about the applicability of tiered cost sharing to dual eligibles. If most plans will have this type of design, how will it be modified to apply to dual eligibles who should be exempt from additional cost-sharing? This is particularly important in assessing how often dual eligibles would have to access exceptions procedures. The procedures outlined here will be extremely confusing for most dual eligibles. It appears that plans will have a lot of flexibility in whether to approve or not approve requests. Given the prevalence of off label use, and unusual conditions among dual eligibles, we are concerned that these provisions will not provide adequate protection.

Out-of-network pharmacies. Reference: Pp. 46662, 46819, §423.124.

It is not clear under §423.124 whether dual eligibles would be exempt from having to pay the price differentials, if any, for out-of-network pharmacy access. Dual eligibles do not have the resources to pay this differential and the rules should be clarified to ensure that any special needs are met without additional cost. In addition, a dual eligible who has traveled outside of the region should be not have to pay the price differential between the network pharmacy cost and the out-of-network price.

We are also concerned about low-income subsidy eligibles who reside in Part D regions that do not necessarily overlap with their local trade areas. We can envision circumstances in which an enrollee resides in one region, and the local pharmacies are in another region. In that situation, a low-income subsidy eligible should not have to pay an out-of-network price differential. In the alternative, CMS should consider requiring plans to consider any branch of a nationwide pharmacy chain under contract with the plan as a network pharmacy.

Coordination of Benefits. References: Pp. 46702, 46832, §423.464

CMS must be aware that the system being developed under this rule may require highly vulnerable frail and disabled dually eligible beneficiaries to understand and typically utilize up to three different benefits and "cards" to access all of their available pharmacy benefits. Typically, some benefits will be provided under a Part D plan, others under the

Medicaid benefit and still others under traditional Medicaid, Part A and B. Beneficiaries will have a very difficult time keeping track of which drugs are covered under which card and which cost-sharing requirements apply. They may have to call three different entities for customer service to assist them just with drug coverage, not to mention other entities that may be involved in other services they need. It will be even more confusing for dual eligibles who have only partial enrollment in either Medicare A or B and may now lose Medicaid coverage for drugs covered under A or B.

For those enrolled in MA-PDs or special needs plans, this could be reduced to two cards and for those enrolled in dual demonstrations like MSHO/MnDHO, PACE, or a dually capitated special needs plan, it could be reduced to one card, avoiding some of the complex data sharing and coordination requirements outlined here. We hope that CMS will consider rules that facilitate dually eligible enrollees to obtain all of their benefits through dual demonstrations, PACE programs and other dually capitated Medicare/Medicaid integrated or coordinated options that can be developed between special needs plans and state Medicaid programs. These options could reduce confusion for consumers while providing more efficient administration, care management and continuity of care.

Absent these programs, the coverage coordination around which drugs are covered under Part D and Part A or B and those still paid under Medicaid programs will be highly confusing to plans, providers, state staff and beneficiaries.

In addition, the administrative burden for plans, providers and pharmacies to track all of these coverage issues and adopt systems to report and track the TrOOP expenditures will be huge and will be magnified by the variety of plans benefit designs and formularies involved. We believe that it will require significant new expenditures for plans, advocates, clinics, pharmacies, long term care providers, and other providers in terms of care coordination and advocacy for beneficiaries to access the correct and coverage. It is also not clear from the discussion whether CMS has an appreciation for the amount of movement there will be from one Part D plan to another, especially among those who are low-income and at risk of institutionalization, creating another level of coordination and tracking between the Part D plans themselves.

We are concerned that time is too short for plans to be able to develop the systems capacity and interface for this tracking. We envision that such system interface issues could delay or significantly interfere with implementation.

We favor CMS hiring an outside facilitation contractor to review and match data with mechanisms similar to sharing of information on crossover claims. We believe such contractors would need to work closely with states as well. But we still have serious questions about the ability of states, plans, providers and others to gear up quickly to handle the tracking and interface that working with the contractor would require.

Part D as primary payer and effective date of coverage rules. Reference: pp. 46751, 46862, §423.906(b).

We are concerned about the combined effect of the effective date of Part D coverage and the provision making Medicare Part D primary. Specifically, it appears that there is a gap in coverage for prescription drugs for people who are determined Medicaid eligible retroactively. Medicaid programs are required to find Medicaid eligibility up to three months retroactively from the month of application. States have 45 days and more with client notice to process Medicaid applications, so the gap period could easily be 5 or 6 months. Part D coverage is effective the first of the month after the month of application for Part D. Is a person who is retroactively eligible for Medicaid going to be ineligible for Medicaid prescription drug coverage for the retroactive period, even though they are not yet able to enroll in Part D? If so, are federal matching funds and rebates available for medications covered by Medicaid in the retroactive eligibility period, and will the states' phase-down contribution be adjusted to reflect the effect of retroactive Medicaid coverage?

Interaction with nursing facility conditions of participation.

42 CFR §483.60 requires as a condition of participation in Medicare and Medicaid that nursing facilities provide "routine and emergency drugs and biologicals." A prescriber may determine that a drug is medically necessary, even though it is not covered under the recipient's Medicare Part D plan and is not covered by Medicaid. Our understanding is that the nursing facility must provide that drug to the recipient. The costs of providing drugs in these situations are reported to the state Medicaid agency and may result in an increase in the Medicaid payments to the facility, or at least produce pressure to do so.

Also, a prescriber may determine that a drug not covered by the Part C plan is medically necessary and the drug is covered by Medicaid. Normally, states will not receive Medicaid matching funds for a drug that can be covered under Part D but is not included in the Part D plan's formulary.

CMS should consider the residual responsibility of nursing homes and Medicaid programs in these situations. Are nursing facilities required to provide a drug deemed medically necessary by the prescriber, even if that drug is not included in the Part D plan's formulary? If so, and if the state Medicaid program covers the drug, can the state reimburse a pharmacy for dispensing the drug to the nursing facility, receive Medicaid matching funds, and collect the rebate?

Non-covered drugs. Reference: p. 46769, 46862, §423.906

The proposed regulations provide: "*Non-covered drugs.* States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as

provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan."

Drugs that *may* be excluded under Medicaid (as listed in the Social Security Act Sec. 1927(d) (2)) *are* excluded under Part D. Minnesota's Medicaid program covers some of these drugs – most importantly, benzodiazepines, phenobarbital, and some prescription vitamins.

We are concerned that the above regulation may be interpreted to mean that state Medicaid programs that cover these optional drugs for the Medicaid non-dual eligibles may be required to also cover them for the full-benefit dual eligibles. There are a number of reasons why a state would elect to cover these types of medications for the Medicaid eligibles who are not Part D eligible, because of the interaction and cost incentives with other Medicaid-covered medications. States should not be required to cover those drugs for the dual eligibles simply because it opts to cover those medications for the Medicaid non-dual eligibles. Such a result will result in potential cost-shifting between Part D and Medicaid, and may cause states to reduce drug coverage for the Medicaid non-dual eligible population.

Furthermore, the provision in §423.906 that states can elect to provide drugs that are non-covered Part D drugs "in the same manner as provided for non-full benefit duals" is an erroneous interpretation of the Medicaid comparability law and regulations. Title XIX requires states to treat individuals *within certain groups* in the same way in terms of the scope of the Medicaid benefit set, but does not require that states have the same benefit set for the entire Medicaid population. For example, a state can have differing benefits for each medically needy group, and those benefits can be less than what is offered to the categorically needy. The proposed regulation seems to require that states must treat the entire Medicaid population the same when it comes to drugs that are not covered by Part D, and we think that is not contemplated in Title XIX or the MMA.

Cost-sharing. Reference: pp. 46649-55, 46817, §423.104(e).

We believe it will be important for dual eligibles to allow contributions from charitable organizations to count toward incurred costs. Dual eligibles will likely have less coverage than they had under Medicaid and will be less likely to be able to pay co-pays and premiums. While it is not a good idea to set up a program that may have to rely on such donations to meet their needs, precluding these arrangements would be even worse.

PLAN BID AND SELECTION PROCESS

Bid process. Reference: Pp. 46674, 46824-24826, §§423.251 to .293.

We are concerned about how dual eligibles will continue to access health plans participating in dual demonstrations such as MSHO/MnDHO as Part D is implemented.

We want to assure that these plans can continue to provide integrated and comprehensive services including Part D pharmacy benefits, under joint arrangements with states. The Part D bid process does not provide assurance that dual eligibles can access these dual demonstrations and other special needs plans especially established under the MMA for them. This would be a tremendous loss for beneficiaries who receive ongoing care coordination and other specialized geriatric management designed especially for their needs that are not available under other MA products.

At this point, because the low income benchmark premium for dual subsidies will not be known, it is not clear whether there will be additional premiums required for enrollment in these demonstrations or special needs plans in Minnesota and other states. This will depend on how the regions are determined, which plans are interested in serving beneficiaries in Minnesota, and whether there are Part C rebates to apply to the premiums.

However, based on CMS discussions and our consultation with actuaries, there is considerable concern that these plans will be particularly disadvantaged in the bid process since they are relatively small, specialized and may lack volume purchasing power. We are concerned that these plans will be less likely to produce savings than standard plans and may not have rebates to buy down any premium. Further, their bids are not considered in the averaging process that will produce the low-income subsidies. As a result, we believe they will be more likely to have residual premiums above the low income benchmark subsidies. We also assume that dual eligibles will not be able to afford additional premiums and that the state will not be able to afford to pay such premiums. The rule seems to indicate that plans will not be allowed to waive or absorb residual premiums.

CMS has said that PACE will be subject to a bid process "similar" to MA-PD and appears to be allowing PACE programs to waive some residual premiums. Special dual demonstrations like MSHO/MnDHO as well as special needs plans will also need some accommodations in this process to adapt it for plans that focus on dual eligibles so that they can continue to serve these beneficiaries.

National average bid amounts. Reference: Pp. 46683, 46825, §423.279

We disagree with CMS' conclusion that while specialized MA plans such as dual demonstrations, PACE or special needs plans are to be left out of the national average bid amounts, they should still be subject to the same bid process. The logical conclusion of that decision is that such plans will not be able to serve the very people they are designed to serve.

While we understand that costs represented in each bid will represent a beneficiary with an "average" risk profile, we are still concerned that the bid process may not adequately account for the special needs of plans that serve dual eligibles. Specialized plans serving

dual eligibles are generally smaller and will have less purchasing power than those serving a broader population to access the lowest drug prices. Dual eligibles are known to have higher than average utilization patterns. Special needs plans may also have to address other design issues involved in serving dual eligibles, such as larger formularies to deal with special conditions experienced by dual eligibles (particularly for people with disabilities), more flexibility in "off label" use, increased access to long term care pharmacy networks, and more intensive monitoring to deal with increased levels of adverse drug interactions due to a higher volume of poly pharmacy problems. Serving dual eligibles may also result in higher administrative costs. Disproportionate numbers of dual eligibles are non-English speaking, frail, cognitively impaired, or have high needs. It may be necessary to have special procedures for appropriate customer service, additional handling of notices, authorizations, claims processing and tracking of eligibility.

Costs for dual plans will be excluded from the national average bid amounts. Therefore national average bid amounts and thus the resulting regional average low income benchmark premiums and subsidies will be based only on bids from plans with an average or below average proportion of dual eligibles. Plans serving an average population are also more likely to have rebates to apply to their Part D bids further reducing their premiums and reducing the average benchmarks for the low income subsidy. Plans are not allowed to adjust their premium bids after the low income subsidy is set and they will not know what the low income subsidy amount is when they submit their bids.

Taken together, all of these things mean it is even more likely that the low income subsidy will be less than any bid amounts submitted by plans especially designed for dual eligibles. This will result in a residual premium that currently enrolled or new dual eligibles cannot pay and will render those plans unable to enroll the very populations for which they were designed. Dual eligibles will have no choice but to disenroll to lower cost PDPs or MA-PDs serving the broader population. Since many of these programs have been successful in reducing hospitalizations and nursing home use, this may actually increase federal costs for Medicare and/or Medicaid as well as reducing any incentive to develop specialized dually-capitated managed care options for dual eligibles. We do not believe Congress intended to make these plans unable to serve the beneficiaries they were designed to serve.

We believe CMS has authority to adjust the bid process to ensure that special needs plans, PACE, dual demonstrations and other specialty plans be subject to an alternative bid process that ensures they can continue to serve dual eligibles.

Payments to PDP sponsors and MA organizations. Reference: Pp. 46685-46694**.**

We are troubled by the discussion suggesting that plans set up to serve these populations would have to deliberately bid low in order to avoid additional premiums, or to try to set

up features specifically attractive to dual eligibles. It appears that the bid process presents obstacles to both of those options. Plans could not be assured that their bid would be low enough to avoid a residual premium, since they will not know in advance what the regional average bid will be. And submission of an artificially low bid could cause other financial issues later. The requirement to bid on the basic benefit set or its actuarial equivalent may limit some rearrangements that might be attractive to dual eligibles. Plans are also prohibited from targeting their designs to avoid serving certain groups of people, though we assume that special needs plans and dual demonstrations, by design, would be treated differently because they serve only dual populations.

Plans might like to reduce or eliminate co-payments for drugs for dual eligibles but it appears those would be considered supplemental benefits for which a premium must be charged. And that premium would have to be risk-adjusted to account for utilization increases, further increasing the amount that dual eligibles would have to pay to remain in the plan. The premium cannot be waived. And if it could be, the plan would then be shortchanged in payments they may need to provide adequate services.

Plans in states with low Medicare capitation payments are additionally disadvantaged. As discussed by CMS on page 46680, MA-PD plans may resubmit information to reallocate portions of their Part C rebates to "buy down" the Part D premium. Currently all Minnesota MA plans charge monthly premiums as well as significant cost sharing for basic Medicare A/B coverage, with few if any, extra or supplemental benefits. There are no "0" premium plans currently operating in Minnesota. Minnesota Medicare managed care monthly capitation payments remain below the national average and 74 of Minnesota's counties are paid at the monthly capitation floor established under the Balanced Budget Act of 1997. Currently, there are no MA plans operating in those 74 counties. Therefore it is less likely that plans operating primarily in Minnesota will be able project the necessary savings from Part C services to fund supplemental benefits without additional premiums. It is even less likely that plans serving dual eligibles in dual demonstrations or special needs plans will have these rebates in low payment states like Minnesota.

Some have suggested that states pick up the residual premiums in these cases. This is also unrealistic. States will already be subject to other payback mechanisms, and may have to incur other unexpected costs for certain eligibles.

CMS discusses their assumptions that beneficiaries will choose a drug plan based on lower drug prices and formulary coverage, and the bid process, benefit and formulary design, and premium pricing all seem to be built on this assumption. We question how these assumptions can apply to programs designed to serve primarily dual eligibles. Plans are limited in the cost sharing that they can charge to dual eligibles and CMS is covering the out-of-pocket costs through subsidies. Dual eligibles have limited ability to respond to or benefit from benefit designs and strategies largely built on price sensitivity and variable cost sharing. Most dual eligibles are going to be limited to plans without

supplemental premiums and additional benefits. It seems this process is likely to further limit dual eligibles to basic formularies that may not have all of the flexibility and access to drug coverage that they have had under many Medicaid programs.

Since Congress clearly intended there be plans that serve dual eligibles, we believe CMS must address the conflicts in the basic assumptions as applied to dual eligibles. We understand that CMS is working on certain adjustments to accommodate PACE programs. We understand that this is suggested by the statute. However, CMS also states that it has broad authority in designing the bid process. It also has waiver authority to reconcile conflicts between Part C and Part D. We would hope that CMS would employ those authorities to consider similar solutions for adjusting the bid process for dual demonstrations and special needs plans.

Some suggestions include:

Work with PACE, special needs plans and dual demonstrations to come up with a more equitable and workable Part D bid process that will clearly allow access for dual eligibles to programs designed for them. This could include setting up a separate class for these programs in which to bid or finding a way to allow the plans to absorb small residual premiums and otherwise accommodate the costs beyond the low income subsidy premium through the risk adjustment and risk corridor system.

CMS could also allow these plans to delay their bid submission until after the average benchmark premium and the low income subsidy is set or to redesign it after that number is known. Since those bids are not being used in the calculations anyway, the delay would allow these special plans to take these factors into consideration in designing their bids without negatively affecting the national bid process.

CMS should also revisit the calculation of the low income premium subsidy in the bid process, such as calculating this amount prior to rebates and/or basing the subsidy on actual Medicaid costs associated with dual eligibles instead of the typical Medicare population.

CMS could address some of the potential inequities for special plans serving dual eligibles through the manner in which it provides the low income cost sharing subsidies and interim payments. CMS suggests that the initial calculations could be significantly variable in the first couple of years and proposes making interim payments based on plan projections with reconciliations. Perhaps the process of interim payments provides some opportunities to address these issues. For example, while the capacity of the risk adjustment system to capture costs for a skewed enrollment of duals, institutional and high chronic needs population is being worked out, CMS could consider basing payments for these special plans on actual historical costs for those plans that have had drug coverage for dual populations under Medicaid or on the historical costs to the state for Medicaid coverage for a like population. Plans could then submit bids based on prior

Medicaid pharmacy cost experience for Part D covered drugs. CMS could base the low income subsidy on those actual Medicaid costs without risk adjustment as risk adjustments and processes are being refined. Actual Medicaid costs for those enrolled beneficiaries would be a better measure of utilization for these enrollees and would also capture the historical purchasing power and rebates provided under previous Medicaid arrangements. CMS might also explore employing differences in the risk corridor limits to better accommodate these plans.

Risk adjustment. Reference: Pp. 46688, 46827, §423.329

Since many issues around access to dual eligible demonstrations and special needs plans are not being fully considered in the bid process, it places much pressure on the risk adjustment portions of the rate to accurately capture the costs of plans that specialize in serving large numbers of frail, dual eligible populations. We appreciate CMS' attention to this issue in the discussion. When CMS developed the CMS HCC risk adjustment system now applied to plans under MA, additional analysis indicated that while the system worked well overall, plans that specialized in high risk populations would be disadvantaged. Despite the improvements, the system continues to underpay frail beneficiaries and overpay those who were healthier. CMS subsequently developed an additional frailty adjustor for community enrollees with high activities of daily living needs and has applied that improvement to PACE, SHMOs, and the dual demonstrations such as MSHO/MnDHO.

With the inclusion of new special needs plan provisions under the MMA, it is clearly the intention of Congress that plans should be able to specialize in serving dually eligible and other populations with chronic care needs. CMS is provided with considerable flexibility in how to conduct the bid process and how to develop the pharmacy risk adjustment system to be used for Part D. If the system does not perform well for these groups, then CMS should consider adjustments to correct the problem.

CMS should not assume that drug utilization is driven by the same service use and diagnostic patterns driving costs under Parts A and B. Particular attention should be paid to diagnoses that may be left out of the HCC model but may still be associated with high pharmacy use, such as cognitive impairments and dementia. Therefore, we think it is crucial that CMS conduct specialized analyses using actual data for dual eligibles (which could be provided through analysis of existing CMS Medicaid data or by Medicaid programs) to test the efficacy of the proposed system on large concentrations of frail, institutionalized and other dual eligibles.

In developing risk adjustment and considering how to address the costs of dual populations, CMS should not rely on incomplete data sources such as the MCBS or the 5% file. Instead, CMS should access historical costs from Medicaid data. There is a wide range of utilization and diagnoses among dual populations. The 5% sample and the MCBS include only a handful of dual eligibles from any given state and is not an

adequate representation for this kind of analysis. We appreciate that CMS has a difficult task in estimating drug costs and risk for the general Medicare population since there are few appropriate data bases available for that purpose. But at least for dual eligibless, there is comprehensive data and it should be utilized to assure that the system adequately addresses their needs.

While we realize that CMS is under tremendous time constraints in developing this risk adjustment system, we would hope that interim payment and settle-up systems could be put in place for plans that serve unusual or skewed distributions of dual elderly, institutional or high chronic care populations until the risk adjustment system adequately addressees performance in these programs.

Compliance with state law and federal preemption. Reference: Pp. 46696, 46830, §423.410.

The MSHO/MnDHO dual demonstration currently relies on state HMO licensure requirements for basic compliance with CMS demonstration parameters and MA rules. Licensure as an HMO in Minnesota is only available to non-profit plans. Minnesota law also requires that a percentage of HMO boards be comprised of consumers. Therefore all plans participating or currently applying to participate in MSHO/MnDHO are non-profit, as are most PACE programs. This statute has been important to consumer advocacy groups involved in monitoring these demonstrations. The fact that all of the participating plans are not only non-profit, but locally operated, provides a sense of security to consumers and advocates in accepting HMO risk based models designed to serve high needs and high risk populations. Consumer advocates also value the fact that they can easily identify and access responsible high level plan officials as well as the state to express their concerns, as well as use the state's political process to advocate for additional protections when necessary. This has helped to reduce the natural skepticism and aversion many consumers and their advocates have around capitated risk-based models for highly vulnerable populations.

Groups involved in MSHO/MnDHO are concerned that Part D may have a significant effect on which plans participate in MSHO/MnDHO. Some fear that the combination of new regions, Part D coverage and state HMO licensure preemption could have the effect of "knocking" small, well-meaning plans that have been serving dual eligibles out of the market, thereby weakening or eliminating the demonstration plans and reducing plan choices for vulnerable populations. Further, these groups worry that they will have no choice but to be forced to accept large, for-profit, out-of-state national plans that have little understanding of the relatively high expectations and trust levels currently experienced with MSHO/MnDHO plans and other Minnesota HMOs. We request that CMS consider these factors when addressing preemption issues and requests.

Application of Part D Rules to MA-PD Plans. Reference: Pp. 46697, 46832, §423.458

We suggest that CMS employ this section to adjust the Part D bid process, risk adjustment and other problematic areas identified in these comments for dual demonstrations and special needs plans, particularly where the CMS discussion also notes these problems. A case can be made that there are conflicts between the two rules and the need to improve coordination of Part C benefits with Part D in that some provisions interfere with the ability of MA plans to successfully serve dual eligibles under Part C under Section 231 or under other established programs such as the existing dual eligible demonstrations. CMS is considering a special rule rather than many individual waivers for PACE programs. While the waivers necessary for dual demonstration projects and special needs plans to continue to serve dual eligibles may not reach that volume since they are not subject to a separate rule as is PACE, we believe some of the issues are similar and would also warrant a special rule provision.

We also note that CMS mentions that plans may access waivers under §422.106 in order to contract with employer groups. Section 422.106 also references plan arrangements with Medicaid agencies. While §423.458, and §422.106 under Part III, discuss how waivers might be applicable to employer groups, there is no mention of how the authority under those sections might also be applicable to resolving some of the conflicts identified between Part D and Part C for dual demonstrations or special needs plans that wish to contract with Medicaid agencies under §422.106. CMS should consider treating states similarly to employer groups for this purpose. Therefore, we recommend that CMS discuss this further with states and consider adding provisions to clarify this section prior to finalizing the rule.

Part D provisions affecting physician self-referral, cost-based HMOs, PACE and Medigap requirements. Reference Pp. 46753.

Much of the discussion on page 46755 about problems faced by PACE programs in the bid and low income subsidy process is also applicable to the dual demonstrations such as MSHO/MnDHO and to special needs plans.

On recent conference calls for states involved in PACE programs, CMS discussed accommodations being made to ensure that PACE can continue to enroll dually eligible and low income beneficiaries. Therefore, dual eligibles in areas where there are PACE sites may have access to some additional benefits that other dual eligibles may lack. However, PACE programs are very small by nature and design, and are able to serve only a small subset of dual eligibles in each state.

CMS states that special needs plans serving dual eligibles under §231 of the MMA are also allowed to reduce cost sharing in the form of supplemental benefits designed only for dual eligibles. It is not clear that this is the same provision being worked out for PACE however. We assume that this special needs plan supplemental benefit would need to be covered by Part C rebates in order to avoid an additional premium for this benefit.

We request that CMS consider how these PACE adjustments may be applicable to dual demonstrations such as MSHO/MnDHO. Currently under MSHO/MnDHO, participating plans have chosen to absorb the costs of Medicaid copays. We would like to continue to have that option available as we move forward to inclusion of Part D benefits. However, it is not clear that the bid process will allow for coverage of a supplemental benefit without a premium or that MSHO/MnDHO plans would be allowed to or be able to absorb the additional premiums for this supplemental benefit under the new payment arrangements.

ADMINISTRATION AND COSTS

User fees. Reference: Page 46636 and 46811.

User fees are currently required for MA plans to defray part of the ongoing costs of beneficiary education. The MMA expands the user fee to apply to PDP sponsors. CMS intends to assess user fees to MA plans and PDP sponsors up to a maximum of $200,000,000 annually. We encourage CMS to apportion these funds to the local certified SHIP programs to provide as much local assistance and outreach as possible. Using the CMS estimate of an average of 30 minutes per call for a beneficiary to choose a Part D plan, Minnesota expects to require more than $4 million annually to serve twenty percent of the eligible beneficiaries in Minnesota. The current SHIP grant is $246,719.

Eligibility costs. Reference: pp. 46727, 46855, §423.774(a).

If states are required to collect and process applications for subsidy assistance for applicants who are not eligible for or not applying for Medicaid, 100% federal funding should be available for the state costs, since this is entirely a Medicare Part D activity. The 50% funding rate in the Medicaid Program is not relevant. Reimbursing states at the 50% rate results in an unfunded mandate.

Consumer satisfaction surveys. Reference: Pp. 4666, 46821, §423.156

We agree that use of a CAHPs type survey or inclusion in CAHPs may be the best approach to a consumer satisfaction survey for services under Part D. However, the current CAHPs survey for health plans leaves out people in institutional settings due to differences in methodologies required to reach that group of people.

While CMS has been considering development of a CAHPs instrument specifically for nursing home residents, we understand that it is not designed to address issues of satisfaction with health plans and health plan services and instead deals mainly with nursing home issues. Questions regarding satisfaction with PDPs and MA-PDs and access to drugs should be included in a redesigned CAHPS survey or in a new survey addressed to nursing home and other institutionalized beneficiaries. CMS should also

assure that appropriate methodologies designed to reach people in institutional settings are including, such as the use of family members as proxies. CMS should plan to cover the additional costs associated with surveying people in nursing homes. Such costs could be highly burdensome for small programs.

CMS should also address availability of the survey in additional languages and access mechanisms for people who do not have written language skills. Current mailed survey approaches are generally inadequate to reach these groups. CMS should consider use of a language block on the forms, indicating where interpreter services or translations may be accessed.

Quality Improvement Organizations. Reference: Pp. 4672, 46821, §423.162.

We are concerned that current and proposed QIO provisions do not allow the QIO to share data or information about the quality of care for dually eligible beneficiaries under Medicare with states, even when the state itself shares Medicaid information with the QIO. Quality information about drug coverage and issues related to provision of drugs to dual eligibles is directly relevant to state's ability to serve duals under the Medicaid program and is required to assure health and safety of frail elders and people with disabilities served in institutions and in home and community based waivers. The state is a partner with CMS in administering and managing Medicaid services. Information on quality issues related to access and coverage of drugs under Medicare will have a direct impact on the state's costs and ability to manage Medicaid services.

Therefore, CMS should build in requirements for sharing of data and additional quality information between its partner states and QIOs or should develop additional data sharing mechanisms that address this issue.

In addition, we are concerned about the impact of quality assurance activities such as QIO measures, surveys and quality assurance requirements on our special dual demonstration project, MSHO/MnDHO. Since this programs serves only dual eligibles and since dual eligibles have different utilization patterns, co-morbidities, and drug management issues, quality assurance measures, surveys and QIO activities should take into account the differences in the population served. Programs serving large numbers of people with disabilities or frail elderly may see pharmacy utilization patterns that are far from the norm and should not be compared to or otherwise penalized for a typical utilization. Our concern is also applicable to any special needs plan serving primarily dual eligibles or institutionalized people.

Phased-down state contribution. Reference: §423.908.

The MMA identifies 2003 as the base year for determining the per capita Medicaid expenditures for full benefit duals. However, the formula for determining 2003 expenditures is not indicative of states' actual expenditures because of the lag time in the

collection of drug rebates. The formula should be adjusted to reflect the full rebates collected.

The formula includes an adjustment for the "estimated actuarial value of prescription drug benefits under capitated managed care plans" for full benefit dual eligibles. As CMS is aware, there are many ways in which it could estimate the actuarial value of the managed care prescription drug benefit, and the methodology chosen will greatly affect state budgets. If CMS does not intend to define the methodology in this regulation, what is the process for doing so?

Thank you for the opportunity for comment. If you have questions about this document, please call or email Ann Berg at 651/296-0642, ann.berg@state.mn.us.

Sincerely,

Mary B. Kennedy
Medicaid Director

CMS-4068-P-1062

Submitter : Dr. Meghan Gerety **Date & Time:** 10/04/2004 06:10:40

Organization : American Geriatrics Society

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4068-P-1062-Attach-1.doc

THE AMERICAN GERIATRICS SOCIETY
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LINDA HIDDEMEN BARONDESS
Executive Vice President

October 4, 2004

The Honorable Mark McClellan, MD, PhD.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-4068-P

Dear Dr. McClellan:

The American Geriatrics Society (AGS), an organization of nearly 7,000 geriatric health care professionals who are specially trained in the management of care for frail, chronically ill older patients, appreciates the opportunity to provide comments on the proposed Medicare prescription drug benefit, also known as the Part D regulations. Our comments on the proposed rule are below.

1) S 423.50 Marketing and Enrollment Forms. The rule explains that a prescription drug plan (PDP) may not accept enrollment forms in providers' offices. This appears to prohibit a physician from taking an enrollment form from a patient and assisting with the enrollment process. We suggest that in certain limited circumstances, such as for dual eligible or frail elderly patients with special health or social needs, providers should assist or facilitate with the enrollment process.

2) S 423.120 Formulary requirements for P & T Committee. If a plan uses a formulary, it must use a pharmaceutical and therapeutic (P&T) committee to develop and review the formulary. The Centers for Medicare and Medicaid Services (CMS) has requested comments on their interpretation of the law that a P & T Committee decision regarding the plan's formulary are binding on a plan. The AGS proposes further review beyond the P & T Committee. Specifically, we recommend, as frequently is current practice, that a quality assurance committee approve the P & T committee recommendations.

3) S. 423.120 P & T Committee Design. The P &T committee will be involved in designing formulary tiers and any clinical programs designed to encourage the use of preferred drugs (e.g., prior authorization; step therapy, generics programs).The majority of the P & T committee would be required to be practicing physicians and/or practicing pharmacists. At least one of each would need to be expert in care of elderly and disabled individuals. Geriatricians and other health care professionals with special training in geriatrics – such as geriatric pharmacists – have special training in pharmacology and specifically in areas involving medical contraindications. For this reason, the AGS suggests that the P & T Committee include at least one health care provider with special and demonstrable training in geriatrics.

   Furthermore, CMS requests comment on their decision to strengthen the regulation by requiring that more than just one pharmacist and one physician is independent and free of conflict. The AGS strongly supports this requirement, which will lead to meeting the best needs of the patient.

4) USP Model Guidelines. The US Pharmacopeias (USP) will develop a model set of guidelines that consists of a list of drug categories and classes that may be used by PDP sponsors and MA orgs to develop formularies, including therapeutic categories and classes. The AGS submitted a comprehensive comment letter on the proposed guidelines and has met privately with members of the USP expert guideline committee. In short, the AGS is concerned that the medications needed to appropriately treat frail elderly populations, those Medicare beneficiaries with multiple chronic conditions or functional limits (1) will not included in the proposed formulary and (2) will not be readily available through the formulary over-ride process. In addition, the proposed guidelines reliance on the ICD-9 code approach does not adequately capture common geriatric syndromes.

5) Treatment Protocols. The rule states that plans would be required periodically to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their plan members are receiving the best care. CMS seeks comments on the minimum timeframes for periodic evaluation and analysis of protocols and procedures. The AGS believes that a quarterly review initially and every 6 months thereafter would suffice as an adequate amount of time for periodic evaluation and analysis of protocols. Identifying problems dictated by a change in practice standards or when the FDA approves a new drug with benefits for older patients and having those addressed early during program implementation would be beneficial. As programs mature, CMS could reduce monitoring of plans to an annual review.

6) Appropriate Notice. The Medicare Modernization Act (MMA) also requires "appropriate notice" to CMS, enrollees and prescribers regarding: 1) removing a drug from its formulary and 2) making any change in the preferred or tiered cost-sharing status. The regulation defines appropriate notice as at least 30 days prior

to such change taking effect during a given contract year. The AGS would recommend a longer notice period of 60-90 days. Beneficiaries may need to see their primary care provider before making changes and this may not be feasible in a 30-day period.

Furthermore, the regulation also only requires notice to be given to those enrollees taking that drug – not to all plan enrollees. The AGS believes that plans should notify all providers since other beneficiaries may be thinking of switching medications and may be in discussions with physicians about making these changes. Such changes would be impacted by PDP decisions in this area.

7) Prior Authorization. PDPs can include use of prior authorization; step therapy; tiered cost-sharing; and other tools. CMS seeks comments on whether these should be under the direction and oversight of a P & T committee to ensure balance between clinical efficacy and cost-effectiveness and if they should involve quality assurance and medication therapy management. In general, evidence based clinical guidelines for medication treatments should be followed. The guidelines that the P & T Committee has chosen should be accessible to beneficiaries and physicians online, and subject to the same notification principles as a change in formulary.

   The AGS objects to prior authorization and step therapy as it interferes in the practice of medicine and inappropriately second guesses the physician. Tiered cost sharing is acceptable provided it is not structured in such a matter that it inhibits the appropriate use of medications

8) S 423.153 Cost Effective Utilization Management. The Part D regulations require each plan to provide a program to include incentives to reduce costs when medically appropriate. This should not come to simply mean "switching," in which one branded drug product is switched with another similar branded drug product, referred to as therapeutic substitution. Therapeutic substitution would always require explicit prescriber notification and approval. We oppose independent therapeutic substitution. In addition, we find the notification and approval procedures burdensome and ineffective for physicians.

9) Medication therapy management – Provider Types, Reimbursement & Eligibility. The Part D regulations require plans to establish medication therapy management programs (MTMP). Targeted beneficiaries include individuals with multiple chronic diseases; taking multiple Part D drugs; and are like to incur high annual costs, CMS seeks comments on which types of physicians and pharmacists should provide these services, which reimbursement mechanisms are appropriate for these services and how to define multiple chronic diseases and multiple Part D drugs.

   MTMP requires a willing provider – the primary care provider – who is available to collaborate. In addition, the pharmacist should have experience or additional

training to provide consulting pharmacist services for nursing homes, such as a special certification and/or membership on an interdisciplinary team. Finally, the physician should be a geriatrician or other primary care provider with demonstrated geriatric experience. This experience is especially significant when there are important potential medication-disease interactions.

The AGS believes that the frail elderly is an excellent target population for the MTMP. We believe there are numerous ways to target this population. Multiple chronic illnesses do not fully capture this population. Instead, we would suggest a patient base that has multiple comorbidities, which includes functional status limits, as well as some other limiting factor, such as inability to self-manage these conditions, high health utilization costs and/or dementia. Effective medication therapy management requires the willingness of the beneficiary and their primary car physician to participate n the process.

10) Medication therapy management – Range of Services. The MMA allows plans to establish a broad range of services under the MTMP. CMS envisions a "range of services, ranging from simple to complex" and defines this very broadly. All prescriptions for medications in the modified Beers criteria drugs for potentially inappropriate use in the elderly should be reviewed. The services should review the patients total medication regimen – current prescription medications, herbal and supplements, and over the counter medicines. Services should also include drug regimen simplification, selection and monitoring, and implementation and management of a therapeutic plan following diagnosis.

11) S 423.564 Grievances, Coverage and Appeals. Plans must maintain grievance procedures for making timely coverage determinations; exceptions to a tiered cost-sharing structure; and handling exceptions to a formulary. Under the exceptions process, a nonpreferred drug could be covered as a preferred drug if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective or would have adverse effects or both. An enrollee or prescribing physician may request that a coverage determination be expedited. The enrollee or physician either must submit an oral or written request directly to the plan sponsor; physician may provide oral or written support for an enrollee's request. CMS should make this process as simple as possible. Physician office staff should be allowed to place calls if calls are required. Plans should have standardized forms that can be completed quickly and faxed and should be required to provide a response in a timely manner, such as 48 hours.

12) Exceptions to formularies**.** PDP sponsors must also establish a formulary exceptions process. Formulary use includes the application of a dose restriction that causes a drug not to be covered for the number of doses prescribed, or a step therapy requirement that causes a drug not to be covered until the requirements of the sponsor's coverage policy are met. The process must address coverage of drugs that are not covered; continued coverage of a drug that sponsor is

discontinuing on the formulary; and exception to the policy that causes a drug not to be covered until the step therapy requirement is satisfied.

The procedures must include a description of the criteria a sponsor uses to evaluate physician's determination; a process for comparing applicable medical/scientific evidence on safety and effectiveness of non-formulary drug with formulary drug; a description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug; if the sponsor covers a non-formulary, and if the cost incurred by the enrollee for that drug is treated as included in meeting the annual out of pocket threshold. An enrollee, representative or physician may file an exception.

The plan may require a written certification from a physician because a drug is medical necessary, because there is not a drug on the formulary to treat the disease or medical condition that is an acceptable clinical alternative; because the alternatives for step therapy have been ineffective in the treatment of the enrollee's disease, based on evidence and known characteristics of the enrollee and the drug, is likely to be ineffective, or the number of doses have been ineffective.

Finally, the plan may require that the written certification may include: enrollee's name; contract number; patient history; primary diagnosis; the reason the formulary drug is not acceptable; why the drug required for step therapy not acceptable; why the available number of doses is not acceptable; why the drug is needed; any other information reasonably necessary.

We have several concerns with the exceptions process. Physicians must go through two separate processes to ensure their patients receive nonpreferred drugs and drugs that are not on the formulary. We object to these processes due to their interference in the practice of medicine/second guessing physician. In addition, the written certifications are extremely burdensome. Finally, the AGS specifically objects to the diagnosis being included on the certification.

13) Independent Review Entity (IRE). The regulations establish an IRE for enrollees who are dissatisfied with re-determinations. The IRE does not occur automatically; an enrollee must request review. The IRE must seek views of prescribing physician. In order for an enrollee to request an IRE reconsideration, the physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition are not as effective for the individual, has adverse effects for the individual, or both. This process is highly burdensome for both the physician and the beneficiary.

14) Transition Issues. Under the Part D regulations, the Medicaid drug benefit ends as of January 1, 2005, but the auto-enrollment does not begin until May 15, 2006. Consequently, dual eligibles that do not enroll in a plan would be without drug coverage until May or June. AGS is concerned about this provision for several

reasons. "Duals" have complex medical and social needs. Many duals have multiple chronic conditions, functional limits and/or dementia and are particularly in need of ongoing medications, many of these specialized. Gaps in coverage or confusion surrounding auto enrollment procedures would particularly harm this population.

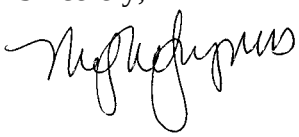
In order to protect the most vulnerable beneficiaries, CMS should incorporate the following protections. CMS should require Part D plans to reimburse current pharmacies for current medications for the first 6 months of the new benefit. This will allow a smooth transition for all parties and allow prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health. CMS should also allow States to obtain federal financial participation for any wrap-around medication until July 1, 2006. Alternatively, the automatic enrollment of dual eligible individuals should occur on December 31, 2005.

15) Special Enrollment Periods (46640) 423.36 – Under the Part D regulations, if an enrollee resides in the community with a PDP plan and moves into the nursing home, there is currently no special enrollment period to allow the beneficiary to change plans upon entry into a nursing home. In comparison, there is such a provision under the discount card program. The AGS recommends comparable treatment under the prescription drug program for this vulnerable and special need's population. In addition, the AGS would recommend that nursing home eligible seniors that are non-institutionalized also have access to this SEP. Given the move for this frail population to enter community based programs it is important to develop all opportunities based on the beneficiaries needs rather than location of care.

Conclusion

We hope to work with CMS on the development of the final rule on the Part D program. If you should have questions or comments on this letter, please contact Susan Emmer in our Washington office at (301) 320-3873.

Sincerely,



Meghan Gerety, MD, AGSF
President
American Geriatrics Society

CMS-4068-P-1063

Submitter : Ms. Leslie Fried **Date & Time:** 10/04/2004 06:10:55

Organization : Alzheimer's Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see our attached comments.

CMS-4068-P-1063-Attach-2.doc

CMS-4068-P-1063-Attach-1.doc

September 17, 2004

Lynn Lang
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790

Re: Comments to the Draft Model Guidelines

Dear Ms. Lang,

The Alzheimer's Association appreciates the opportunity to comment on the Draft Model Guidelines developed by the United States Pharmacopeia (USP) pursuant to the Medicare Prescription, Drug, Improvement and Modernization Act of 2003 (MMA). The Alzheimer's Association is the premier source of information and support for the 4.5 million Americans with Alzheimer's disease. Through its national network of chapters, it offers a broad range of programs and services for people with the disease, their families, and caregivers and represents their interests on Alzheimer-related issues before federal, state, and local government and with health and long term care providers. The largest private funder of Alzheimer research, the Association has committed nearly $150 million toward research into the causes, treatment, prevention, and cure of Alzheimer's disease.

General Comments

In its introduction to the model guidelines, USP states that a primary goal of the expert committee was "to assure beneficiary access to the drugs they need, preventing substantial discouragement from enrollment." This is a laudable goal especially since these Model Guidelines will serve as a "safe harbor" for any prescription drug plan that uses them to develop its own formulary. As USP undertakes the revision process, it should ensure that these guidelines are sufficiently inclusive to permit doctors to effectively treat their Medicare patients. Access to the most effective medical treatment must be paramount to the benefits of prescription drug plans to negotiate the best drug prices.

We are concerned that the guidelines may encourage the use of older drugs that often result in increased side effects and adverse reactions in older, frailer beneficiaries, such as those with Alzheimer's disease. With impaired memory and judgment, individuals with Alzheimer's disease may not be able to recognize, understand or report early signs of adverse reactions until it results in an acute episode.

Due to the increased age, lower metabolism and co-existing conditions of this population, physicians require a wider range and greater flexibility when treating their patients. Ninety-five percent of Medicare beneficiaries with dementia have one or more other chronic conditions, including congestive heart failure (28%), diabetes (21%), chronic obstructive pulmonary disease (17%) and coronary heart disease (30%). These patients

are taking a combination of medications to appropriately manage these conditions. It is a delicate balance that requires access to specific medications to enhance the care to the beneficiaries. The data that would inform a physician about the risks and benefits of changing such medications, even among the same class, is missing or inadequate. The Model Guidelines must be revised to provide for sufficient granularity to ensure that Medicare beneficiaries will have access to the medications that their physicians deem necessary to treat them. The exceptions process, which is burdensome and time-consuming, is not an appropriate solution to an inadequate classification system or formulary.

The MMA requires that the Model Guidelines be revised "from time to time" to reflect the changes in therapeutic uses of Part D drugs and to cover new FDA-approved drugs. There is nothing in the draft Model Guidelines that reflect a plan that provides for this review procedure. Given the recent increase in research and development of drugs for Alzheimer's disease that would benefit the Medicare population, this process should be expedited and require automatic inclusion of these drugs within 30 days of FDA approval.

Specific Comments

We believe that the third column of the Draft Model Guidelines, "Recommended Subdivisions," should be equivalent to the first two columns, therapeutic category and pharmacologic class. Plans would be required to offer at least two drugs in the third column, thereby assuring beneficiaries access to statins, pain medications, anticonvulsants, hormone replacements and other medications which they are most frequently prescribed. Without this modification, many Medicare beneficiaries would be forced to change their current medications to drugs with unpredictable results.

Of particular concern to individuals with Alzheimer's disease is access to medications to treat neuropsychiatric symptoms. In a recent study, *Prevalence of Neuropsychiatric Symptoms in Dementia and Mild Cognitive Impairment; Results form the Cardiovascular Study*, JAMA, September 25, 2002-Vol 288, No. 12, 1475, researchers found a high prevalence (60-80%) of neuropsychiatric symptoms in participants with dementia. These symptoms include agitation, depression, apathy, anxiety, delusions, hallucinations and sleep impairment and have serious adverse consequences on the patients. Appropriate treatment of these symptoms provides substantial benefits to these individuals. Other studies have shown that therapeutic interventions can improve function, reduce disruptive behavior and mitigate excess disability for individuals with Alzheimer's disease.

Accordingly we make the following recommendations to revise the draft Model Guidelines:

1) Antidepressants (15-17): The antidepressants should be five classes: Monoamine Oxidase Inhibitors - Type A, SSRI, SNRI, Tricyclics and Other. The current pharmacologic class of Reuptake Inhibitors, which includes SNRI, SSRI and Tricyclics, is erroneous since they each work differently on different receptors and have different

effects on clinical profile. In addition, trycyclics is an older generation of antidepressants that produce significant side effects in the elderly population.

2) Antipsychotics (54-56): We are pleased that the Draft Guidelines includes three classes of antipsychotics and encourage their inclusion in the final guidelines. Given the current pharmacologic classes, it is unclear in which group a phenothiazine atypical would be considered.

3) Anxiolytics (70) - Under anxiolytics and sedatives, it is important to include sedative hypnotics to treat sleep disturbances which are prevalent for individuals with dementia. We are disappointed and concerned that Benzodiazepines, a group of medications commonly prescribed to Alzheimer's patients for the treatment of insomnia and anxiety, has been specifically excluded from and will not be covered by the Medicare prescription drug benefit.

4) Memory Enhancers- Dementia (128-129) – We are pleased that the Model guidelines include cholinesterase inhibitors and glutamate pathway modifiers. We recommend that this category name be changed to be called antidementia drugs or similar, since they do not improve memory in normal individuals. We also suggest that class #128 be called cholinesterase inhibitors since their action is primarily centered in the CNS, not the PNS. We believe that the inclusion of all three cholinesterase inhibitors should be considered. Research confirms that patients' responses to the individual agents vary widely. Therefore clinicians require access to the full selection of these drugs in order to prescribe the best agent for a particular patient. In addition, if only two of the drugs are covered, some patients may be forced to cease a medication in the middle of its course. It is an unknown risk to discontinue patients from an agent during the course of treatment and should be avoided.

We appreciate the opportunity to comment on these Model Guidelines. The Alzheimer's Association is ready to work with you, and to assist in identifying appropriate clinical experts, to assure access to medically necessary drugs for beneficiaries with dementia. Please feel free to contact Leslie B. Fried, Director of the Association's Medicare Advocacy Project, (202) 662-8684, to further discuss these matters.

Sincerely,

Bonnie Hogue
Director, Federal and State Policy

Leslie B. Fried
Director, Medicare Advocacy Project

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Public Policy Office
1319 F Street, NW, Suite 710
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202 393 7737 p
202 393 2109 f

alzheimer's association

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

October 4, 2004

Re: CMS File Code – 4068-P:
Comments on Medicare Prescription Drug Program
Comments on Subparts B, C, D, F, M, P

Dear Sir or Madam:

The Alzheimer's Association appreciates the opportunity to comment on the proposed regulations for the Medicare Prescription Drug Benefit of the Medicare Prescription, Drug, Improvement and Modernization Act of 2003 (MMA), published in the Federal Register on August 3, 2004. The Alzheimer's Association is the premier source of information and support for the 4.5 million Americans with Alzheimer's disease. Through its national network of chapters, it offers a broad range of programs and services for people with the disease, their families, and caregivers and represents their interests on Alzheimer-related issues before federal, state, and local government and with health and long term care providers. The largest private funder of Alzheimer research, the Association has committed nearly $150 million toward research into the causes, treatment, prevention, and cure of Alzheimer's disease.

General Comment

The Alzheimer's Association supported the MMA because it will provide significant relief to 4.5 million Americans who have Alzheimer's disease. For the first time, Medicare beneficiaries will receive coverage for outpatient prescription drugs. The breadth of the proposed regulations published on August 3, 2004, are evidence of the daunting challenge that faces the Centers for Medicare and Medicaid Services (CMS) to implement this law in accordance with the intent of Congress.

Our comments and concerns reflect our objective to ensure access to medications that treat Alzheimer's beneficiaries. Access to effective medical treatment must be paramount to CMS during the revision process. We encourage CMS to consider the impact of these regulations on the most vulnerable Medicare beneficiaries, including the chronically ill, the dual eligibles and the residents in nursing facilities.

Specific Comments

We have the following comments with regard to the proposed regulations that are of specific concern to the Alzheimer's Association, as they will significantly impact beneficiaries with Alzheimer's disease or other dementias.

Subpart B: Eligibility and Enrollment

Part D Enrollment Process (§423.34): In order to ease the transition of dual eligibles to Medicare Part D, CMS should seek authority to extend Medicaid prescription drug coverage for six months, and in addition, require plans to maintain an open formulary for a set period of time.

On January 1, 2006, more than 6.4 million dual eligible individuals will lose their Medicaid drug benefit and transfer their drug coverage to Medicare Part D. As provided in the proposed regulation, dual eligibles who do not enroll in a plan will be automatically enrolled in a low income plan on May 15, more than five months after the termination of their Medicaid drug coverage. Therefore, these individuals must be enrolled in a Medicare Part D plan prior to the end of 2005. CMS plans to permit dual eligible individuals to choose a Prescription Drug Plan (PDP) or Medicare Advantage (MA) plan within their region beginning on November 15, 2005. Individuals who do not choose a plan voluntarily will be automatically enrolled through random assignment to a plan in their region. Dual eligible individuals will only be able to enroll in plans that are at or below the benchmark cost within their region. Thus, all dual eligibles, the sickest and poorest Medicare beneficiaries, will be enrolled in only the lowest-cost plan(s) in the region.

If CMS begins auto-enrollment prior to December 31, as is necessary, the auto-enrollment would occur in early December, providing only a two-week window for dual eligibles to evaluate and enroll in a specific plan before being randomly assigned. Choosing from among multiple PDPs will be a complicated decision for these individuals. Critical factors to be evaluated include:

- Whether the individual's pharmacy is included in the PDP network
- Whether the individual's medications are covered by the PDP formulary
- Whether prior authorization or other restrictions apply to any of the formulary medications taken by the individual

In regions where more than one plan is available to duals, the complexity of evaluating all the critical factors and selecting a plan will likely mean that few individuals will choose a plan during the brief time permitted. This is especially true for the dual eligible population, which has a high prevalence of Alzheimer's disease, mental illness, chronic conditions and other barriers to decision-making. Those individuals will be randomly assigned to an available plan.

The likely result of random assignment is that many individuals will no longer be able to get prescriptions filled at their customary pharmacy, forcing them to seek assistance in locating a participating pharmacy near their home. They are also likely to discover that one or more of their medications will no longer be covered by their drug program, as it was under Medicaid. Individuals will be forced to contact their physicians to obtain a

prescription for a different medication, or seek assistance in applying for permission to continue their current medication.

When this scenario is multiplied by millions of individuals, it is clear that physicians will be overwhelmed by millions of requests for assistance with medication changes or appeals to continue existing medications. If all of these changes are expected to occur in the space of a few weeks, as currently proposed by CMS, then the expectation is unrealistic.

The Alzheimer's Association is particularly concerned about the automatic enrollment of dual eligible individuals who reside in nursing facilities. Most, if not all, nursing facility residents require multiple medications. On January 1, 2006, their medications may need to be changed to comply with the plan formulary.

In addition, if the pharmacy serving the long-term care facility is enrolled in only one of the available PDPs, all of the dual eligible individuals in that facility should be enrolled in the plan for which the long-term care pharmacy is included in that network. It would not make sense to auto-enroll dual eligibles into plans for which the long-term care pharmacy is not included in the network

We recommend that the transition of dual eligible individuals from Medicaid to Medicare Part D be substantially lengthened for at least six months. In addition, CMS should require that PDPs and MA-PDs offer an open formulary for all dual eligible individuals for a minimum of six months, through June 30, 2006, to ensure adequate time for physicians and patients to navigate administrative barriers and change medications to comply with formularies. This will permit dual eligible individuals to continue their existing medications while adequate time is permitted for a transition to the new drug benefit.

Special Enrollment Periods (§423.36(c)): CMS should allow a special enrollment period when a beneficiary moves into a nursing facility.

Under the drug discount card program, a move to a nursing home is considered a change in residence allowing the enrollee to choose a new discount card plan with no penalty. The proposed regulation does not specifically address this issue. We are concerned that without a comparable special enrollment period for the Part D benefit, there would be considerable delay (until the next open enrollment period) in allowing the beneficiary to change to a PDP plan for which the long-term care pharmacy serving that nursing facility is "in-network." In turn, this would cause the beneficiary (or CMS, in the case of full benefit dual eligibles) to incur a higher cost for the purchase of drugs from an out-of-network pharmacy.

A special enrollment period comparable to the discount card program would increase choices for Medicare beneficiaries seeking the best plan for their needs, and allow the beneficiary (or CMS, in the case of full benefit dual eligibles,) to avoid additional costs until the next open enrollment period. Therefore, we recommend that admission into a nursing facility should qualify as a beneficiary for special enrollment into a different PDP plan.

Disenrollment by the PDP (§423.44(d)(2)): CMS should eliminate the provisions allowing for involuntary disenrollment of beneficiaries for "disruptive or threatening" behavior.

The proposed rule would permit plans to involuntarily disenroll beneficiaries due to disruptive, unruly, abusive, uncooperative or threatening behavior. The Alzheimer's Association strongly believes that this provision could result in the inappropriate disenrollment of beneficiaries with Alzheimer's disease or other dementias. This is of particular concern given the prevalence of neuropsychiatric symptoms in Alzheimer's individuals. In a recent study, *Prevalence of Neuropsychiatric Symptoms in Dementia and Mild Cognitive Impairment; Results form the Cardiovascular Study*, JAMA, September 25, 2002-Vol 288, No. 12, 1475, researchers found a high prevalence (60-80%) of neuropsychiatric symptoms in participants with dementia. These symptoms include agitation, depression, apathy, anxiety, delusions, hallucinations, paranoia and sleep impairment and have serious adverse consequences on the patients. Appropriate treatment of these symptoms provides substantial benefits to these individuals, such as the improvement of function and the reduction of disruptive behavior. However, if an Alzheimer's beneficiary is not stable, possibly because the unsuccessful attempts to find the proper medication for the individual or due to a plan's "step therapy" requirement, there may be incidents that are perceived as "disruptive" behavior.

Alzheimer's disease is not a "one size fits all" condition. Each individual has different manifestations of particular symptoms. Providing symptom relief for an individual requires an understanding of the specific symptoms of the individual and creativity in devising the treatment plan. Treatment must be dynamic and flexible. Treatment plans are often developed by trial and error to acquire the correct combination of medications. Some medications take several weeks to show any therapeutic impact.

Although we acknowledge CMS' desire to have parallel provisions for the PDPs and the MA-PDPs, it is difficult to understand when the disenrollment of a beneficiary for disruptive behavior in a PDP would ever be appropriate. A beneficiary should never have in-person contact with PDP employees. Should there be a problematic encounter with pharmacy personnel, then the pharmacy could take appropriate protective measures as the situation warrants.

Should plans be allowed to disenroll beneficiaries for disruptive behaviors, these provisions will create severe hardships and barriers to access to all medications. Those who are disenrolled will 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 some Alzheimer's beneficiaries, especially those who are also on Medicaid, they will be forced to forgo medications that may stabilize them because they cannot afford to pay out of pocket for them. In addition, as noted in the preamble, if a beneficiary is disenrolled from the sole PDP in the region, the beneficiary will be denied any access to the Medicare drug benefit. Plans must be required to re-enroll a beneficiary who has been disenrolled if there is no other drug plan in the area. Unlike the Medicare Advantage program, there is no alternative program, such as Original Medicare, to provide coverage to the individual. Disenrolled beneficiaries should be provided a special enrollment period during which time they can enroll in an alternative plan or re-enroll in the plan if there is only one PDP in the area.

Congress intended for all Medicare beneficiaries to have access to the drug benefit. If CMS decides to maintain this troubling disenrollment provision in the final regulations, CMS must require plans to develop mechanisms for accommodating the special needs of these individuals, and ensure that this vulnerable population does not lose access to drug coverage.

Late Enrollment Penalty (§423.46): CMS should allow an initial grace period and provide for appeals before imposition of the late enrollment penalty.

Implementation of the late enrollment penalties should be delayed for one year while beneficiaries are informed about this complex, new program. We believe that individuals most at risk of not applying for the Part D benefit are the most vulnerable beneficiaries, such as those with Alzheimer's disease. Community studies indicate that 20 to 25% of people with dementia live alone.[1] About half of these people have a relative or friend who functions as a caregiver, and the other half have no one to assist them. It is doubtful that they will have the ability to understand and navigate the application process without assistance and to impose the significant penalty of an additional 1% for each month of late enrollment would be inequitable.

In addition, CMS should incorporate an enrollment "grace period" for individuals with disabilities, including Alzheimer's disease. In the preamble, CMS explains the rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to beneficiaries with Alzheimer's disease, and these beneficiaries might well require additional time to make a selection and complete the enrollment process. Therefore, CMS should incorporate a late enrollment "grace period" for the disabled, vulnerable population.

Approval of Marketing Materials and Enrollment Forms (§423.50): CMS should require that marketing materials, notices relating to formulary changes and all other communications to plan enrollees regarding plan benefits and formularies be written in accordance with the principles of clear health communications so that beneficiaries, their families and their caregivers have the ability to obtain, process and understand available health information.

Literacy skills are a stronger predictor of an individual's health status than age, income, employment status, education level, race or ethnicity. When health literacy (that is, the ability to read, understand and effectively use basic medical instructions and information) is low, individuals are less likely to comply with prescribed treatments and self-care regimens and often fail to seek preventive care. These individuals are at higher risk for hospitalization, they remain in the hospital longer, and they generally require additional care that results in higher annual health care costs.[2]

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[1] Prescop KL, Dodge HH, Morycz RK, et al. Elders with dementia living in the community with and without caregivers: an epidemiological study. *International Psychogeriatrics*. 1999;11:235-250.
Webber PA, Fox P, and Burnette D. Living alone with Alzheimer's disease: Effects on health and social service utilization patterns. *The Gerontologist*. 1994;34:8-14.

[2] Partnership for Clear Health Communication, Partnership for Clear Health Communication Fact Sheet, available at http://www.askme3.org/pdfs/partnership_fact_sheet.pdf.

To ensure that Medicare beneficiaries have the ability to obtain, process and understand instructions and information related to the Part D benefit, CMS should require that all enrollee communications be written in accordance with principles of clear health communications. Specifically, all documents should be appropriate for Medicare beneficiaries and family members with low health literacy. In addition, for beneficiaries who are cognitively impaired, it is imperative that their caregivers or personal representatives also receive copies of all pertinent notices and information.

CMS should prohibit plans sponsors from marketing other services to Medicare beneficiaries.

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.

Allowing plans to offer additional service would blur the line between a government program and private services. It would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved card." For beneficiaries who are cognitively impaired, there is the additional potential of financial abuse or exploitation. This section specifically prohibits marketing activities that could "mislead or confuse." Permitting plan sponsors to market additional services will create situations that confuse and mislead beneficiaries and should be forbidden.

Subpart C: Benefits and Beneficiary Protections

Access to Covered Part D Drugs (§423.120, §423.124): We urge CMS to explore administrative or legislative remedies to ensure coverage of benzodiazepines in 2006.

The Alzheimer's Association is extremely concerned that benzodiazepines are specifically excluded from coverage by statute as passed by Congress. This exclusion will result in a loss of coverage for dual eligibles since benzodiazepines are currently covered by nearly every state. Benzodiazepines are a group of medications commonly prescribed to Alzheimer's beneficiaries for the treatment of insomnia and anxiety. It is estimated that benzodiazepines are prescribed to 1 in 5 Medicare recipients and approximately 10% of nursing home residents.

Without benzodiazepines, acute anxiety and agitation will have to be managed with alternative medications that are either more toxic, more expensive, or both. For example, Meprobamate is an old antianxiety agent that is highly addictive and sedating. It is on the "Beers list" of medications considered to be generally inappropriate for use in the elderly. Antipsychotic medications can be used but can produce significantly more long term side effects, many of which are irreversible. The atypical antipsychotics are also much more expensive than generic benzodiazepine medications.

An estimated one million dual eligible individuals take benzodiazepines. When coverage of benzodiazepines is terminated on January 1, 2006, the likely result will be a flooding of

emergency rooms and thousands of hospitalizations resulting from withdrawal symptoms of benzodiazepine cessation, and exacerbations of acute anxiety. We fear that among those most adversely affected by this exclusion will be beneficiaries with Alzheimer's disease.

Balancing convenient access with appropriate payment for long-term care pharmacies.

In the preamble, CMS requested comments on how to balance the need for convenient access to LTC pharmacies with appropriate payment to them. Government figures from the required Minimum Data Set (MDS) assessment show that in 2001, 46% of nursing home residents had moderate to severe cognitive impairment, and 26% had mild cognitive impairment.[3] Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. The Alzheimer's Association believes plan enrollees residing in LTC facilities should have access to the in-network pharmacy in the facility where they reside or should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy. 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 prescription drug plans to contract with all LTC pharmacies;

- Alternatively, the final rule could require prescription drug plans to make available a standard contract to all LTC pharmacies, and 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.

Formulary Requirements (§423.120): CMS should ensure that the full range of prescription drugs commonly used in clinical practice for treating chronically ill and disabled populations is available to all Medicare beneficiaries.

Although the MMA directed CMS to request that the U.S. Pharmacopeia (USP) develop a list of categories and classes of drugs that may be used by plans, CMS retains significant discretion under the statute with respect to formulary development. The new Medicare Part D benefit should provide a comprehensive range of medications to

[3] Centers for Medicare and Medicaid Services (CMS), unpublished data provided by CMS, Feb. 4, 2003.

Medicare beneficiaries. The scope of prescription drugs covered under plan formularies will dramatically affect beneficiary access to care. As a result, the Alzheimer's Association urges CMS to use its authority and work aggressively to ensure that the full spectrum of necessary medications is available.

The final Medicare Model Guidelines should reflect a broad range of categories and classes to ensure that Medicare beneficiaries, especially the chronically ill and disabled, have sufficient access to critical prescription drug therapies. In some instances, the USP's draft Model Medicare Guidelines are too narrow to encompass drugs needed by Medicare beneficiaries and could create barriers to access. Therefore, we urge CMS and USP to expand the list of categories and classes to prevent impediments to beneficiary access caused by overly restrictive formularies. At a minimum, the Alzheimer's Association believes that the USP's final Medicare Model Guidelines should have as many categories and classes as Medicare's Prescription Drug Discount Card and the VA health system.

In addition, the MMA requires that the Medicare Model Guidelines be revised "from time to time" to reflect the changes in therapeutic uses of Part D drugs and to cover new FDA-approved drugs. There is nothing in the draft Medicare Model Guidelines that reflect a plan that provides for this review procedure. Given the recent increase in research and development of drugs for Alzheimer's disease that would benefit the Medicare population, this process should be expedited and require automatic inclusion of these drugs within 30 days of FDA approval. We are including a copy of our specific comments to USP for your consideration.

The Alzheimer's Association urges CMS to revise its proposal to require coverage of more than two drugs for each formulary category or class. This provision is much too restrictive and will cause a problem for many beneficiaries, as well as their physicians. In many instances, especially among the chronically ill and disabled Medicare populations, two drugs per category or class will not provide sufficient access to prescription drug therapies. The drug-to-drug interactions and adverse drug reactions make prescribing a challenging task and sometimes physicians need to shift among several drugs in a class to find the one that works best for the specific patient. For example, the inclusion of the three FDA approved cholinesterase inhibitors should be considered. Research confirms that patient's responses to the individual agents vary widely. Therefore, clinicians require access to the full selection of these drugs in order to prescribe the best agent for the particular patient. Forcing a change in medications could cause adverse health outcomes among this vulnerable population.

CMS should revise its requirements relating to P&T committee procedures.

CMS should institute procedural requirements for P&T committees to ensure access to medically necessary medications. These requirements should include the following:

- CMS should ensure that evidence-based clinical guidelines weigh heavily in any P&T committee decision relating to formulary coverage or classification. The Alzheimer's Association, as well as several provider associations, has developed evidence-based guidelines which are an importance reference for many clinicians.

- CMS should require that P&T committees engage in a timely review of every newly approved drug or biologic and every newly approved therapeutic use of an approved drug or biologic within 30 days of FDA approval. While the P&T committee undertakes this review, enrollees should have access to the new drug or biologic (or new therapeutic use) through a plan sponsor's exception request process.

- The Alzheimer's Association recommends that patient and physician organizations as well as other stakeholders be provided an opportunity to offer timely and meaningful comments to the P&T committees as part of the review of new drugs and biologics and therapeutic uses. We comment frequently on draft Local Coverage Determinations

  proposed by Medicare carriers and intermediaries. We believe our concerns are often considered and reflected in the final coverage policies.

- We recommend that plans provide public notice of all P&T committee meetings. Such public notice could include listing the meeting on the plan's website, sending notice electronically to plan members via a list serve, and/or in writing. The P&T committee meetings should be open to the public to ensure transparency in P&T committee determinations related to formulary coverage and classification decisions.

Without implementation of these procedural safeguards, beneficiaries may encounter barriers, such as potentially long and unnecessary delays that hinder their access to medication therapies.

CMS should create standards for off-label use of prescription drugs as well as combination therapies.

CMS states in the proposed rule that physicians and other health care professionals may prescribe drugs for off-label indications, although CMS strongly encourages physicians to clearly document and justify the off-label use in patients' clinical records. Plan sponsors also may assign an FDA-approved drug to a category or class based on an off-label use so long as the FDA has not determined that such use is unsafe. The Alzheimer's Association does not believe that the language in the proposed rule is sufficient to protect beneficiaries' access to appropriate off-label use of medications. Atypical antipsychotics are FDA-approved for the treatment of schizophrenia. In the late stages of Alzheimer's disease, behavioral problems are significant issues for patients, families and other caregivers. The treatment of hallucinations, psychosis, and paranoia are off-label uses of these drugs. They work well, are used in over 25% of nursing home patients and have a permanent place in the successful treatment of late stage disease.

The Alzheimer's Association strongly recommends that CMS preserve the flexibility for drugs to be prescribed for "off-label" uses. CMS should ensure that the USP's Medicare Model Guidelines are constructed to include sufficient categories and classes of drugs that will include the drugs most often used for their off-label uses. In addition, coverage for off-label uses of formulary drugs, including cost-sharing requirements equivalent to the formulary's most favorable terms, should be provided regardless of whether the drug is classified under the formulary for treating the enrollee's specific condition.

CMS should recognize beneficiaries with Alzheimer's disease as a vulnerable population for purposes of the Part D benefit. Additional protections and restrictions on plan sponsors should be incorporated to protect this vulnerable patient population.

We are concerned that the cost containment strategies employed by some of the plans may encourage the use of older or less effective drugs that often result in increased side effects and adverse reactions in older, frailer beneficiaries, such as those with Alzheimer's disease. With impaired memory and judgment, individuals with Alzheimer's disease may not be able to recognize, understand or report early signs of adverse reactions until it results in an acute episode.

Due to the increased age, lower metabolism and co-existing conditions of this population, physicians require a wider range and greater flexibility of therapeutic agents when treating their patients. Ninety-five percent of Medicare beneficiaries with dementia have one or more other chronic conditions, including congestive heart failure (28%), diabetes (21%), chronic obstructive pulmonary disease (17%) and coronary heart disease (30%). As previously noted, 60-80% of Alzheimer's individuals suffer from neuropsychiatric symptoms including agitation, depression, apathy, anxiety, delusions, hallucinations, paranoia and sleep impairment.[4] These patients are taking a combination of medications to appropriately manage these conditions. It is a delicate balance that requires access to specific medications to enhance the care to the beneficiaries.

In the proposed rule, CMS expressed concern regarding the potential impact of plans' cost-saving strategies on vulnerable populations. For example, CMS highlighted that Medicare beneficiaries enrolled in long-term care facilities tend to be more sensitive to and less tolerant of many medications. This dynamic has resulted in many long-term care facilities permitting physicians to prescribe a wide variety of medications in different dosages and forms. CMS suggested that these institutionalized patients could suffer as a result of formulary restrictions or cost-sharing requirements that hinder access to necessary medications.

The Alzheimer's Association shares CMS' concern for vulnerable patient populations and urges CMS to recognize patients with Alzheimer's disease as a vulnerable population for purposes of the Part D benefit. Many formulary restrictions and cost-sharing requirements could have significant and disproportionate adverse impacts on patients Alzheimer's disease.

Given the high prevalence of neuropsychiatric symptoms and co-existing conditions, these beneficiaries often rely heavily on multiple medications to treat their conditions and are likely to be more sensitive to and less tolerant of many medications. To ensure appropriate access to necessary prescription drugs, CMS should provide meaningful beneficiary safeguards for vulnerable populations, including those with Alzheimer's disease.

[4] See comments to Subpart B for a more thorough discussion of the prevalence of neuropschiatric symptoms in people with dementia.

CMS must enhance the notification requirements for enrollees directly affected by a formulary change.

The proposed rule requires that plan sponsors provide only 30 days notice of an intended formulary change, such as removal of a drug or a change in the drug's preferred or tiered cost-sharing status. The Alzheimer's Association believes that 30 days does not provide beneficiaries and their providers sufficient time to respond to a formulary change. We are particularly concerned about the most frail and vulnerable individuals, which includes those who have the greatest difficulty with drug compliance, both intentional and unintentional. These individuals, their visiting nurses, case managers and families, need as much lead time as possible for smooth transitions in therapy to avoid drug misadventures resulting in hospitalizations or other adverse events. Accordingly, we strongly recommend that CMS require plan sponsors to provide enrollees with at least 90 days written notice of a formulary change, which should include information about the exceptions and appeals process. The 90-day time period would permit beneficiaries to consult with their

physicians regarding alternative medication therapies or request an exception to the coverage determination. In addition, CMS should include a provision to require plans to allow vulnerable enrollees to continue the course of the "removed" medication regimen (grandfather) if the enrollee has been stabilized on it.

CMS should impose limitations on mid-year formulary changes.

The Alzheimer's Association recommends that the final rule place strict limitations 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 or when all manufacturers discontinue supplying a particular covered Part D drug in the United States.

As previously noted in our comments to Subpart B, many Alzheimer's beneficiaries have had trials and errors on multiple medications and have achieved therapeutic benefits on a medication that may then be removed from the formulary. At the minimum, CMS must assure that the exceptions and appeals procedures and beneficiary protections are sufficiently strong to assure that the beneficiaries, who have worked hard with their physicians to find the correct therapeutic combination, can be maintained on those medications.

Should the final regulation fail to effect such a restriction, we strongly recommend that plans 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. In addition, CMS should restrict the frequency of mid-year formulary changes to once during the contract year.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drub Benefit Plans

Medication Therapy Management Programs (§423.153(d)): CMS should require a wide range of services and stress quality outcomes of patents overall health.

The Alzheimer's Association believes that the medication therapy management programs (MTMP) could provide a special opportunity to enhance health outcomes and reduce adverse effects for chronically ill beneficiaries, such as those with Alzheimer's disease.
A characteristic feature of Medication Therapy Management (MTM) services is a focus on the total patient. Whereas some drug utilization programs focus on use of a particular drug or on a single disease, MTM services should focus on all the drugs and diseases related to a specific patient. This comprehensive approach is the best strategy to optimize therapeutic outcomes in the frail elderly population, which is characterized by multiple chronic conditions, high use of medications, and high drug costs.

We believe that individuals with Alzheimer's disease should be identified as "targeted beneficiaries" who should be eligible to receive these services. As previously noted, of all Medicare beneficiaries with Alzheimer's disease and dementia:

- 29% also have coronary heart disease;
- 23% also had diabetes;
- 28% also had congestive heart failure, and
- 17% had chronic obstructive pulmonary disease.

This vulnerable population takes many medications, some of which may result in adverse drug reaction or drug interaction. They have higher use of Medicare hospital and physician services, higher Medicare costs for hospital, skilled nursing facility services and home health services, and higher total Medicare costs compared with all other Medicare beneficiaries.

The type and intensity of MTM services provided to an individual beneficiary should be determined by the needs of that individual. We support the CMS approach of ensuring that PDPs offer a range of MTM services to assure that needs of diverse Medicare beneficiaries are met. As noted by CMS, "One beneficiary may require only a fifteen-minute phone consultation, while another would be better served by a one-hour in-person visit with the pharmacist." CMS should require that PDPs provide a wide range of MTM services, rather than limiting these services to exclusively telephone provision, for example. A telephone consultation will not work with a person with cognitive impairments. In addition, it would be imperative to include the individual's caregiver as a participant to any MTM services for an Alzheimer's enrollee.

We urge that the financial incentives in MTMPs encourage quality outcomes and not solely reduced costs. Payment for reducing costs without regard to quality could impede access to certain drugs. The preamble says that CMS "may provide a mechanism for plans to demonstrate" the value of their MTMPs to the public. We urge CMS to develop such a mechanism to ensure quality outcomes. Given that PDPs are not financially

responsible for poor health outcomes of Original Medicare beneficiaries, we are concerned that they may not have sufficient incentives to devote significant resources and attention to developing MTMPs that would improve overall health.

Subpart F: Submission of Bids and Monthly Beneficiary Premiums: Plan Approval

Nondiscrimination provision (§423.272): CMS must ensure that the design of all plans and their respective benefits (including any formulary and tiered-formulary structure) do not discourage enrollment of people with chronic diseases and/or disabilities.

The MMA's nondiscrimination clause prohibits plans from substantially discouraging enrollment by high-risk Part D eligible enrollees. The statute gives CMS the authority to utilize significant tools to protect beneficiaries from inappropriate use of case management tools. Although we applaud the regulatory provision that provides that a plan would not be approved if its design were likely to substantially discourage enrollment, it is merely a recital of the law. The preamble language interprets discriminatory to mean discouraging enrollment "on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability and disability." The preamble goes on to say that CMS would review plans for features that have "differential impacts for beneficiaries with particular medical conditions." This preamble language should be included in the final regulations and strictly enforced by CMS.

In 1999, after an extensive analysis of carrier and intermediary local medical review policies, the Alzheimer's Association presented then-HCFA with evidence that its contractors were systematically discriminating against Medicare beneficiaries with Alzheimer's disease. These beneficiaries were automatically denied payment of claims for medically necessary services solely because of their Alzheimer's diagnosis. CMS issued several Program Memorandums and Transmittals to prohibit these barriers to payment of claims. But for the research, analysis and advocacy of the Alzheimer's Association, and ultimately cooperation by CMS, these discriminatory practices would still be operational. CMS must be vigorous in its review and monitoring of all plans for anti-discrimination behavior that may impact beneficiaries' access to prescription drugs.

The statute also provides that plans implementing formularies modeled after the USP's Medicare Model Guidelines cannot be determined on the basis of their therapeutic categories and classes alone to violate this statutory provision. As stated in the proposed rule, plans that adopt the Medicare Model Guidelines may still be found to discriminate against groups of Medicare beneficiaries based on factors other than their formulary structure. For example, a plan that covers only certain drugs or assigns select drugs to a particular tier in the cost-sharing structure, thereby imposing higher cost-sharing requirements on the beneficiary, may be found to discourage enrollment by individuals requiring those medications. Similarly, a cost-sharing tier will have a different impact if the beneficiary pays 50% of the cost of the drug if the prescription costs $10 or $200. Other case management tools, such as prior authorizations and step therapy, must also be reviewed for discriminatory impact. Again, there is some important language and examples provided in the preamble and the issue paper that were not included in the proposed regulations. We strongly encourage the preamble language, as well as other strong nondiscrimination provisions, to be incorporated into the final regulation.

Enforcement of the nondiscrimination standard will be a significant but important challenge for CMS. CMS must develop a timely process to review and monitor all plans for anti-discrimination behavior that may impact beneficiaries' access to prescription drugs. In addition, CMS must devote adequate staff and financial resources to ensure that the nondiscrimination provision of the law is enforced.

Subpart M: Grievances, Coverage Determinations and Appeals

CMS proposed regulations in this area are highly complicated and fail to provide needed protections for Medicare beneficiaries.

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.

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 timeframes, the paperwork, and the processes should be simplified into one course of action that beneficiaries may hope to understand.

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 time frames 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.

Exceptions Process (§423.578): CMS should ensure that there is sufficient consistency in the exceptions processes among all plans in a given region so that providers can assist beneficiaries in an efficient and effective manner.

The proposed rule requires that plan sponsors establish and maintain a process through which enrollees (including their authorized representative or their physician) can seek exceptions to the application of a plan's tiered cost-sharing structure as well as exceptions to a plan sponsor's decision not to include a drug in its formulary. Although the proposed rule provides some guidelines for plan sponsors to follow when establishing exceptions processes, plan sponsors nonetheless retain significant discretion to develop their own procedures for determining coverage of non-formulary drugs.

The potential variation in plans' exceptions processes could create substantial challenges for Medicare providers who seek to assist beneficiaries in requesting exceptions across a number of plans. To ensure that beneficiaries and their providers can access necessary prescription drugs through the exceptions process, we strongly recommend that CMS develop a standardized, quick process to minimize the burden on providers and patients.

CMS should not allow plans to require an enrollee to try the preferred drug and suffer adverse consequences when there has been a change in the sponsor's formulary

The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug would not be as effective or cause adverse effects. The statute does not support allowing 'fail first.' For many enrollees, a fail first requirement *per se* would cause adverse effects. Such requirements would be dangerous for the medically vulnerable populations of frail elderly, dual eligible, and long-term care individuals.

CMS should require plans 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

We are deeply concerned that the timeframes for exceptions determinations are far too long. 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.

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.

CMS should adopt its proposal that enrollees be permitted to obtain refills of medications at the same cost-sharing level without requesting additional approvals once a plan extends an initial approval.

Under the proposed rule, a plan sponsor must continue to cover a drug approved under an exception request, including refills, so long as the drug continues to be prescribed for the enrollee and is considered safe for treating the enrollee's condition. Plan sponsors also are prohibited from imposing a special formulary tier, co-payment or other cost-sharing requirement that applies only to drugs that have been approved under the exceptions process.

The Alzheimer's Association strongly supports these requirements and urges CMS to adopt them in the final regulations. Such requirements would ensure that beneficiaries

for whom certain drugs have been determined to be necessary will have uninterrupted access to these important medication therapies.

Subpart P: Premiums and Cost Sharing for Low-Income Individuals

Definition of Personal Representatives (§423.772): CMS should clarify who is permitted to act as an individual's personal representative.

The Alzheimer's Association supports the definition of personal representative which will broaden the range of individuals who can act in that capacity. Many individuals with Alzheimer's disease rely on family, friends, neighbors and others to assist with a variety of tasks, including handling health insurance matters. We would recommend a revision to be incorporated into the definition to prohibit any employee of a plan or plan sponsor from acting as the personal representative, unless the employee is a family member. This would alleviate concerns about a conflict of interest of the personal representative.

Definition of Institutionalized Individual (§423.772): CMS should include nursing home eligible beneficiaries who are receiving waiver services in the definition of institutionalized individual for purposes of cost-sharing subsidies.

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.

Many states have increased the use of home and community based waiver programs (e.g. 1915c) to allow nursing home eligible individuals to remain in the community or in alternative settings, such as assisted living or board and care homes. Many individuals with Alzheimer's disease opt to participate in home and community based services waiver program rather than reside in a nursing facility. Under proposed regulation §423.782(2)(ii), "institutionalized individuals" are exempt from prescription drug cost-sharing for covered Part D drugs. If states use waiver programs to encourage nursing home eligible individuals to remain in the community, the beneficiaries would be required to pay the co-payments. Including these individuals in the definition of institutionalized individuals removes the perverse financial incentive to admit these individuals into nursing homes.

It should be noted that low-income nursing home eligible Medicare beneficiaries who live in alternative settings, such as assisted living, often are provided with only a minimal cash allowance (e.g. $20 per month) to pay for haircuts and incidentals. For these individuals, prescription drug co-payments could serve as a significant deterrent to living in these alternative settings, forcing them into the more expensive nursing home facility.

Conclusion

The Alzheimer's Association appreciates the enormous effort of CMS to implement these provisions of the Medicare Modernization Act. We recognize the challenges that this entails, including the difficulty of balancing the interests of the various stakeholders

with the need for protection of vulnerable Medicare beneficiaries. We hope that our comments will assist CMS in achieving the proper balance. Given the breadth of these regulations, the numerous agency requests for comments on substantive issues and the importance of these regulations to implementation of the Part D program, we urge CMS to provide another second comment period before promulgation of final regulations.

We appreciate the opportunity to comment on these proposed regulations. Over the years, we have had successful collaborations with CMS to ensure that the needs of individuals with Alzheimer's disease are met. The Alzheimer's Association is ready to work with you, and to assist in identifying appropriate clinical experts, to assure access to medically necessary drugs for beneficiaries with dementia. Please feel free to contact Leslie B. Fried, Director of the Association's Medicare Advocacy Project, (202) 662-8684, to further discuss these matters.

Sincerely,

Bonnie Hogue Duffy
Director
Federal Policy

Leslie B. Fried
Director
Medicare Advocacy Project

CMS-4068-P-1064

Submitter : John Folkemer **Date & Time:** 10/04/2004 06:10:23

Organization : Maryland Dept. of Health and Mental Hygiene

Category : State Government

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

?423.458(d) of the proposed rule establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. Because many of the Part D requirements duplicate, conflict with, or inhibit coordination of existing PACE requirements, CMS anticipates a significant number of waivers would be necessary for PACE organizations. CMS expressed concern about the potential burden this would place on PACE organizations and proposed to include a provision that would allow for CMS to identify all Part D provisions requiring waivers and waive these provisions on behalf of PACE organizations. In other words, CMS is considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule (see discussion in Subpart T of the preamble) without a plan-specific application process. Maryland supports the automatic waiver of these requirements for PACE and other similar health plans such as social health maintenance organizations that also serve significant numbers of full-benefit dual-eligible individuals.

ELIGIBILITY, ELECTION, AND ENROLLMENT

?1860D-1(b)(1) of the Act requires the establishment of a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and
change of enrollment rule for Medicare Advantage prescription drug plans under certain provisions of ?1851 of the Act. In accordance with ?1860D-1(b)(1)(C) of the Act, CMS is seeking to establish a process to automatically enroll a full-benefit dual-eligible individual (as defined under ?1935(c)(6) of the Act) who has failed to enroll in a prescription drug plan or Medicare Advantage prescription drug plan by either the end of the individual?s initial enrollment period or upon becoming dual-eligible after his/her initial enrollment period. For full-benefit dual-eligibles, this timeframe runs from November 15, 2005 to May 15, 2006. Maryland believes that the auto-enrollment process, for those who do not select a plan during their designated enrollment period, may present difficulties.

In implementing the automatic enrollment process for full-benefit dual-eligible individuals, CMS is 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. As written, it could be interpreted that a full-benefit dual-eligible individual who does not actively enroll in a plan will only be automatically enrolled after May 15, 2006. In this case, dual-eligibles who have not enrolled prior to January 1, 2006 would not receive Part D coverage until they are either automatically enrolled in May or they actively enroll in a plan. Not only will full-benefit dual-eligibles not qualify for Part D benefits if not enrolled, but federal matching funds would no longer be available to State Medicaid agencies as of January 1, 2006. In essence, the States will be paying 100 percent of the cost for these dual- eligibles during this six-month time-period, or alternatively, these individuals may face a gap in pharmacy coverage.

In addition, the auto-assignment provision ?1860D-1(b)(1)(c) includes the use of the term ?random? for the enrollment of full-benefit dual-eligibles. Maryland feels that this process must include a detailed algorithm for auto-assignment. This may be a more significant issue in service areas that include existing PACE plans and special needs plans that could include full-benefit dual-eligibles.

CMS provides under ?423.44(d) of the proposed rule that prescription drug plans may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. According to the rule, an individual who is disenrolled for failure to pay monthly prescription drug plan premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided a Special Enrollment Period permitting him or her to enroll in another prescription drug plan. Maryland believes that this approach should be reassessed given the unique aspects of dual-eligible individuals. Because Medicaid will no longer be able to receive federal financial participation for paying for prescription drugs, dual-eligible beneficiaries who are involuntarily disenrolled would face a significant hardship. In addition, many members of this population have mental illness or financial limitations that could make them more likely to face involuntary disenrollments than the Medicare Part D population at large. Maryland recommends that CMS develop a higher threshold for involuntary disenrollment for this vulnerable population.

Issues 11-20

SPECIAL RULES FOR STATES

Under the Proposed Rule, states would provide a State phased-down monthly contribution to Medicare Part D drug benefit costs. This amount is based on drug expenditures on covered Part D drugs during calendar year 2003. This baseline amount will then be adjusted by a growth factor. During fiscal years 2004-2006, the growth factor, under the proposed rule, would be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure projections). For 2007 and beyond, the factor would equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs for Part D-eligible individuals for the 12-month period ending in July of the previous year.

We believe that this methodology is flawed because it assumes a uniform cost of drugs nationwide. Drug pricing varies widely even among small geographic regions, making it very likely that pricing would also vary across State lines. Thus the use of national data could cause disproportionately higher drug expenditures for many States. Accordingly, we suggest that the formula be modified to include State-specific data which would represent a more equitable approach to estimating drug expenditures and the total amounts due the federal government each month.

In addition, Maryland has concerns about the inclusion of its State pharmacy assistance program as part of the calculation of the phased-down monthly contribution. While the State does not object to including Medicare beneficiaries who are enrolled in the Maryland Pharmacy Assistance Program in the formula used to establish the baseline cost per-person, it would be totally inappropriate to count them as part of the future Medicaid enrolled population that is multiplied by the trended per-person cost as part of the formula.

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CMS-4068-P-1064-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

Re: Notice of Proposed Rule-Making With Comment Period for Medicare Prescription Drug Benefit

Dear Dr. McClellan:

The State of Maryland respectfully submits the following comments regarding the Notice of Proposed Rule-Making for the Medicare Prescription Drug Benefit, published in the Federal Register on August 3, 2004.

Enrollment Process

§1860D-1(b)(1) of the Act requires the establishment of a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and change of enrollment rule for Medicare Advantage prescription drug plans under certain provisions of §1851 of the Act. In accordance with §1860D-1(b)(1)(C) of the Act, CMS is seeking to establish a process to automatically enroll a full-benefit dual-eligible individual (as defined under §1935(c)(6) of the Act) who has failed to enroll in a prescription drug plan or Medicare Advantage prescription drug plan by either the end of the individual's initial enrollment period or upon becoming dual-eligible after his/her initial enrollment period. For full-benefit dual-eligibles, this timeframe runs from November 15, 2005 to May 15, 2006. Maryland believes that the auto-enrollment process, for those who do not select a plan during their designated enrollment period, may present difficulties.

In implementing the automatic enrollment process for full-benefit dual-eligible individuals, CMS is 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. As written, it could be interpreted that a full-benefit dual-eligible individual who does not actively enroll in a plan will only be automatically enrolled after May 15, 2006. In this case, dual-eligibles who have not enrolled prior to January 1, 2006 would not receive Part D coverage until they are either automatically enrolled in May or they actively enroll in a plan. Not only will full-benefit dual-eligibles not qualify for Part D benefits if not enrolled, but federal matching funds would no longer be available to State Medicaid agencies as of January 1, 2006. In essence, the States will be paying 100 percent of the cost for these dual-eligibles during this six-month time-period, or alternatively, these individuals may face a gap in pharmacy coverage.

In addition, the auto-assignment provision §1860D-1(b)(1)(c) includes the use of the term "random" for the enrollment of full-benefit dual-eligibles. Maryland feels that this process must include a detailed algorithm for auto-assignment. This may be a more significant issue in service areas that include existing PACE plans and special needs plans that could include full-benefit dual-eligibles.

State Phased-Down Monthly Contribution for Medicare Part D Drug Costs

Under the Proposed Rule, states would provide a State phased-down monthly contribution to Medicare Part D drug benefit costs. This amount is based on drug expenditures on covered Part D drugs during calendar year 2003. This baseline amount will then be adjusted by a growth factor. During fiscal years 2004-2006, the growth factor, under the proposed rule, would be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure projections). For 2007 and beyond, the factor would equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs for Part D-eligible individuals for the 12-month period ending in July of the previous year.

We believe that this methodology is flawed because it assumes a uniform cost of drugs nationwide. Drug pricing varies widely even among small geographic regions, making it very likely that pricing would also vary across State lines. Thus the use of national data could cause disproportionately higher drug expenditures for many States. Accordingly, we suggest that the formula be modified to include State-specific data which would represent a more equitable approach to estimating drug expenditures and the total amounts due the federal government each month.

In addition, Maryland has concerns about the inclusion of its State pharmacy assistance program as part of the calculation of the phased-down monthly contribution. While the State does not object to including Medicare beneficiaries who are enrolled in the Maryland Pharmacy Assistance Program in the formula used to establish the baseline cost per-person, it would be totally inappropriate to count them as part of the future Medicaid enrolled population that is multiplied by the trended per-person cost as part of the formula.

Involuntary Disenrollment

CMS provides under §423.44(d) of the proposed rule that prescription drug plans may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. According to the rule, an individual who is disenrolled for failure to pay monthly prescription drug plan premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided a Special Enrollment Period permitting him or her to enroll in another prescription drug plan. Since the individual generally will not be able to enroll in either a prescription drug plan or an Medicare Advantage drug plan until the next annual coordinated election period, he or she may be subject to late enrollment penalties under §423.46 of the proposed rule. In the preamble, CMS states that if the individual is prohibited from re-enrolling in each of the Medicare Advantage plans available in an area, original Medicare is always available to provide and deliver services to that individual. Maryland believes that this approach should be reassessed given the unique aspects of dual-eligible individuals. Because Medicaid will no longer be able to receive federal financial participation for paying for prescription drugs, dual-eligible beneficiaries who are involuntarily disenrolled would face a significant hardship. In addition, many members of this population have mental illness or financial limitations that could make them more likely to face involuntary disenrollments than the Medicare Part D population at large. Maryland recommends that CMS develop a higher threshold for involuntary disenrollment for this vulnerable population.

Programs of All-Inclusive Care for the Elderly (PACE) Program Waivers

§423.458(d) of the proposed rule establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. Because many of the Part D requirements duplicate, conflict with, or inhibit coordination of existing PACE requirements, CMS anticipates a significant number of waivers would be necessary for PACE organizations. CMS expressed concern about the potential burden this would place on PACE organizations and proposed to include a provision that would allow for CMS to identify all Part D provisions requiring waivers and waive these provisions on behalf of PACE organizations. In other words, CMS is considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule (see discussion in Subpart T of the preamble) without a plan-specific application process. Maryland supports the automatic waiver of these requirements for PACE and other similar health plans such as social health maintenance organizations that also serve significant numbers of full-benefit dual-eligible individuals.

The State of Maryland greatly appreciates the opportunity to submit comments on the Proposed Rule. We welcome the opportunity to discuss our comments with you and your staff. If you have questions or need more information, please contact me at (410) 767-5806.

Respectfully submitted,

/s/

John G. Folkemer
Deputy Secretary for Health Care Financing

CMS-4068-P-1065

Submitter : Dr. Michael Negrete **Date & Time:** 10/04/2004 07:10:01

Organization : Premier Pharmacists Networks

Category : Private Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See attached

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

See Attached.

CMS-4068-P-1065-Attach-1.doc

CMS-4068-P-1065-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
Baltimore MD 21244-8014

Re: CMS-4068-P

Dear Sir or Madam:

Premier Pharmacists Networks is a new wholly owned subsidiary of the California Pharmacists Association and was created to develop business models related to pharmacist provided medication therapy management services. We welcome the opportunity to offer the following comments on the proposed rule for the Medicare Prescription Drug Benefit, particularly as it relates to medication therapy management programs.

Subpart D – 423.153(d) Medication Therapy Management Programs

Premier Pharmacists Networks (PPN) applauds the inclusion of MTMPs within the Part D benefit. Truly, the most expensive medication is the one that does not achieve the desired result. Unfortunately, unintended results are exactly what many patients experience from their medication. As a matter of fact, researchers Ernst and Grizzle calculated that in the year 2000 alone, the overall cost of drug-related morbidity and mortality in the US exceeded $177 billion. Other researchers have shown that the costs associated with drug related problems exceed the cost of the medications themselves! Fortunately, a great majority of these problems and costs can be avoided through committing resources to the promotion of appropriate medication use.

As our population begins to take increasing numbers of medications for increasing numbers of conditions, medication therapies and the psychosocial factors that surround them become increasing complex. Adding to this complexity is the fact that more and more individuals are deciding to take increasing numbers of herbals, OTC products and even prescription medications from the internet without first consulting with a healthcare provider. What used to be a simple task of obtaining a comprehensive medication list is fast becoming an difficult chore. Even more difficult is fostering a patient's understanding of what each medication is for, why they need to take it, how they should take it, and what to expect from it. Wading through all the potential side effects, drug-drug interactions, drug-disease interactions, and drug-food interactions is an even more difficult task. Unfortunately, the extreme difficulty of this task is highly underestimated and that is why we find ourselves in the current situation where only 50% of patients take their medications as prescribed and hundreds of billons of dollars are spent dealing with the problems that medications cause, mainly because of inappropriate use.

Pharmacists are trained to be medication experts and they spend far more time learning about the complexities, subtleties, and nuances of medications than any other healthcare provider. Study after study (see attachment A) has shown the value that effectively positioned pharmacists can have on improving outcomes and controlling costs. It is for these reasons that medication therapy management services should be required to be performed by pharmacists or at the very least under the supervision of a

pharmacist. No other healthcare professional has the training or expertise needed to effectively address the vast variety of complex issues that surround the use of pharmaceuticals that have the power to both cure and kill.

PPN also advocates that PDPs and MA-PDs be required to make MTM services from pharmacists available to patients *in person*. These visits can take place anywhere such as an office, a pharmacy consultation room or even in the patient's home. Ensuring face-to-face encounters is important for a variety of reasons including:

- The best way to identify all the pharmaceuticals a patient is taking is to have them bring everything in their medicine cabinet an in-person visit
- Some medications must be administered/applied in a fashion that can only be taught and assessed in a visual encounter (e.g. eye drops, inhalers, etc)
- Some medications must be administered/applied in a fashion that can be negatively impacted due to a disability that may only be made obvious through visual observation (arthritis, visual impairment, etc)
- Some medications cause adverse events that can only be identified through visual contact (e.g. bruising from coumadin, rashes from antibiotics, tardive dyskinesia from antipsychotics)
- The efficacy of some medications can only be assessed from a physical assessment such as blood pressure, weight, observance of peripheral edema, etc.
- Some patients may need to have pill counts performed and special compliance packaging (medication boxes) provided directly to them to improve adherence.

These are just a few of the reasons that underscore the importance of a meaningful face-to-face encounter between a patient and a pharmacist.

PPN also advocates for CMS to require that community *pharmacies* be included in any MTMP that is offered by a PDP or MA-PD. The great advantage that pharmacies have over every other healthcare venue is patient access. According to the American Pharmacists Association, the equivalent of the entire US population enters a pharmacy *every week*. Many states and organizations have begun to take advantage of this increased access by positioning community pharmacies to be access points of services such as emergency contraception and adult immunizations.

While some degree of medication therapy management already occurs in community pharmacies, shrinking reimbursements and misaligned financial incentives have forced most community pharmacists to focus their activities around the simple act of product distribution. Nonetheless, patients see community pharmacists more than any other member of their healthcare team and these ubiquitous medication experts represent an untapped resource that holds a great deal of potential.

One pragmatic way to tap into this potential is to modify the use of existing information systems and realign financial incentives to position community pharmacists to be able to quickly identify problems for targeted patients, resolve them if possible in a 5-10 minute "mini-intervention," and/or make a patient referral to a pharmacist that has the time needed to provide more intensive medication therapy management services. The referenced "existing information system" is the real time, online, pharmacy drug utilization review (DUR) system. Every time a pharmacy adjudicates a drug claim, a real-time DUR check is performed and information is (or can be) sent to the pharmacy from the claims processor. Unfortunately, as it is currently used, the online DUR system

is largely ineffective. In fact, one study showed that up to 88% of online alerts are routinely overridden by pharmacists. To make this system more effective and utilize it in the manner described above, a program could be developed as part of an MTMP that would facilitate the integration of claims data and alerts with the pharmacy claims processing system. Combined with a pragmatic, easy to use, documentation and billing process, such a system could position community pharmacists to be able to provide many valuable "mini-interventions" to targeted patients who have "fallen through the cracks" or need extra help.

Finally, PPN has some concerns about the degree of utilization that will be observed in the MTMPs for the following reasons:

- The eligibility criteria are overly restrictive – many patients who do not fit the criteria could benefit greatly from MTMPS. Consequently, the PDPs and MA-PDs should be required to make the eligibility criteria be as liberal as is allowed under the statute. In addition, CMS should put in place incentives that encourage the PDPs and MA-PDs to include a broader range of patients in MTMPs (i.e. in their enhanced benefit packages)
- The eligibility criteria dictate that a patient who obtains benefits from ongoing participation in a MTMP be excluded from the MTMP simply because they experience a decrease in their number of medications or drug costs.
- Since MTMPs are considered an "administrative function," and since the PDPs have no financial stake in costs associated with the medical budget (where the real savings will be realized), and since many MA-PDs are skeptical about the value of MTMPs, there appears to be a financial disincentive for the PDPs and MA-PDs to promote active participation in MTMPs because they might perceive that "any money paid to MTMP providers money out of their pockets."
- There appear to be no incentives to or accountability for PDPs and MA-PDs to promote active patient participation in MTMPs –benchmarks for participation should be established as part of a quality improvement initiative.
- There appears to be no requirement for the PDP's and MA-PDs to show CMS how they plan to tell patients that they are eligible or to tell providers which of their patients are eligible.
- PDPs and MA-PDs should be required to provide patient incentives for participation in MTMPs such as lowering or waiving patient co-payments for medications. The City of Asheville, NC has had great success with this strategy.
- There is no requirement for PDPs and MA-PDs to assess whether their MTMP provider payments are adequate to encourage pharmacists to be providers.

These are some of the things PPN feels CMS should address to ensure patient and provider participation in a program that will add value to the healthcare system.

APPENDIX A – Evidence of the Value of the Pharmacist

Pharmacists Impact on Healthcare Cost and Quality	Study Citation
Pharmacists collaborating with physicians to care for high-risk patients reduced the number of prescriptions per patient and **saved nearly $600 per year per patient in drug costs.**	Jameson J, VanNoord G, Vanderwoud K. The impact of the pharmacotherapy consultation on the cost and outcome of medical therapy. *Journal of Family Practice*. 1995; Nov.; 41(5):469-72
Pharmacists providing pharmaceutical care to patients in an ambulatory care clinic saved nearly $250,000 in one month.	Hatoum HT, Witte KW, Hutchinson RA. Patient care contributions of clinical pharmacists in four ambulatory care clinics. *Hospital Pharmacy.* 1992; 27(3): 203-6, 208-9 Schumock, GT, Butter M.G. et al.
This study shows that costs Pharmacists providing services for an HMO to patients in their community **saved** an average of $20 per prescription.	Knapp KK, Katzman H, Hambright JS et al. Community pharmacist interventions in a capitated pharmacy benefit contract. *American Journal of Health-System Pharmacy.* 1998; 55(11):1141-5
Pharmacists providing pharmaceutical care services to patients in long-term care facilities **increased the number of patients receiving optimal care** by 45% - resulting in an estimated $3.7 billion in cost avoidance.	The Fleetwood Project, American Society of Consultant Pharmacists
Pharmacist services provided in community pharmacies **saved** approximately $3.47 per prescription.	Dobie RL, Rascati KL. Documenting the value of pharmacist interventions. *American Pharmacy.* 1994; May; NS34(5):50-4
Pharmacists providing pharmaceutical care services generate a return-on-investment (ROI) of $17.00 per patient for every dollar invested.	Evidence of the economic benefit of clinical pharmacy service – 1996-2000. *Pharmacotherapy.* 2003; 23: 113-125
Pharmacists providing pharmaceutical care to patients in a managed care organization **saved $640 per patient per year.**	Borgsdorf LR, Miano JS, Knapp KK. Pharmacist-managed medication review in a managed care system. *American Journal of Hospital Pharmacy* 1994; Mar 15; 51(6):772-7

Pharmacists Impact on Healthcare Cost and Quality	Study Citation
Pharmacist services saved over $75,000 in 3 months time and **prevented additional medical problems from occurring** by identifying prescribing errors.	Rupp MT. Value of community pharmacists' interventions to correct prescribing errors. *Annals of Pharmacotherapy*. 1992 December; 26(12):1580-4
Pharmacists providing pharmaceutical care services in a general medicine clinic saved nearly $4 per prescription and **decreased the number of prescriptions** per patient.	Britton ML, Lurvey PL. Impact of medication profile review on prescribing in a general medicine clinic. *American Journal of Hospital Pharmacy.* 1991 February; 48(2):265-70
Pharmacists providing pharmaceutical care in a VA outpatient clinic reduced the number of medications taken by patients by an average of 2.4 prescriptions.	Galt KA. Cost avoidance, acceptance, and outcomes associated with a pharmacotherapy consult clinic in a Veterans Affairs medical center. *Pharmacotherapy* 1998 Sept-Oct;18(5):1103-11
In one month, six pharmacists providing pharmaceutical care decreased the drug costs from a cohort of patients by 41%.	McMullin, T., Hennenfent J., etal. A prospective, randomized trial to assess the cost impact of pharmacist-initiated interventions. *Archives of Internal Medicine.* 1999 Oct 25; 159(19):2306-9
Pharmacist services **saved** over $32 per prescription.	Fincham J, Gottlob A. The Kansas report. *America's Pharmacist.* 1997 May; 119(5): 30-3
Pharmacists providing asthma management services and pharmaceutical care to two employers decreased cost, **improved care,** and improved work absence rates.	The Asheville Project. *Pharmacy Times.* Romaine Pierson Publishers, Inc. Westbury:NY. October 1998. Bunting B. (excerpt) Asheville Project Continues to Produce Positive Results. *America's Pharmacist.* May 2000:43-44
Pharmacists providing pharmaceutical care to patients with high cholesterol in their community improved patient compliance with medication from a national average of 40% to 90%.	Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia. *Journal of the American Pharmaceutical Association* 2000;40(2):157-165

Pharmacists Impact on Healthcare Cost and Quality	Study Citation
Pharmacists working with patients with high blood pressure in an HMO family practice saved $20.61/patient in drug costs and **decreased the number of drugs prescribed.**	Forstrom MJ, Ried LD, Stergachis AS et al. Effect of a clinical pharmacist program on the cost of hypertension treatment in an HMO family practice clinic. *Annals of Pharmacotherapy.* 1990; 24(3):304-9
Pharmacists providing disease management services in their community saved an average of $2700 per year per patient in total medical costs.	Munroe WP, Kunz K, Dalmady-Israel C et al. Economic evaluation of pharmacist involvement in disease management in a community pharmacy setting. *Clinical Therapeutics.* 1997; 19(1):113-23
Pharmacists providing pharmaceutical care services to diabetic patients in their community **saved $219,000 per year.**	Fincham JE, Lofhom PW. Saving money and lives. Pharmacist care for diabetes patients. *America's Pharmacist.* 1998 March; 120(3): 49-52
Community pharmacists providing pharmaceutical care to asthma patients in an HMO decreased hospitalizations by 77% and decreased emergency room visits by 78%.	Rupp MT, McCallian DJ, Sheth KK. Developing and marketing a community pharmacy-based asthma management program. *Journal of the American Pharmaceutical Association;* 1997 Nov-Dec; 37(6):694-9
Patients treated with blood thinners in a pharmacist-managed anticoagulation clinic had fewer emergency room visits, fewer hospitalizations, and showed a total cost savings of $1,621 per patient.	Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care. Anticoagulation control, patient outcomes, and health care costs. *Archives of Internal Medicine* 1998;158:1641-7

CMS-4068-P-1066

Submitter : Mrs. Mindy Rasmussen **Date & Time:** 10/04/2004 06:10:29

Organization : Wyoming Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attached word document

CMS-4068-P-1067

Submitter : Mr. Jack Gardner **Date & Time:** 10/04/2004 06:10:55

Organization : NAMI NJ

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed regulations would limit the Medicare coverage of certain important antipsychotic medications. By picking just two drugs in a category, you could seriously limit the options that a physician and patient have to proper care. Antipsychotic medications are not like pain relievers .... different ones produce profoundly different effects in different patients. Finding the right medication to keep a patient out of the hospital is a long and difficult process. if the proposed regulations are approved, you can count on putting more patients back in the hospital. This will mean a greater cost to the healthcare system, rather than providing savings for the system.
The proposal is wrong for the patients, wrong for their doctors, and wrong for the taxpayers. You can do better.

CMS-4068-P-1068

Submitter : Dr. Don Hawley **Date & Time:** 10/04/2004 07:10:29

Organization : Utah Dept. of Health, DHCF

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

1. It is not clear how the flexibility in allowing PDPs to establish their own drug classification schemes will be sufficiently controlled to assure drug coverage for medically necessary drugs. This issue may prove life threatening for some dual eligibles. The process must be clearly defined and more responsive than the current appeal process outlined in section 423.568 of the regulations. At a minimum, a limited supply of needed drugs should be provided by the plan to allow time for the client to get through the first level of appeal.

2. The President?s New Freedom Commission on Mental Health report discusses the fact that untreated and under-treated mental illness have very high financial costs. Limited formularies could have a devastating impact on all of the above goals by resulting in untreated and under-treated mental illness. In addition to the consequences that those with mental illness would experience, the health care system will experience increased costs in other areas as emergency and inpatient services become necessary for their health and safety. There needs to be broad coverage for mental health drugs, especially the atypical antipsychotic drugs. The drugs in this therapeutic class each act differently from the others and are not interchangeable as other therapeutic classes.

3. Definitions of ?Institutionalized individual? should be broader than that described as skilled nursing and nursing facilities. Medicaid programs have diverted the need for institutional care through the use of home and community based waivers. They have also used waivers to move people from institutions to community based residences. In both cases, the enrolled individuals should have the same level of subsidy as those in the institutions as defined in 423.772. To do otherwise will aggravate the current institutional biases, which is contrary to the stated intent of HHS and the current administration.

4. We recommend that CMS designate people living with HIV/AIDS as a ?special populations? and require drug plans to exempt these populations from formulary restrictions and granting them special protections from cost-sharing requirements and other cost-containment measures that may impede access to prescription drugs.

5. We recommend that ADAP be recognized as a state pharmacy assistance program and allowed to wrap around the Medicare Part D Drug Benefit. We see nothing in the legislation prohibiting the designation of ADAPs as SPAPs and fear that disallowing this request would deny some patients a viable option in assessing care, Further, we recommend that ADAP expenditures be counted as true out-of-pocket expenses.

6. We recommend requiring all plans offering drug coverage to include all FDA-approved medications to treat HIV disease, in all approved formulations, as reflected in federal HIV-related guidelines. Each of the federal HIV guideline is a living document developed by experts in the field informed by the latest clinical research and clinical practice research and practice experience. Regulations also should require plans to cover medications to treat conditions that are frequently related to HIV disease. As the FDA approves new drug therapies for HIV/AIDS, they should be immediately added to Medicare-related formularies.

7. We note that participation in the 340B Program is not mandatory but rather strongly encouraged by the Health Resources and Services Administration (HRSA), the federal agency that oversees the Ryan White CARW Act and the 340B Program.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

1. We advise against letting plans engage in direct marketing. At a minimum, all marketing plans as well as marketing materials ought to go through a prior approval process with CMS. It might be best to allow beneficiaries to choose whether or not they want to have their mailing information shared with the PDP marketing staff. Phone solicitation by PDP marketing staff should not be permitted. Plan availability and coverage options should be made available by CMS. Reference 423.50

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

1. PCPs are required to provided drugs under a drug utilization management program or a medication therapy management program. States need timely access to that data to help assess the impact of the this program on other medical care utilization. This should be made clearer in section 423.153 of the regulations.

2. Phenobarbitol and benzodiazepines are excluded in Part D. Benzodiazepines must be covered because they are the mainstay for treatment of anxiety. This is a relatively inexpensive, high volume drug group and could replace many more costly products and might result in significant savings. Reference 423.100

3. Lifestyle drugs, such as Viagra, Levetra, Cialis (drugs to treat impotency), should not be covered as they are patient choice. This should follow the logic of excluding fertility drugs. Reference 423.100 and proposed Therapeutic Classes.

ELIGIBILITY, ELECTION, AND ENROLLMENT

1. There needs to be coverage options for dual eligibles who are involuntarily disenrolled.? Gaps in coverage can be fatal for some in this population. Dual eligibles should never be put in a situation where they have no coverage options. Often the behaviors that lead to the desire to dis-enroll a recipient from any plan are a result of severe mental health disabilities or brain injuries. To exclude this population for coverage will aggravate the problems and likely lead to greater costs as conditions worsen due to a lack of prescription drug coverages. We suggest a better approach is one followed by Medicaid programs. Utilization control in Medicaid restricts the patient to a single pharmacy and primary provider. This provides better control over utilization and the ability to provide needed case management. Reference section 423.44

2. We recommend that the dual eligibles be auto enrolled as earlier as possible and then have time to modify their choice of PDP. An alternate proposal might be to allow the Medicaid pharmacy benefit to extend beyond the January 1, 2006 date until these dual eligibles are enrolled in Part D. Let the states receive the federal match for pharmacy benefits for these clients so they will have time to make any needed prescription changes in consultation with their physician. This would help prevent any gaps in coverage. Reference Subpart B, 423.36 and FR 46636.

3. Enrollment is problematic as the state has enrollment responsibilities per the Part D statute. A particular problem is how can Medicaid help in the PDP selection in a timely way to meet the January 1, 2006 deadline as the formularies and drugs available in each plan might not be readily available until late 2005. If the decisions as to the PDPs is delayed until October or November 2005, there is insufficient time to accomplish the task. CMS may not be able to process all the applications submitted between November 15, 2005 and December 31, 2005 and make the benefit active for recipients on January 1, 2006. Reference 423.36

4. The state, according to statute, does not enroll, but is require to help the applicants in the enrollment process for Part D. More definition is needed as to how this process will occur. Without significant details, states will have problems gearing up with staff process training and programing to facilitate the enrollment process. Reference 423.772

5. More consideration is needed to address the transition from Medicaid to Medicare in the initial month of Part D eligibility, particularly, when the enrollment determination occurs late in the month prior to the Part D effective date. For example, Medicaid requires a 10-day notice prior to termination of a benefit. In addition, there will be operational barriers to ensuring Medicaid prescription drug coverage does not over lap Part D coverage. Reference 423.36

6. It will be important to have a hardship clause that allows for changing PDPs more often than once per year, if the medically necessary medication can not be obtained through the chosen PDP: (1) because the PDP changed the formulary to exclude the needed drug and alternate drugs are not equally effective, or (2) the medical condition of the client is such that the physician changes the drug regimen resulting in non-covered drugs. This hardship clause is most important for the dual eligible population. Reference Subpart M

GENERAL PROVISIONS

1. It is understood that medigap insurance with pharmacy coverage will not be allowed after Jan. 1, 2006, but will wrap-around or supplemental insurance be allowed for the Part D benefit? This could be similar to supplemental insurance for Part B. This is an important benefit and would not affect the actuarial integrity of Part D. Reference 1860D-22.

2. We disagree that there will be significant savings realized by the states. Any savings will be offset by the increase in administrative costs to manage the Part D program as it relates to Medicaid. Also, the additional enrollees resulting from the effects of Part D enrollment may cost more than the savings generated, even in the out years of the program. All costs should be estimated and published indicating both state and federal share of costs. FR 46807

3. Section 423.100 should also address ?frontier? areas in access standards.

4. We recommend that dual eligibles not be limited to the ?average cost plan?. This restriction could leave dual eligibles without meaningful access to the full range of prescription drug plans in their area. Medicare beneficiaries who are most dependant on drugs need access to the plan that will best meet their needs rather than limiting them to what could be the plan with the weakest drug benefit. If the dual population is not distributed across most plans, there is likely to be significant adverse selection into the low cost plans. As currently designed with the dual eligible population?s subside, this will probably occur. The low cost plans will either have to exit the program due to financial losses or significantly increase premiums the next year. This may cause an artificial increase in cost to the program. This may also result in the dual eligible population having to change plans in large numbers each year.

CMS-4068-P-1069

Submitter : **Date & Time:** **10/04/2004 06:10:06**

Organization : **Families USA**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

see attached file

CMS-4068-P-1069-Attach-1.doc

FamiliesUSA
20 Years as the Voice for Health Care Consumers

October 4, 2004

The U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services

Comments on Proposed Regulations
File Code [CMS-4068-P]

Families USA is pleased to submit the following comments on the above referenced proposed rule, which would implement the new Medicare prescription drug benefit. Families USA is a consumer advocacy organization that has represented the interests of health care consumers nationwide for over 20 years. We are deeply concerned with the implementation issues surrounding the Medicare prescription drug benefit.

Organization of Comments

Our comments begin with introductory observations that outline our general concerns. These are followed by more specific comments addressing the following Subparts and specific sections within those Subparts. In addition to the specific sections on which we have comments, in many cases we have noted overriding concerns with some or all of the sections in a Subpart.

INTRODUCTORY COMMENTS

These Introductory Comments reflect our overarching concerns and relate to the entirety of the Proposed Regulation.

Use Authority to Ensure Access to Affordable Medications. The law gives the Secretary broad discretion to set policy for many aspects of the prescription drug benefit. However, the proposed regulation does not, in many areas, suggest that the Secretary will use that authority to ensure that all Medicare beneficiaries have access to affordable medications. The detailed comments include a number of provisions that should be added to the final regulation to ensure that the law fulfils its promise.

Many Pro-Consumer Comments in the Preamble Do Not Appear in the Proposed Regulations.
We are concerned that many statements in the Preamble that we support do not appear to be reflected in the proposed regulation. We urge that more be done to reflect the Preamble's good intentions in the actual body of the regulation. 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 just says that notice should be provided, without specifying 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 when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulatory language does not include the examples CMS discusses in the preamble.

While specifying beneficiary protections in the Preamble is well and good, they bear no weight unless captured in the regulation.

Need for Second Round of Comments Given Large Number of Issues Not Addressed.
We are also surprised at the large number of issues that are not addressed and for which only the vaguest suggestion of the final regulation is offered. We fear that the final regulation will include a number of errors and provisions that result in unintended consequences because so much of the final

regulation will not have been seen by the public. We urge that CMS 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 regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

Need for Technical and Corrective Amendments.
There are clearly a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation-writers. We urge the Department to 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.

Cost Reductions in the Future.
In its Preamble/Regulatory Impact Statement, CMS notes:

> "We are very interested in developing further evidence on the best ways to encourage outcome improvements and overall health care cost reductions through drug coverage…."

In response, we urge that the Department fund the MMA Section 1013 "Research on Outcomes of Health Care Items and Services." The law authorized $50 million for this in FY 2004, but no funds were requested and Congress provided none. But the law says "such sums as may be necessary for each fiscal year thereafter." Adequate funding of this research could achieve enormous savings, in lives and money, in the years to come, and we urge the Department to make this a funding priority.

We also urge the Department to seek the legislative repeal of the MMA section 622 ban on Medicare considering functional equivalence in its payment for drugs under Part B. This ban is anti-consumer and anti-taxpayer and will prevent the Department from saving hundreds of millions of dollars in the years to come.

Simplify as Possible.
The sheer size and complexity of these regulations is also a testament to the fact that this new law is terribly confusing to most Medicare beneficiaries—and confusion will make enrollment and use of the new program very difficult, particularly for the lower income, the sicker, and those with English literacy problems. In general, whenever it is possible and whenever it is not anti-

consumer, CMS should seek to simplify the new program. In most cases, simplification will be the pro-consumer position.

SUBPART B—ELIGIBILITY AND ENROLLMENT

Overarching Concerns Regarding the Enrollment Process.

We are very concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries, beneficiaries with mental illness, and other populations with special needs.

Officials at the Centers for Medicare and Medicaid Services (CMS) have indicated that they will rely heavily on State Health Insurance Assistance Programs (SHIPs) to assist with enrollment. SHIPs have played a critical role in helping Medicare beneficiaries navigate the Medicare drug discount cards and will continue to play an important role helping Medicare beneficiaries as enrollment begins for the new prescription drug benefit. However, additional funding is critical if SHIPs are to continue to successfully serve the Medicare population and help diverse Medicare beneficiaries navigate the complicated new law's provisions (the need to augment SHIP funding is discussed in greater detail in section 423.48).

While SHIPs will be critical to education and enrollment efforts, other community-based groups with historical expertise working with the unique needs of and issues for beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs, will also need to be integral to education and enrollment strategy development and implementation. These groups also must be engaged and provided funding if all beneficiaries are to identify and enroll in the best plan available. The potential for new partnerships between these groups and SHIPs should be explored and supported.

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. For example, 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, including but not limited to schizophrenia, bipolar disorder, depression,

anxiety disorder, dementia, and attention deficit/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes." [Report No. 108-391, pp. 769-770.] Experience implementing Medicaid managed care programs over past 10 years shows that to successfully enroll individuals with mental illness, cognitive impairments (like Alzheimer's disease) and disabilities, outreach, education, and enrollment opportunities must be incorporated at multiple points within the health communities.

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries with special needs, CMS must partner with community-based organizations focused on addressing the needs of people with special disease and disability conditions, (such as mental illness) and state and local agencies that coordinate benefits for these individuals. Beneficiaries with disabilities know and trust these organizations, and it is to these organizations that they will likely turn 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 disabilities about the new benefit. CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (§423.48). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. 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 disabilities in each region. This plan must incorporate collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. In addition, in their bids, PDPs and MA-PDPs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness.

Overarching Concerns Regarding Enrollment of Dual Eligibles in Medicare Part D.

Enrollment of Dual Eligibles: Coordinating and Timing Transfer from Medicaid.
Our specific comments on enrollment of dual eligibles and our recommendations appear in our comments on Sections 423.34, 423.36, 423.48 and in Subparts P and S. Much that is outlined below is repeated in those sections. However, this is such a critical and overriding concern with the enrollment process that it merits special attention.

The NPRM fails to adequately address how drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the dual eligibles) will be transferred to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of operationalizing the enrollment process. The NPRM does not address either in any way that will ensure that these 6.4 million beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences for these individuals,

Timing. Automatic enrollment of dual eligibles will not begin until the end of the initial enrollment period on May 15, 2006. However, states' Medicaid drug benefit for dual eligibles will end on January 1, 2006. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education (outlined above), 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 automatic enrollment. This completely foreseeable situation is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D (see below). The transfer of drug coverage from Medicaid to Medicare Part D must be delayed.

Operationalizing automatic enrollment. CMS requests 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; therefore, we recommend that states have the option of performing automatic enrollment. However, this added responsibility must include sufficient administrative payments (see our discussion in Section 423.34).

Continuity of Care for Dual Eligibles.
We are extremely concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. (For a more detailed discussion of formulary requirements, the need for different formulary treatment of specific populations, and recommendations regarding defining those populations, see our comments on Subpart C, Section 423.120.)

In our following discussion of concerns regarding continuity of care for dual eligibles, and for others with special health care needs, we frequently illustrate the problem with foreseeable situations that could arise related to treatment of mental illness. A disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications: According to MedPAC, 38% of all duals have cognitive or mental impairments. These issues and concerns, however, apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (again, see our comments in Subpart C, Section 423.120 for a discussion of populations with special needs).

As proposed in the NPRM, duals would be forced 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 in states that have restricted access to drugs in Medicaid programs with preferred drug lists and prior authorization requirements, most of these states have exempted selected conditions, such as mental illness, from these restrictions.

Without access to the coverage they need, dual eligibles will be forced to switch medications. In the treatment of HIV/AIDS, such switches can be deadly. As another example, in a letter to Dr. Mark McClellan, Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, advises that "[a]ppropriate continuity of care provisions for psychiatric medications for dual eligibles are critical and need to be considered in the development of this program. It has been shown that once a patient has evidence of successful response to a particular medication or treatment regimen, switching the treatment without clear clinical indication is deleterious."

We believe the same is true for a number of other illnesses and categories. To use just one disease group as an example of the problem in many sectors, we cite the danger of changing psychiatric medications. It can take up to 6-12 weeks to determine if a medication works and almost as long to wash a

medication out of a consumer's system. Abrupt changes in psychiatric medications bring the risk of serious adverse drug interactions. Moreover, each failed trial results in suffering and possible worsening of a person's condition. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who do not and their treatment typically costs about 50 percent more than it would have if they had been allowed to continue taking a medication that had already been deemed appropriate.[1]

Not ensuring continuity of care for dual eligibles will greatly increase costs. In his letter to Dr. McClellan, Dr. Hogan states that "[p]atients who are not adequately treated, or treated with the wrong therapeutic agent, tend to utilize more costly crisis intervention, inpatient hospital, and intensive case management services. They also will tend to be less adherent to prescribed medications from that point forward, even when a more clinically appropriate treatment regimen has been prescribed." A study of the overall medical costs and use of services among people who had mental illnesses and were uninsured revealed that continuity of medication therapy resulted in a 65 percent reduction in inpatient costs, a 55 percent reduction in emergency costs, a 23 percent increase in outpatient care and an overall mean cost savings of $166 per patient per month.[2] Fewer prescriptions are needed when access to medications is not limited, but increased restrictions are associated with more physician and emergency room visits, hospitalizations and prescriptions which become increasingly costly each year.[3]

Moreover, it is clear that Congress was concerned with ensuring access to psychiatric medications under the new Part D benefit. The conference report states 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]

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[1] Hensely, PL and Nurnberg, H.G. (2001). Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls. *Pharmacoeconomics*, Vol. 19, No. 10, pp. 973-982.

[2] Del Paggio, D., Finley, P., and Cavano, J. (2002). Clinical and economic outcomes associated with Olanzapine for the treatment of psychotic symptoms in a county mental health population. *Clinical Therapeutics*, 24.5, 803-817.

[3] Horn, W. Unintended Costs and outcomes: The Fiscal Case for Open Access. *Drug Benefit Trends*, Vol. 15, Supplement 1.

This type of cost to the system can be cited in disease after disease category. It is clear that CMS needs to find a way to ensure continuity of care for all of those with pharmacologically complex conditions.

The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§ 423.36). However, as noted in more detail below in the discussion of that section, this provision as written is inadequate to meet the special needs of dual eligibles.

In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (Section M, Appeals and Grievances; our concerns with specific language related to appeals and grievances are addressed in our comments on that Subpart). But the process proposed is extremely complex and 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 extremely 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. Again, using comments citing treatment for mental illness as just one example, Michael Hogan, former chair of the President's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, stated in a letter to Dr. McClellan, "patients with significant psychiatric illness, especially those that are disabled as a result of their illness, have an extremely limited capacity to navigate [grievance and appeals] procedures." Dr. Hogan also urges CMS not to rely on the existence of grievance and appeal processes as a substitute for open formulary access to medications.

Honoring Congress and the Administration's Promise to Dual Eligibles. Congress and the Administration have promised that dual eligible beneficiaries will be better off with this new Part D drug benefit than they are 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 just as a number of states (e.g., WI, OR, KY, TX, CA) have done in implementing preferred drug lists for their Medicaid programs. For the very vulnerable dual eligible population, for those with life-threatening diseases, such as HIV/AIDS, mental illness, cancers, and other extreme conditions (groups which could be classified as having pharmacologically complex conditions), drug plans must be required to cover their existing medications. At a minimum this protection should be given to dual eligibles because they have so few financial resources. Higher reimbursement for this coverage could be based on "allowable and allocable

costs" as CMS has proposed to pay fallback plans. Increased federal payments are warranted as coverage of the full array of medications by these drug plans will prevent increased utilization of more costly inpatient and outpatient services and resulting increases in Medicare Part A and B costs.

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. Again, increased payments for drug plans based on "allowable and allocable costs" as proposed for fallback plans is warranted to account for the savings to Medicare Parts A and B that will result from ensuring access to needed medications. A more detailed discussion of this alternative flexible formulary proposal can be found in our comments on section 423.120, Access to Covered Part D Drugs.

Section 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 should 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), Operationalizing enrollment of 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. States opting to conduct auto assignment should receive full federal financing for this function given the MMA's explicit directive for the Secretary to accomplish this function. *See* 1860D-1(b)(1)(A) and (C). CMS should not require all states to perform the auto-assignment task, however, because some states may lack

the capacity to complete it in an acceptable manner. CMS will therefore have to develop its own systems to automatically enroll dual eligibles in states that do not elect to perform the autoenrollment.

However, this is an additional and considerable burden on the states that perform autoenrollment, and the structure of the program with its "clawback" provision builds in a financial disincentive for states to maximize enrollment in Part D. Under the law, the "clawback payment" will be based on the number of dual eligibles enrolled in the new Part D benefit: the fewer enrolled, the smaller the giveback to the Federal government. To blunt that disincentive and to maximize enrollment, administrative payments to the states for autoenrollment must be adequate and must be sufficient to counter the built in financial disincentives inherent in the "clawback" provision. We urge CMS to reimburse the states for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.

In addition, regardless of which entity performs the auto-enrollment, strong accountability measures and oversight from CMS will be essential. The regulations should specify that after beneficiaries are automatically enrolled in plans, they must be clearly informed via telephone, mail, and other means about the plans in which they have been enrolled, as well as their right to choose a different plan and where they can get assistance to do so.

Finally, because the proposed rule left unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, we reiterate that, as we have stated in the introduction to these comments, 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), Enrollment requirements for full benefit dual eligibles, timing between end of Medicaid's benefit and automatic enrollment.
The NPRM 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.

CMS's 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 would be a considerable hardship and could have serious health consequences for this vulnerable population. (see our discussion of Overarching Concerns at the beginning of our discussion of Subpart B, above).

To prevent catastrophic consequences for dual eligibles, we believe the transition of drug coverage for dual eligibles must be delayed by a year, or at a minimum six months. MEDPAC indicates that six months is needed for a successful transition in private sector drug plans. MEDPAC, June *2004 Report to Congress*. Dual eligibles will need a longer transition period given their higher drug use, increased incidence of cognitive impairment, and need for personalized counseling and assistance to select the most appropriate Part D coverage. This extension may require a statutory change. If so, the Secretary should request the appropriate legislative action.

In the absence of a delayed transition for drug coverage, we believe the least harmful approach would be for dual eligibles to 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 (see our proposed definition of "random" in section 423.34(d)(2), below). 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 to educate them about their new drug coverage before January 1, 2006.
To make this process work more smoothly, even before plan information is released on October 15, 2005, states can begin profiling individuals' drug history to prepare for random auto-assignment among plans that are appropriate for the individual. Additionally, it is critical that CMS must fund a massive campaign of individualized counseling and assistance both before and after auto-enrollment to a) explain to individuals their choices and how to enroll in a plan, b) if applicable, explain how to get benefits under the plan to which they have been auto-assigned and c) 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 (see also our suggestions on information and outreach for dual eligibles under section 423.48).

423.34(d)(1)(ii), Enrollment requirement for full benefit dual eligibles in MA plans.
It is essential that CMS develop an adequate solution to the issue of automatic enrollment and 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. Forcing a dual eligible to choose between continued MA enrollment, paying added premiums, or foregoing drug coverage is inherently disruptive.

Although absent a statutory change we do not have a comprehensive solution to the problem, we have suggestions to assist some beneficiaries. For institutionalized duals enrolled in an MA-PD plan whose premium is higher than the fully-subsidized premium amount, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly share of cost to the facility. For non-institutionalized duals in such situation, in states where State Pharmacy Assistance Programs (SPAPs) will wrap around Part D coverage and will cover duals, SPAPs should be authorized to pay the difference. Or, 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-PD back into original Medicare.

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 define "on a random basis" in this section as "among all such plans in the region that meet the beneficiary's particular drug needs."

Section 423.36, Enrollment Periods.

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 (see comments under section 423.44). 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.

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 the needs of dual eligibles. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare+Choice plans in the past. In addition, these individuals will not have the resources to pay more in premiums 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), Other special enrollment periods
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, (i.e., 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.

Section 423.44, Disenrollment by the PDP.

423.44(b)(2)(i) Required involuntary disenrollment by the PDP.
CMS stated that it was "particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area."

The disenrollment requirement in this section raises the issue of "snowbirds"—the large number of Medicare beneficiaries who move for large parts of the year. 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 (as described in the June, 2004 MedPAC report to Congress), 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.

We suggest several ways that CMS can better address this issue:

- **Require traveler benefits policies.** We believe the disruption and paperwork involved in this issue is so severe that we urge CMS to require as a condition of participation that plans have a system of visitor or traveler benefits.

- **Allow PDP exceptions.** We ask CMS to consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement. At a minimum, beneficiaries must have a clear understanding of how a plan will serve people temporarily out of the service area.

- **Require plans provide information on traveler benefits.** In addition to requiring traveler benefit policies, we urge that CMS require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies." In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. Beneficiaries who are traveling and need emergency pharmaceutical services need to know how their plan will (or will not) reimburse for those services.

- **Define time period.** The regulations should also clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." This should be defined to accommodate seasonal travelers who maintain a residence in the service area.

423.44(d)(2), Disenrollment for disruptive or threatening behavior*.* General concerns with/comments on this section.
We have a number of very serious 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" (§ 423.44). These provisions create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's disease, 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.

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 minimal beneficiary protections are as follows:

Lower involuntary disenrollment standard. CMS has proposed to lower the standard for involuntary disenrollment in these Part D regulations (as well as the proposed regulations for the new Medicare Advantage (MA) program) from that provided in similar provisions in the Medicare+Choice (M+C) program regulations (after which these regulations were clearly modeled). The preexisting M+C regulation allowing for disenrollment for disruptive behavior states that M+C plans may not disenroll an individual if the behavior at issue is "related to the use of medical services or diminished mental capacity." The NPRM for Part D plans (and the new requirements for MA plans) would lessen the degree of protection for beneficiaries against involuntary disenrollment for disruptive behavior. The proposed regulations state that "disruptive behavior may not be based on noncompliance with medical advice." This standard would unfairly deny protection for beneficiaries who complied with medical advice, for example, by trying an on-formulary drug instead of the drug needed, and as a result experienced a bad reaction causing their disruptive behavior.

Although the proposed regulations would also require that the behavior be committed by someone with "decision making capacity", this standard is not as broad as protections for people with diminished mental capacity as previously provided under the M+C program. It is patently unfair and discriminatory to deny protections for those whose allegedly disruptive behavior is a result of diminished mental capacity. Moreover, this lower standard would impose unacceptable risks to the health and well-being of these beneficiaries many of whom are likely have very low incomes with no way to access needed medications during the extended period when they would have no drug coverage as a result of being involuntarily disenrolled.

Addition of “threatening” to list of behaviors. The proposed regulations also add "threatening" to the list of behaviors that could merit disenrollment under the M+C program, in addition to disruptive, abusive, unruly, and uncooperative. Under the preexisting regulations, a beneficiary had to have at least taken some action to merit disenrollment. Moreover, the highly subjective term of "threatening" is not defined.

We strongly urge that CMS not include in the final regulation this lower standard for involuntary disenrollment for disruptive behavior that it has proposed in the NPRM.

Expedited disenrollment. We are alarmed by CMS's 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. The proposed expedited disenrollment process is itself undefined, and provides no standards, requirements or safeguards. Moreover, the NPRM 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. We strongly oppose the inclusion of this expedited disenrollment process in the final rule.

Reenrollment. 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. These 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. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify beneficiaries, and may in fact be an indication that they are in need of medical assistance. Congress clearly intended for all Medicare beneficiaries to have access to this benefit as evidenced by the fact that the Medicare Modernization Act requires that there be fallback plans available in areas where there are not at least two private drug plans.

The stigma that continues to surround mental illness and other cognitive impairments that could manifest in disruptive behavior all but assures that where these regulations open the door, such discrimination will occur. Congress' clear concern in the conference report for assuring access to needed medications for individuals with mental illness argues for exercise of the greatest care in the development of these regulations to ensure that avenues for potential discrimination are barred. Absent such steps here, the disenrollment processes proposed in the NPRM will have a disproportionate impact on individuals with disabilities particularly those with mental illness and Alzheimer's disease, either because they will be used purposefully to discriminate against these individual or 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.

In the preamble, CMS states that PDPs must apply policies for involuntary disenrollment consistently among beneficiaries enrolled in their plans, "unless we permit otherwise" and must comply with laws against discrimination based on disability. We question under what circumstances would CMS permit plans not to apply these policies in a consistent manner. There is already a significant and highly troubling risk that these provisions will be used to discriminate against certain individuals, and we urge CMS to review plans' requests for approval with the utmost scrutiny and to strictly require consistency in the applications of these provisions.

Individuals that 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 in the first place and given the high risk of discrimination presented by these provisions.

Protections to include. At the very least, 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. In addition, we strongly recommend the following protections be included in the regulations implementing the Part D benefit and the Medicare Advantage program to lessen the grave risks inherent in authorizing sanctions on "disruptive behavior":

- PDPs and MA-PDPs must be prohibited from disenrolling an enrollee 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;

- PDPs and MA-PDPs may not disenroll an enrollee 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 enrollee must include documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities, if applicable, in accordance with the Americans with Disabilities Act; and

- Documentation that the plan provided the enrollee with appropriate written notice of the consequences of continued disruptive behavior or written

notice of its intent to request involuntary disenrollment;

- PDPs and MA-PDPs 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.

Section 423.46, Late enrollment penalty.

General concern/comment on this section.
We urge CMS to delay implementation of this section for all enrollees for two years. The drug benefit is a new 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 know from experience with the Medicare-endorsed prescription drug discount card that reaching beneficiaries is challenging—for example, even with significant outreach, the majority of individuals eligible for the drug discount card's low-income subsidy have not yet taken advantage of the $600 available to them.

After the first two years, CMS should require plans to allow individuals with disabilities, as well as other specific population with special health care needs, a grace period if they miss an enrollment deadline. (See our comments under Subpart C, section 423.120(b) for our discussion of populations with special needs and see also our comments below in this section under the heading "Omissions in this section.")

Additionally, we recommend that the late enrollment penalty not apply to individuals eligible for the low-income subsidy. Subsidy-eligible 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. Beneficiaries should not be penalized because of program complexity.

Omissions in this section.
Beyond that general comment, we have several more specific concerns regarding omissions in this section.

- **Add appeals opportunity.** There should be an opportunity for enrollees to appeal late enrollment penalties. This should be noted in this section and should be incorporated as part of the general system for appeals outlined in Subpart M.

- **Coordinate with "special enrollment periods."** Late enrollment penalties should be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties. The exemption of time during special enrollment periods from late penalties should be stated in this section.

- **Exemption for individuals involuntarily disenrolled.** Unless CMS adds special enrollment opportunities for individuals who are involuntarily disenrolled—as strongly recommended under our comments on section 423.36(c)—those who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period. At that point, they may be subject to a late penalty and increased premiums. This is patently unfair, especially since it may be based on an arbitrary and unjustified decision by the plan to 'get rid of' high cost patients. The disruptive behavior may have resulted from denial of access to needed medications. The late enrollment penalty should be waived for these individuals as well.

- **Late enrollment penalties and people with disabilities and special health care needs**. CMS should incorporate an enrollment "grace period" for individuals with disabilities, as well as for other specific population with special health care needs (see our comments under Subpart C, section 423.120(b) for our discussion of populations with special needs). The rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to these beneficiaries, many of whom require on-going treatment for one or more conditions or illnesses. These individuals may well require additional time to make a selection and complete the enrollment process—the confusing nature of the program, coupled with their on-going treatment needs, may make plan choice and selection particularly difficult for them. Therefore, CMS should incorporate a late enrollment "grace period" for these populations.

- **Special enrollment opportunities/no penalties for incorrect notice of change in coverage status (see also Section 423.56).** 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 of a change in status of that coverage, and that coverage is not creditable, beneficiaries should not face late enrollment penalties.

Section 423.48, Information about Part D.

General concern/comment on this section: 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. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate.

SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and Area Agencies on Aging, 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.

Information plans must provide.
This section states that "each PDP and MA-PDP plan must provide …information necessary" to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient.

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. Plans should also be required to notify CMS during the year within 2 business days of any changes in a plan's formulary, pharmacy network, drug prices, or any other aspects of

plan benefits or operation that could affect enrollees' access to prescription drugs or financial liability for drug costs. In order to ensure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance.

In addition, CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments as well. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. Furthermore, plans must be required to make information available in languages other than English, to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. CMS should continue to make the information available upon written request and through 1-800-Medicare. We urge CMS to continue to work to improve these information sources, as they sometimes are difficult to use by consumers.

Minimal information plans should be required to provide. While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on the benefit itself that potential enrollees will need in order to make a choice among plans and plan offerings. That should be specified in this section. Specifically, beneficiaries will need to understand:

- 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 copay 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. (Plans should be required to report formulary changes during the year to CMS and to update information on their websites to reflect those changes.)

- Participating pharmacies, mail order options, out-of-service options.

- Appeals and grievance processes.

- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans.

Beyond providing this information to CMS, plans should also 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 (see comments on section 423.50, below). Therefore, we urge that CMS specify the minimal information that plans will need to provide. As noted, guidance is insufficient.

Specifically, we urge CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees, who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. We urge CMS to require plans to publish, as part of their marketing materials, price information in addition to posting negotiated price information on their website.

Printed price information for marketing materials could be provided in a manageable format. For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish, in a standardized format, their negotiated price for each of those drugs, with clear information on how to get price information on additional drugs through a toll-free number (the plan's and 1-800-MEDICARE) or the Internet (referencing both the Plan's site and the Medicare website). Such a list would be easy to prepare and take only about one page in marketing materials (again, see comments on 423.50, below).

Information and outreach for dual eligibles.
In the Preamble, CMS states that "prior to [this] automatic enrollment process, a widespread education and information campaign (described later in this subpart at Section 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled" (Federal Register, Vol. 69, No. 148, Tuesday, August 3, 2004, Proposed Rules, page 46638). Such an education and information campaign targeted to dual eligible individuals and that does equip them to select among plans and enroll prior to automatic enrollment is critical. However, the proposed regulations fall far short.

In the Preamble, CMS discusses education and information materials that it will provide to beneficiaries. This discussion focuses on support through the Internet sources and the 1-800-Medicare number. Both are necessary but, as noted above, insufficient to meet the needs of the Medicare population and particularly insufficient to meet the education and information needs of dual eligibles. This is a difficult to reach population with limited Internet access and, in many cases, limited telephone access. Further, the NPRM does not outline any requirements for meeting the needs of this population in the proposed Section 423.48.

The regulations should include specific requirements for plans and states, as well 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. Extensive outreach and assistance has helped limit the need for default enrollment in Medicaid managed care programs. The states or CMS must also involve community-based organizations and providers that serve and work with dual eligibles in this enrollment process. CMS should offer grants and other resources to help these organizations and providers inform dual eligibles of their choices and what they need to do to sign up. These organizations can provide culturally appropriate outreach and assistance to help duals find the best plan available to them and let them know that they can switch plans through the special enrollment provision in § 423.36 if they have been automatically enrolled in a plan that is not the best for them.

In addition, as early as possible, and no later than October15, 2005 (assuming information is available as recommended in 423.34(d), above), CMS or the states should mail standardized, easy-to-understand notices to

dual eligibles that, among other things: (i) inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA; (ii) list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; (iii) 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; (iv) explain how they may change their drug plans if they wish at any time; and (v) 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.

Section 423.50, Approval of marketing material and enrollment forms

General Comments/Concerns
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(c) Guidelines for CMS review.
This section vaguely specifies benefit information that plans must provide in their marketing materials in subparts (i), (ii), and (iii). We urge CMS to include more specific requirements. It will be important that beneficiaries have comprehensive information on plan benefits and drug prices, since the drug co-pays, coinsurance and donut hole costs they might have to pay could be substantial. We recommend that CMS require that plans make available add to the following critical points for information —through the Internet, toll-free customer service lines, and in print—on benefits and benefits structure:

- **Information on the formulary**: What the formulary is; information on the fact that the formulary might change; what notice will be provided if there is a formulary change; and, a complete formulary list, with cost-share tier information for each formulary drug. The complete formulary list with corresponding cost-share tier information should be required on each plan's website (and should be required to be current) and in print material available to beneficiaries. Plans should be required to provide some specific formulary information in their standard print marketing materials. For print marketing materials the formulary list might be shortened, for example, to cover the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries as outlined in section 423.48, above. However,

CMS should require that all plans provide information on the same drugs so that beneficiaries can more easily make plan-to-plan comparisons. With this list, plans should be required to provide instructions on how to access information on additional drugs through the Internet, the plan's toll-free number, and 1-800-MEDICARE.

- **Information on drug prices.** A description of the "negotiated price," what it is, when it applies, how it might change, and (on the Internet and available in print through request) the negotiated price for each drug. For standard print marketing materials, plans should be required to provide some price information. For this material, the list might be shortened, for example, to price information for the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries, comparable to the suggestions for formulary information, above. In standard print marketing materials, plans should be required to provide instructions on how to access price information for additional drugs through the Internet, a toll-free number, and 1-800-MEDICARE.

- **Premium information**. Information on plan benefits and the premium (for the basic benefit and any other benefit structures offered). If a PDP offers multiple plans in a single area, marketing material should include a side-by-side comparison of the benefits for each offering. For each offering, PDPs should be required to note, clearly and conspicuously, whether individuals qualifying for the low-income subsidy will have to pay a premium and, if so, the amount that will have to be paid.

- **Information on plan performance**. After 2006, plans should be required to include in their marketing materials basic information on the plan's prior performance: number and type of appeals and grievances filed and outcome for each type, and performance on other quality measures collected by CMS.

All of the information outlined above will be critical if beneficiaries are to make informed choices among plans. It should be part of standard marketing materials; potential enrollees should not have to request this basic information.

423.50 (e), Standards for PDP marketing.
Prohibit telemarketing. Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. There have been numerous reports of

telemarketing fraud under the Medicare Drug Discount Program.[4] The Part D benefit is susceptible to even more fraudulent business practices. 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.

Prohibit marketing of other services. 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 seems to believe that this would encourage entities such as financial services firms to participate as prescription drug plans. 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. This would be unadvisable for several reasons:

- Having plans offer added services would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved plan"; the difficult task of comparing plans would become even more complex for potential enrollees; beneficiaries might mistakenly believe that they need to take an entire package of offered services when they sign up for the drug plan. This section prohibits marketing activities that could "mislead or confuse." Allowing plan sponsors to market added services is so apt to create situations that confuse and mislead beneficiaries that it is in direct conflict with the provisions of this section.

- Financial institutions claim they are exempt from the HIPAA Privacy Rule; CMS should not encourage entities that take this position 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.

Prohibit provider marketing.
CMS asked for comment on the applicability of MA marketing requirements for PDP marketing.

We recommend that marketing 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.

[4] See Lori Racki, *Medicare Scams Prey on Seniors*, Chicago Sun-Times, News Special Edition at 8 (May 24,2004).

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.

We can easily foresee such skewed marketing occurring if a pharmacy has a contract with only one PDP or has more favorable contract terms with a specific PDP. Providers with relationships with a PDP plan might market that plan more heavily. We urge CMS to consider the potential for provider and pharmacy-based marketing to steer beneficiaries into inappropriate PDPs and, in response, to make marketing requirements extremely protective of consumers. Given the high potential for abuse, we recommend that providers, including pharmacies, not be allowed to market specific PDPs or MA-PDPs. Health care providers should be a source of balanced information on the program, plan choices, and how to select a plan. They should not be allowed to verbally, or otherwise, promote a specific PDP or MA-PDP.

While we recommend against allowing providers, including pharmacies, to market individual PDPs, if providers are allowed to engage in marketing, we recommend the following minimal requirements:

- Pharmacies and any other providers displaying plan materials should be required to provide equal space and prominence to materials from all PDPs/MA-PDPs available in the area, not just those with which they have relationships;

- Marketing be limited to the display of information as outlined above. Active promotion of any specific plan by a provider should be prohibited.

Do not allow plans to use Medicare discount card enrollee and applicant information. The regulations should prohibit prescription drug plans from obtaining and using Medicare Drug Discount Card enrollee and applicant information, and information collected from any other card programs the company might sponsor.

It is foreseeable that many Discount Card sponsors will apply to be prescription drug plans. As Discount Card plans, these entities will have beneficiary-level information on drug use, creating the potential for prescription drug plans to use Discount Card information to target marketing to low-cost beneficiaries, either directly or through marketing firms.

Section 423.50(e)(2) prohibits drug plans from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." The regulations should:

- Specifically prohibit prescription drug plans from obtaining or using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor.

- Prohibit others from using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor to market on behalf of a prescription drug plan sponsor.

Specify whether and how the Secretary can provide information to prescription drug plans. The MMA added section 1860D-1(b)(4)(A) to the Social Security Act. This permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."[5]

The proposed rule does not contain any provision governing whether and how this information will be provided and in the Preamble, CMS seeks comments on a number of operational issues as well as on the provision in general.

The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair information practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. There may be some marginal benefit in the Secretary's providing information to prescription drug plans if the plans send information to eligible individuals information that would actually be useful in determining which plan to select. We recommend the following in the disclosure of identifiable information:

[5] H.R. CONF. REP. NO. 108-391, at 432 (2003).

- If the Secretary provides information to prescription drug plans, the information provided should be limited to the minimal amount necessary: the potential enrollee's name and address. No health or financial information should be disclosed.

- The Secretary should disclose identifiable information to prescription drug plans to facilitate marketing or enrollment only if the plan's marketing materials contain formulary and drug pricing information or are accompanied by an application form. This approach could help balance privacy concerns with the need for beneficiaries to obtain important plan information.

- The Secretary should not disclose telephone numbers. Telemarketing should be prohibited; there is no need for plans to have beneficiary phone numbers unless provided by the beneficiary.

- Beneficiaries should be given the choice of whether they want this information disclosed. We suggest that an opt-in approach be used to ensure that beneficiaries do, in fact, want their information disclosed. The op-in notice should be clear; written with the Medicare population in mind; state what will be shared; and clearly state that even if a beneficiary elects to opt-out, they can still enroll in the benefit, they will still receive information about the benefit from CMS, and they can still request information directly from plans.

Section 423.56, Procedures to determine and document creditable status of prescription drug coverage.

Section 423.56 (e), Notification. 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. We recommend the following as minimal notice to beneficiaries.

- **Notice in 2005.** In 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such valuable documents as quarterly retiree income statements, medical

billing correspondence, etc.

- **Notice after 2005.** In future years, we urge CMS to develop standard notices, through its Beneficiary Notice Initiative, to be used in this regard. The standard notices CMS has developed through this initiative have helped ease confusion about Medicare coverage in other situations.

- **Changes in status of coverage.** The most important point is that in years after 2006, when creditable status changes, special notification is needed. Individuals need to know as soon as the decision is made to reduce coverage, so that they can begin shopping for a PDP and avoid a lifetime of premium penalties. As MedPAC has reported, six months lead time in switching plans is ideal, and shorter transitions are fraught with confusion and chaos. An individual should be notified as soon as the entity's management decides to reduce coverage below the "creditable" requirement. Such a notice is too easy to miss in the wave of mail and solicitations that many households receive. Because it is a very important notification, we urge that it be sent by registered mail, or e-mail with proof of receipt.

- **Information on value of the creditable coverage benefit.** We support the CMS idea that "given the importance of knowing whether coverage constitutes 'creditable coverage'" health plan sponsors should provide information to their enrollees about the value of the benefit, the annual premium, and the amount that the beneficiary will be required to pay. More information to consumers will help them understand how their coverage compares and whether they may want to seek Medicare coverage.

In cases where individuals 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). In other words, each individual adversely impacted by the failure of the employer or other entity to adequately inform should not have to apply or appeal for a SEP. (See also comments on Section 423.46.)

In addition, in the appeals section (subpart M), it should be made clear that questions relating to creditable coverage and notice of when such coverage changes should be eligible for the full range of appeals rights.

Finally, we urge CMS to make clear to those attesting to actuarial equivalence (or non-equivalence) and creditable coverage what the penalty is for false attestation. We assume that this would be a violation of the False Claims Act or other laws.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

Section 423.100, Definitions.

Definition of "dispensing fee" to permit coverage of home infusion-related services.
We recommend that the final rule include a definition of "dispensing fee" that is 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.

We do not support option 1 for the definition of "dispensing fee" because we believe it 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 we do not support option 2 because we do not believe that the definition captures all of the true costs associated with the dispensing of a covered Part D drug.

Definition of "long-term care facility" to 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. 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 Requirements related to qualified prescription drug coverage

Definition of "person" so that family members can pay for covered Part D drug cost-sharing.
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, HRAs, and FSAs by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) do not count as incurred costs.
The proposed regulations state that contributions made by an AIDS Drug Assistance Program (ADAP) on behalf of a beneficiary will not count towards the beneficiary's true out-of-pocket costs, which is necessary to reach the catastrophic limit. We strongly recommend that the final rule count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. If a state ADAP program decides to provide cost-sharing subsidies, these subsidies must be counted as incurred costs. 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 in gaps left by other federal programs, including Medicaid and Medicare.

Federal funds for ADAP programs are appropriated by Congress on a discretionary basis. Notwithstanding the decision by a state to use ADAP funds to subsidize Part D cost-sharing, federal costs do not increase. Further, ADAP funding has not kept pace with growing need over the past decade, and this has led to increases in the number of individuals on waiting lists for ADAP services, as well as restrictions and limitations in ADAP formularies. In this environment, should a state prioritize providing Part D cost-sharing subsidies, federal policy should not create a disincentive for states to make the most prudent resource allocation decisions. Furthermore, the populations

served by ADAPs are predominately low-income and often take multiple prescription drugs. Therefore, even Medicare subsidized cost-sharing for low-income Medicare Part D enrollees could provide a significant barrier to accessing prescription drugs. This has grave implications both for the medical management of HIV/AIDS in the affected individual, but also public health implications resulting from increased risk of the development of resistance to currently available HIV-related antiretroviral medications and therefore an increased risk of transmission. Discouraging ADAPs from subsidizing beneficiary cost sharing by not counting as incurred expenses ADAP expenses spent on premiums, deductibles, cost-sharing or the amount spent filling in the donut hole, could leave people living with HIV/AIDS who receive Medicare benefits vulnerable to fall through the cracks.

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 counting state dollars 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 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 appropriated state dollars. It is inexcusable to exempt people living with HIV/AIDS from receiving this type of help from their state, while allowing people with other medical conditions to benefit from their state dollars.

Similar consideration should be given to payment from the Veterans Administration and the Indian Health Service. These programs serve disproportionately vulnerable populations who, like people with HIV/AIDS, need the extra assistance.

Maximizing savings for people needing HIV/AIDS medications under the 340B program.

The regulations encourage state ADAPs to move toward the model of purchasing their drugs directly, under the 340B program, instead of using a rebate model. We feel it is completely inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by the Health Resources and Services Administration (HRSA), the federal agency that oversees the Ryan White CARE Act and the 340B Program.

As mentioned, there are several states that use a rebate option model available to ADAPs under 340B to purchase drugs instead of the direct purchase model. These states, including California and New York, the two largest ADAPs, have carefully analyzed the cost benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study which demonstrated that after calculating rebates, they receive prices for HIV pharmaceuticals comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms.

Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size and geography and demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen. ADAPs have and will continue to use every mechanism available to receive the best prices for their HIV-related drugs, including negotiating for supplemental rebates and discounts.

Coordinating between ADAPs and Medicare Part D benefits.
Any coordination between ADAPs and the Medicare Part D PDPs is, under the proposed rules, completely voluntary on the part of the PDPs. There are several issues that would inhibit the coordination of benefits between ADAPs and PDPs. Most importantly, since ADAPs' expenditures for beneficiaries would not count as incurred costs and thereby not allowing many of the HIV-positive beneficiaries living with HIV/AIDS to reach the catastrophic limit, ADAPs would have no strong incentive to collaborate with private drug plans. Furthermore, PDPs could charge ADAPs for any coordination between the two entities. The proposed coordination would not result in any significant amount of cost savings and would not be cost-effective for the ADAPs. Finally, it could potentially be very difficult for ADAPs to coordinate with multiple PDPs participating in the Medicare program in a given area. Under these proposed rules, it is not feasible for ADAPs to coordinate with PDPs. However, if CMS would allow payments made by ADAPs to count as incurred costs, coordination between ADAPs and PDPs could result in substantial costs savings and therefore provide incentive for ADAPs to collaborate with PDPs.

We are interested in exploring methods of collaboration between ADAPs and PDPs that could allow beneficiaries living with HIV/AIDS to benefit from the 340B pricing. We understand that several 340B entities have begun entering into partnerships with various state and local government programs to provide more individuals access to 340B pricing. However, there are so many

complexities and unknowns about the Medicare Part D prescription drug program and its effects on ADAPs that we are not prepared to comment on the details of any such collaboration at this time.

423.104(e)(2)(ii), 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 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. In another section, we also comment on what we view as a wholly inadequate exceptions process.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would place Medicare Part D enrollees in 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% 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).

423.104(g), Basic alternative benefit designs that go beyond actuarially equivalent standard coverage.
We are strongly opposed to the provisions of § 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 § 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. We further recommend that 423.104(e)(2)(i)(B) (re: actuarially equivalent cost sharing) should be moved and should be included as an option under the description of alternative coverage at 423.104(f), re-numbered as 423.104(f)(2).

423.104(h), Access to negotiated prices when the beneficiary is responsible for 100 percent cost-sharing.
We strongly oppose allowing any plan 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.

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.

Section 423.120, Access to covered Part D drugs.

423.120(a), Access standards must be met in each local service area.
We support the inclusion in the final rule of the provision in the proposed rule that requires 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. A key principle of the MMA is that Medicare beneficiaries will have convenient access to a local pharmacy. By permitting plans to meet the access standards across more than one local service area could only lead to individuals in some local service areas to not have convenient access to a local pharmacy.

Counting only retail pharmacies as part of their networks for the purpose of meeting access standards.
We support the inclusion in the final rule of the provision in the proposed rule that only counts retail pharmacies for the purpose of meeting pharmacy access standards. Because of the principle that Medicare beneficiaries should have convenient access to a local pharmacy, it would undermine this principle 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.

Counting Indian and Tribal pharmacies as network pharmacies for the purpose of meeting access standards.
We recommend that the final rule 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.

If the final rule requires plans to offer a standard contract to I/T/U pharmacies, then we are supportive of counting these pharmacies for purposes of meeting

network access standards. We believe it is an important national policy goal and an important treaty obligation to preserve and protect access to programs providing health services to American Indian/Alaska Native populations through I/T/U programs. Further, I/T/U programs should be fully reimbursed for all costs associated with providing prescription drugs through the Medicare Part D program.

Requiring prescription drug plans and MA-PD plans to offer their standard pharmacy contracts to some or all long-term care pharmacies in their service areas.
We recommend that the final rule 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.

Balancing convenient access with appropriate payment for long-term care pharmacies.
We believe 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 prescription drug plans to contract with all LTC pharmacies;

- Alternatively, the final rule could require prescription drug plans to make available a standard contract to all LTC pharmacies, and 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.

Permissible ways to assure Part D enrollees' access to FQHC and rural pharmacies, among others.
Federally qualified health centers (FQHCs) and rural health centers play a critical role in bringing doctors, basic health services and facilities into the nation's neediest and most isolated communities. These programs operate in over 3,600 communities - spanning urban and rural communities in all 50 states, the District of Columbia, and all territories. We recommend that the final rule require prescription drug plans to offer to contract with all FQHC and rural pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an FQHC or rural 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.

423.120 (a)(4), Requiring PDP sponsors and MA organizations to make available a standard contract for participation in their plan's network.
We recommend that the final rule require plans to make available to all pharmacies a standard contract for participation in their plan's network. Section 1860D-4(b) of the MMA requires plans to permit the participation of any willing pharmacy, and also requires prescription drug plans to provide for convenient access for network pharmacies. We believe that these requirements are best achieved by requiring plans to make available a standard contract for participation in their plan's network. We also believe that this also has other important advantages in terms of ease of administration and expanded beneficiary access.

423.120 (a)(5), Permitting lower cost-sharing for preferred pharmacies through higher cost-sharing for non-preferred pharmacies or as alternative prescription drug coverage.
We recommend that the final rule permit lower cost sharing for preferred pharmacies only when the plan's network of pharmacies exceeds the minimum regulatory requirements for network adequacy. In addition, as recommended previously, enrollees who are required or who have specialized needs that make it desirable to use specialized pharmacies, including I/T/U pharmacies and LTC pharmacies, should not be penalized by having to pay higher cost-sharing.

423.120(a)(6), Counting the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy (vs. a network mail-order pharmacy) as an incurred cost.
We recommend that the final rule ensure that beneficiary costs paid out-of-pocket used for the purchase of covered Part D drugs count as incurred

costs. A key principle of the MMA is that Medicare beneficiaries will have convenient access to a local pharmacy. We believe that 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. 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: use authority to review plan design to ensure non-discrimination.

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.

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, cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs.

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), Requiring P&T committee decisions regarding the plan's formulary to be binding on the plan.

We strongly recommend that the final rule ensures that 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 rationale for 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.

We also believe 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, we will make clear that we have 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 plan financial considerations and it must reinforce the independence and broad-based clinical expertise of P&T committees.

423.120 (b)(1), Requiring certain P&T committee members to be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers.
We support the proposal in the proposed rule to ensure that the final rule interprets the requirement that certain P&T members be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers. The essential function of the P&T committee 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.** We strongly recommend that the final rule include far stronger provisions than are found in the proposed rule 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 expand on the MMA's requirements for independent expertise in the care and treatment of the elderly and people with disabilities. Because of their unique experience at serving institutionalized populations, a significant subset of the Part D eligible population, the final rule should expand the P&T committee requirement to also include members who are independent LTC pharmacists.

  At a minimum, 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.

  Notwithstanding the size of the committee, it will not be possible for any committee to have adequate expertise in all areas. Therefore, 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.

- **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 public. The final rule should require P&T committees to hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies. The final rule should specify that meetings of the P&T committee should be open to the public. Further, 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 disabled populations.

- **Timely Review:** The final rule must require P&T committees to meet at least quarterly, and have processes for making formulary revisions between regularly scheduled meetings when new clinical information or FDA approval of medications occurs that could be used for the treatment of life threatening conditions.

423.120(b), Formulary requirements.
We have many concerns related to formulary requirements.

Ensuring continued access to accepted "off label" use.
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 prescribers to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

While we understand concerns by CMS that certain pharmaceutical manufacturers may violate federal law by marketing drugs for off-label uses, 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 strongly 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.

- **Recommendations for preventing access barriers to covered Part D drugs for off label uses.** We strongly recommend that the final rule include a clear prohibition that prevents plans from denying coverage for a covered part D drug solely because it is prescribed for an off-label indication. We are deeply concerned that while the MMA clearly permits plans to cover covered Part D drugs for off-label indications, financial incentives could lead plans to inappropriately restrict coverage for off-label uses. As stated previously, off-label prescribing has become a common practice across a broad spectrum of clinical conditions. In enacting the MMA, Congress did not carefully consider issues related to off-label prescribing and it would be improper to implement the MMA in a way that removes the ability of treating physicians to prescribe the full pharmacopoeia of FDA-approved medications when medically necessary.

Standards and criteria for determining that a PDP sponsor or MA organization's formulary does not discriminate against certain classes of Part D eligible beneficiaries when using a classification system not based on the USP model guidelines.
In a CMS Discussion Paper, *The Role of USP Draft Model Guidelines for Formulary Classification in Determining Formulary Adequacy for the Medicare Drug Benefit*, CMS states the following:

> Our formulary review standards and processes are under development and will be released in draft form in the Fall for public comment. We are seeking preliminary comments at this time on the factors to include in this guidance and on how our formulary assessments should interact with formulary classification systems…CMS will evaluate formularies at a more granular level than described by the Model Guidelines to make sure they include sufficient choices of clinically significant drugs…CMS also will not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. For example, plans will not be allowed to price all antiretroviral drugs in the highest tier. However, this does not mean that these beneficiary groups cannot be subject to tiered cost sharing, just that such tiering cannot be designed to discourage enrollment of that specific beneficiary group…Finally, CMS will review drug plan prior authorization requirements, exceptions criteria and appeal policies. We

> understand that prior authorization techniques include clinically appropriate step therapies or diagnosis-related restrictions. Nevertheless, our focus will be to determine if specific beneficiary groups are disproportionately affected by such requirements. CMS will examine the drugs that are subject to prior authorization and the associated criteria for obtaining approval.

We are supportive of many of the intentions stated in this discussion paper. Nonetheless, we strongly believe that any review standards developed by CMS must be published as legally-enforceable regulations, and not as guidelines. Moreover, the standards for public comment on these critical standards must meet the requirements of the Administrative Procedures Act.

However, we object to some of CMS' stated intentions. In particular, the example provided in the text highlighted above illustrates a major concern with CMS' planned review process. CMS stated that, "plans will not be allowed to price all antiretroviral drugs in the highest tier. However, this does not mean that these beneficiary groups cannot be subject to tiered cost sharing, just that such tiering cannot be designed to discourage enrollment of that specific beneficiary group." We assert that the treatment of antiretrovirals is a clear example when tiered cost-sharing should be prohibited, and is per se discrimination. This is because directing utilization to particular antiretroviral drugs on the basis of cost (or other plan criteria) is in every instance clinically inappropriate and irresponsible. In this context, there are serious public health implications in shifting prescriber behavior away from providing the most efficacious treatment regimen based on highly individualized criteria and the experience of an HIV treating physician consistent with Federal clinical practice guidelines. This is true of many other disease categories.

CMS has stated that it will not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. We urge CMS to interpret groups to extend beyond health status. In particular, there is a growing body of evidence that highlights racial and ethnic differences in responses to specific drugs. We urge CMS to ensure that they evaluate plan formularies for their impact on racial and ethnic groups, in addition to other "groups" for whom group status may be unrelated to health status.

As stated above, CMS has acknowledged that, "prior authorization techniques include clinically appropriate step therapies or diagnosis-related restrictions." We also strongly recommend that CMS publish in the final rule a list of conditions for which it is clinically inappropriate to require step therapies. For

guidance on developing such a list, we recommend that CMS consider the experience of many state Medicaid programs. In most states employing fail-first or step therapy requirements, clinical experience has led many states to exempt certain conditions, including mental illness and HIV/AIDS.

Special treatment for specific populations and defining which specific populations to include.
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 that could create insurmountable access barriers. ***We recommend that the final rule must provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs with a valid prescription.*** 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 income except 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. According to a Metlife survey, in 2002, the average monthly cost of a private room in a nursing home was $5,110 and the average monthly cost of a semi-private room was $4,350. By July/August of 2004, Metlife reported that for a private room, the average monthly costs had risen to $5,840—a 14 percent increase over 2002.

- **Persons with Life-Threatening Conditions:** Persons with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening need to have unrestricted and affordable access to the full range of available treatments. Protections in the MMA intended to ensure that beneficiaries will have access to all needed medications are inadequate for persons with life-threatening conditions. For example, the MMA requires P&T committee 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. For example, research shows that different antipsychotic medications affect different portions of the brain. The Report of President Bush's New Freedom Commission on Mental Health states that "any effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services" (New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in American; Final Report*, p. 26).

  We recommend 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 require access to an affordable and flexible alternative formulary. This category should encompass:

  - Persons with conditions that are recognized for their pharmacological complexity. At a minimum, the list must include 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 critical dose drugs and 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.

Require plans to accept evidence of prior documented therapy failures.

If, prior to enrolling a specific PDP, an enrollee has tried a preferred therapy under medical supervision and the enrollee or enrollee's physician can document that preferred drug is not appropriate, the PDP should be required to accept the prior medical record as proof that the therapy is inappropriate, rather than requiring the enrollee to try and again fail on the preferred drug. The prior medical record should be sufficient evidence for coverage appeals and requests for formulary exceptions (see comments on section 423.578(b).

Minimum timeframes for periodic evaluation and analysis of protocols and procedures related to plan formularies.
We recommend that the final rule require plans to evaluate and analyze their protocols and procedures related to plan formularies at least quarterly. For many conditions, every month brings significant advances in the clinical management of disease, making it essential that the final rule require regular ongoing and timely review of their formulary protocols and procedures.

Notification requirements for enrollees directly affected by a formulary change.
The proposed rule provides notification provisions regarding formulary changes that are inadequate 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 the 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.

Recommendations for limitations on mid-year formulary changes.
We 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. 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 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, we strongly recommend that plans 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

Broader out-of-network standards as an alternative to emergency access standards.
We support inclusion in the final rule of provisions that establish out-of-network access standards. Nonetheless, this requirement is insufficient to provide for emergency access to covered Part D drugs. 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 that 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.

Out-of-network access requirements.
We recommend that the final rule 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:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;

- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;

- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her plan's pharmacy network; and

- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly

from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail order pharmacies.

Definition of usual and customary price.
We recommend that the final rule define "usual and customary price" to be, "the maximum price that a pharmacy would charge a customer who is a Medicare beneficiary participating in an in-network Part D plan."

Counting the cost differential for receiving a covered Part D drug at an out-of-network pharmacy at the usual and customary price (vs. a network pharmacy) as an incurred cost.
We recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs. Therefore, if the final rule permits Part D participants to be charged the cost differential for receiving a covered Part D drug at an out-of-network pharmacy versus at a network pharmacy, then the rule must require that this differential is counted as an incurred cost.

Proposed payment rules at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.
We recommend that out-of-network pharmacies that are outside of an individual Medicare beneficiary's local service area be required to charge beneficiaries no more than the maximum charged to any in-network plan that they participate in. Further, we recommend that pharmacies be permitted to charge out-of-network customers who are out of their local service area prices as low as the deepest discounted price for in-network participants in any Part D plan accepted by the pharmacy.

Section 423.128, Dissemination of plan information.

423.128 (d), 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.

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:

- **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. (See our comments in Subpart B, Section 423.48, Information about Part D.) 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% 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.

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. With today's technology, this information should be available at each point of the sales transaction. The notice should also tell people how to appeal or to request an exception.

In addition, information on a beneficiaries' annual out-of-pocket and total spending to date should be available at the point of sales. Since the standard benefit includes a benefit "gap", it will be especially important for a senior to know how much each prescription will cost as well as whether the next prescription filled will have higher or lower cost sharing due to the beginning or end of the benefit gap.

Section 423.132, Public disclosure of pharmaceutical prices for equivalent drugs.

Costs to nursing home patients.
The law requires that in general a person be told about the lowest cost generic available under a plan at the time they pick it up at a network pharmacy (or receive it in the mail). The Secretary is given discretion to waive that disclosure requirement, and the Preamble discusses (p. 46665) whether such information should be given to long term care residents, given the special ways in which medicines are delivered in nursing homes. We believe that many nursing home residents, their families, or their representatives would like to know if savings are possible, and we urge that such information be made available.

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.

We have serious concerns that the proposed regulation 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 regulation 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.

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." 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.

We also strongly recommend that the final rule 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. 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.

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.

For example, after the state of Michigan implemented a restrictive preferred drug list for its Medicaid program, a hotline was established for consumers and providers to report their experiences: sixty-six percent reported medication delays or said they had suffered negative consequences after being forced to switch medications (*Report on Prescription Access Hotline, April 22 – June 14, 2002,* Mental Health Association in Michigan and Michigan Association for Children and Families, February 2003). 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, and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, 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 consumers who have been stabilized on a particular psychiatric medication to switch to another medication can be very dangerous for the consumer 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.

In a very recent report entitled "Psychiatric Medications: Addressing Costs without Restricting Access" (August 20, 2004), CMS encourages State Medicaid Directors to implement innovative approaches to controlling costs without restricting access. CMS must encourage Part D prescription drug plans implementing the Medicare drug benefit to implement these same cost management techniques as alternatives to the more common approaches that restrict beneficiary access to medications. 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). They 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.

Section 423.153, Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

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.

More needed in quality assurance.
In the preamble, CMS lists the elements that are "desirable" for quality assurance programs (electronic prescribing, clinical decision support systems, educational interventions, bar codes, adverse event reporting systems, and provider and patient education.) but then says "We do not expect PDPs and MA-PD plans to adopt all of these elements." This is insufficient. We recommend that the final rule require all plans to operate quality assurance programs with all of the listed elements.

In addition to the listed elements described above, the final rule must require plans to include clinical decision support systems and educational interventions including –

- Programs that use claims data and physician referral triggers to identify treating-physicians and consumers who have specific diseases such as asthma, diabetes, schizophrenia, depression, and substance abuse/addiction disorders and provide educational tools and materials to

these providers to encourage more coordinated care for these consumers;

- Programs that 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 and provide educational interventions designed to align these physicians prescribing practices with best practice guidelines;

- Closer scrutiny of utilization data to manage cases of polypharmacy; and,

- Algorithms and other practice standards that promote appropriate prescribing based on clinical data and evidence-based practice.

These interventions not only serve to contain drug costs as discussed above, but also improve the quality of patient care.

The public needs to know about a plan's quality.
The preamble notes that "In the future, we may require quality reporting that includes error rates." This is a key quality indicator that should shape consumer selection of plans. We urge that data on plan error rates, even if just a sampling in 2006, be made public in the first year of the program and all in future years.

Medication Therapy Management Programs: The need to stress quality improvement and let the public know the outcomes.
We urge that the financial incentives in MTMP (423.153(d)(5)) encourage quality outcomes and not reduced costs. Payment for reducing costs without regard to quality will lead to creative and devious forms of rationing. The preamble says that CMS "may provide a mechanism for plans to demonstrate" the value of their MTMPs to the public. We urge CMS to make it clear that such a mechanism shall be developed.

The preamble to the proposed rule states that "MTMPs can lead to improved overall health for individuals while at the same time decreasing overall healthcare costs resulting from improper medication use and adverse drug events". States are using many of these components in their Medicaid programs for individuals with mental illness and other chronic illnesses and are observing improvements in treatment outcomes, reductions in polypharmacy, and successful efforts to contain costs. CMS should look to provider education interventions programs in Pennsylvania and Missouri and the Texas Medication Algorithm Project for best practices that should be implemented by drug plans in their MTMPs.

In the preamble, CMS states that plans should have discretion to design or "customize" their MTMPs because the best approach is to let the market shape these programs. We disagree with this reliance on the market to set required parameters for the MTMPs. We do not believe that stand alone prescription drug plans have sufficient incentives to devote significant resources and attention to developing MTMPs that would improve overall health.

The proposed rule proposes to delegate to private prescription drug plans authority to set an annual cost threshold and invites comments on how to set this level and what persons with multiple chronic diseases to include. Although the types of activities described by CMS as components of MTMPs would save drug costs in the long run, in the short term there will be added costs in implementing these activities and thus PDPs and MA-PDs will have a disincentive to identify enrollees as qualifying for this additional benefit. Therefore, it would be highly inappropriate for CMS to delegate to these plans authority to determine the annual cost threshold to qualify for this benefit. Furthermore, plans will not be interested in attracting enrollees who would qualify for these benefits and thus they would naturally want to set the threshold drug cost amount very high. We recommend that you look to Medicaid claims data for dual eligibles to develop estimates of annual drug costs of beneficiaries with multiple medications and multiple chronic diseases.

In the preamble to the proposed rule, CMS suggests that it may be appropriate to go beyond the statute's requirement that pharmacists provide MTMP services. We agree. MTMP services cannot all be appropriately delivered by a pharmacist. Many of these activities will require complex interactions with a trusted provider and will require face-to-face consultations that cannot be adequately performed over the telephone – e.g., health status assessments, monitoring patient response to drug therapy, and coordination with other case management. As discussed in the preamble, to ensure the effectiveness of their MTMPs, plans must develop and maintain on-going beneficiary-provider relationships and enable beneficiaries to choose providers of these services. Having services delivered by a trusted provider is critical to successful medication therapy.

CMS proposes to leave it up to plans to determine whether to pay other providers to perform MTMP services. Given the importance of the beneficiary-provider relationship that CMS acknowledges and the fact that they state that all MTMP services should not be performed by pharmacists (e.g., developing drug treatment plans for complex and comorbid conditions), CMS must specify in the final rule that MTMPs are to incorporate the services of physicians, as well as pharmacists, and that beneficiaries shall be able to

choose the providers from whom they would receive MTMP services. The final rule should also require that, to the greatest extent possible, beneficiaries may receive MTMP services from their current providers. To ensure that MTMP services are readily available to those beneficiaries who qualify for them, adequate fees must be provided to the pharmacists and physicians offering these services. Adequate fees are also critical to ensuring that beneficiaries have a meaningful choice among pharmacist and physician providers of the MTMP benefit.

Section 423.156, Consumer Satisfaction Surveys.

Consumer satisfaction surveys: start in 2006.
We urge that the first surveys be conducted starting in 2006 with the results available before the fall 2006 open season. The preamble and the proposed rule do not describe an effective date.

Section 423.159, Electronic Prescription Program.

Electronic Prescription program: Initiate as soon as possible.
We support and commend CMS's efforts to expedite, in every way possible, the development and widespread use of e-prescribing. The life-saving safety and quality improvements from such a system will be enormous.

Section 423.165, Compliance deemed on the basis of accreditation.

Compliance deemed on the basis of accreditation.
We do not support the proposed deeming requirements in the proposed rule. We believe that deeming compliance significantly diminishes the beneficiary protections in the MMA and serves only to protect certain organizations from having to comply with key provisions of the statute. We strongly recommend that the final rule delete the provisions in § 423.165.

SUBPART F, SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUM; PLAN APPROVAL

Section 423.265, Submission of bids and related information.

423.265 (a), Eligibility for bidding.
There is nothing in paragraph (a) that precludes a prescription drug plan (PDP) from being owned by or affiliated with a drug manufacturer. The recent history of drug manufacturer and drug delivery firm cooperation shows that this type of relationship invariably leads to the products of the manufacturer being promoted, regardless of whether they are the best product, or the lowest cost. It will be nearly impossible for CMS to prevent such abuses of beneficiaries, and therefore we urge that the regulations prevent groups affiliated with manufacturers from providing the Part D benefit. As the Preamble states in the discussion of fallback plan negotiations, CMS "would also ensure that there is no conflict of interest leading to higher bids." Banning financial relationships between manufacturers and PDPs is the best way to prevent such a conflict.

423.265(d)(2)(iv), Actuarial value of bid components: ensuring that low-income beneficiaries pay no more than the cost-sharing specified by law.
Prescription drug plans are allowed to vary the cost sharing from the standard benefit if the resulting benefit design is actuarially equivalent. As reflected in our comments in Subpart C, section 423.104, we have serious concerns about plans' use of actuarial equivalence to create benefit designs that, in effect, discriminate against high-cost enrollees. We also have serious concerns regarding the use of "actuarial equivalence" and the low-income benefit.

If plans are allowed to claim "actuarial equivalence" to increase the upper-end of the low-income cost-sharing amounts beyond what was specified in law, plans could effectively place all but the lowest tier drugs completely out of the financial reach of low-income enrollees. For low-income individuals, plans should not be allowed to have a higher cost-sharing amount than the upper-end of the range specified in the law. The proposed regulation should clarify that prescription drug plans cannot use an alternative benefit design to charge cost sharing to low-income beneficiaries that exceeds the amounts set out by the statute.

Section 423.272, Review and negotiation of bid and approval of plans

423.272 (b)(2), Approval of proposed plans, plan design.
The NPRM in (b)(2) states that "CMS does not approve a bid if it finds that the design of the plan and its benefits….are likely to substantially discourage enrollment by certain Part D eligible individuals under [in?] the plan." We urge that the regulation drop the word 'substantially.' Any cherry picking is an abuse of beneficiaries, the Medicare program, and taxpayers in general.

Elsewhere, we and others comment on the many deficiencies in the formulary proposal and the weaknesses in the proposed model formulary developed by the USP. We hope that the USP model becomes more detailed and offers more classes and subclasses. But assuming that the USP model does not become less granular (less detailed) and stays approximately as it is, then CMS should make it known that it will not approve any plan application which develops its own formulary that has fewer classes and categories than the USP model. Any plan which spends money and P&T effort to develop its own formulary that is likely to cover fewer essential, high technology medicines should be presumed to be trying to avoid HIV/AIDS, mental health, complex cancer, and other cases. The potential for abuse of the program by cherry-picking is so enormous that CMS needs to be much stronger in its advice in this subsection.

SUBPART J—COORDINATION UNDER PART D WITH OTHER PRESCRIPTION DRUG COVERAGE

Section 423.464 Coordination of Benefits with other providers of Prescription Drug Coverage.

Recognize AIDS Drug Assistance Programs as State Pharmaceutical Assistance Programs (SPAPs).
We urge that AIDS Drug Assistance Programs (ADAPs) be recognized as State Pharmacy Assistance Programs and be allowed to wrap around the Medicare Part D drug benefit and that ADAP expenditures be counted as true out-of-pocket costs. We see nothing in the law that prohibits ADAPs as being designated as SPAPs and they certainly serve the same function and purpose as traditional SPAPs, for the low income HIV/AIDS population.

Let State Pharmacy Assistance Programs help their residents pick the best plan.
The NPRM Preamble prohibits SPAPs 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*. But despite the Preamble language, the 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 Preamble language be dropped and 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.

423.464 (e), Coordination with State Pharmaceutical Assistance Programs.
We are hopeful that existing SPAPs and new SPAPs will be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance.

In order 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.

SUBPART K –APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Section 423.504, General provisions.

While we strongly support the strong new anti-fraud provisions in this section, we also hope that CMS will make it clear that this program **will**—not "may"—be subject to extensive annual audit. The history of providers in this sector (for example, the $1.1 million settlement of Omnicare of Maine with the State of Maine announced August 25 as a penalty for switiching patients from lower cost forms of a generic to a more expensive form), coupled with the billions of dollars at stake, make this a very high risk program.

Section 423.507, Non-renewal of Contract.

423.507(a)(2) and (a)(3), Timeframes.
In light of the MedPAC's June, 2004 report to Congress on the importance of long-lead times in transferring files, we believe the timeframes in this section are too short and should be lengthened if at all possible. We also note that MedPAC reported a case where one provider refused to cooperate with another provider in file and data transfer. As a condition of participation in the program or recovery of surety bonds, PDPs and MA-PDs should be required to cooperate in a timely manner in all file and data transfers, including in cases where the PDP is leaving the market.

Section 423.512, Minimum enrollment requirements.

We are concerned that some of the minimum enrollment standards being set (5,000 and 1,500 in rural areas) are too low. We do not believe that plans with this small an enrollment base can obtain adequate discounts, maintain 7/24 advice and information lines, and employ the expertise needed for pharmacologically complex condition patients. We support small businesses, but in this case, too small a business may not be good for the health of those enrolled. CMS should carefully evaluate minimum enrollment requirements; minimum enrollment should be sufficiently high to ensure that every PDP will have the ability to both negotiate adequate discounts and provide the level of service beneficiaries will require.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS AND APPEALS

Overarching concern and general comments.

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution and 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 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 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.*** 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. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 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 timeframes, the paperwork, and the processes should be simplified into one course of action that beneficiaries may hope to understand.

Section 423.560, Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines authorized representative as someone authorized by 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 also act on behalf of an enrollee in exceptions and grievances.

Section 423.562, General provisions.

423.562 (c)(1), Appealing when enrollee has no further liability.
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.

423.562 (c)(2), Challenging non-network coverage determinations.
This subsection may preclude an enrollee from challenging a plan's determination that it has no obligation to cover a drug received from a non-network pharmacy and should be deleted. As stated elsewhere in these comments, the actual regulatory language in 423.124 does not establish clear criteria as to when a plan must cover drugs received from non-network pharmacies. Thus, there is no guarantee that plans will interpret the regulation as CMS describes in the preamble. Taken together, proposed 423.124 and 423.562(c)(2) place at risk vulnerable individuals such as those in institutions whose purchases from long-term care pharmacies are treated as if they are from a non-network pharmacy.

Section 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. We refer CMS to the website of the Florida Agency for Health Care Administration, http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/multi_source.shtml, for an example of information Florida pharmacies must provide when they deny a prescription under the Florida Medicaid program.

Section 423.568, Standard timeframes and notice requirements for coverage determinations.

Timeframes.

Section 423.568(a), Timeframe for request 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.

Section 423.568(b), Timeframes for request for payment.
This section should be eliminated, per our opening comment about the need to simplify these regulations and provide more uniform timeframes, etc.

There should be no distinction in time frames when an enrollee requests payment.

Notice.

Section 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 situations 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. See our previous comment about the Florida Medicaid program.

Content of the notice (Applies also to 423.572(d)).
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 the following:

- Notice about exceptions and appeal rights should be presented immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist) and should explain why coverage was denied and options for obtaining necessary medications as well as appeal procedures.

- Notice should include clinical or scientific basis for denial.

- Notice should be available in multiple languages and the availability of language services noted (see below).

- A recently settled Florida class action lawsuit filed on behalf of Medicaid recipients determined that the state had not provided written notification to people whose prescription coverage was denied of their right to appeal the decision. The settlement's provisions require the state to provide:

    - Written notification that explains why the coverage request was denied
    - Information on how to resolve the issues that triggered the rejection
    - Instructions that explain how consumers can request an appeal
    - Steps 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).

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. We support the August, 2000 HHS OCR guidance on how programs can meet their Title VI obligations to provide written materials in 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.

Section 423.570, Expedited consideration.

423.570(a), Requests for expedited determinations.
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 time frames 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.

Section 423.572, Times frames and notice requirements for expedited coverage determinations.

(See comments above re content of notice.)

Section 423.572 (b), Timeframe.
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 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.'

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 NPRM what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. (This is also discussed in the next section.) The statute says plans

must make the change in information available on the internet, the Preamble discusses a mailed notice, and the NPRM 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.

Section 423.578, Exceptions process.

Overall, the exceptions process does not comply with the statutory requirements or meet the basic elements of due process.

Notice.
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 (pg 46661), the regulatory language just says that notice must be given, and the statute requires posting on the Internet.

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 reasons why a drug is not included on/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), Plan criteria.
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 regulations propose 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, for example :

- Consideration of the cost of the requested drug compared to the cost of the preferred drug has no bearing on whether a drug would not be as effective or would have adverse effects and should not be a consideration.

- Consideration of whether the formulary includes a drug that is the therapeutic equivalent also is not relevant to the statutory standard. The FDA requires that 80 percent to 125 percent of the medication be the same to be considered "therapeutically equivalent." Treatment for certain conditions, including mental illness, is highly individualized given the non-interchangeability of many medications even within the same class, the high degree of variability in how these diseases present themselves in terms of symptoms, and the many other factors that must be taken into account, including overdose lethality in light of heightened risk of suicide. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the deciding factor.

- Consideration of the number of drugs in the plan's formulary that are in the same class as the requested drug, for the reasons stated above, also is not relevant to the determination of the treating physician that the requested drug is needed.

Inadequate guidance for physicians.
The proposed rules fail to provide adequate guidance concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or cause adverse effects has been met.

- The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug would not be as effective or cause adverse effects. The statute does not support allowing 'fail first.' In fact, for many enrollees, a fail first requirement in and of itself would cause adverse effects. A fail first standard might apply if the statute required—which it does not—the doctor to certify that the drug is not as effective or causes adverse effects.

- The regulation says that the plan sponsor "may require the written certification to include only the following information…" Given that the statute requires a determination by the doctor that the preferred drug would not be as effective, would cause adverse consequences, or both, plans are going to require some kind of written statement. However, the regulation should limit the statement only to the statutory standard. It should read "The sponsor may only require the written certification to include the following information."

- The preamble states that a PDPs exceptions process also would have to describe how a determination on an exception request would affect the enrollee's cost-sharing under the PDP's tiering structure. 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 criteria, which were omitted:

- Rule permitting continued access to a drug at given price when there is a mid-year formulary change.

- 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.

Exceptions involving nonformulary drugs

423.578(b), Defining formulary use, 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 ".(p. 46720). ***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" (p. 46721).*** 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 criteria and process described in 423.578(b)(2) will make it impossible to get an exception. The process is not transparent, as is stated in the preamble (pg 46720), because it is left totally to the discretion of each plan. We urge CMS, and not each individual plan, to establish the criteria for evaluating the request. 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.

The regulations must also establish standard criteria that plans must use in evaluating a prescribing physician's determination that any on-formulary drug would not be as effective or would cause adverse effects. In addition, independent review entities must be charged with reviewing plan criteria to ensure that they comply with these federal standards and implement the statutory standard requiring that the prescribing physician determine that all on-formulary drugs would not be as effective or have adverse effects.

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.

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.

The regulations need to establish fixed criteria for evaluating the prescribing doctor's determination that using all formulary drugs would not be as effective or would cause adverse consequences to the enrollee. Requiring this amount of evidence would make it impossible to meet this standard. Instead the regulation 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 plan 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 older people, people with disabilities, and people with co-morbidities. While some such evidence exists, there may not be this level of evidence for all drugs and conditions. Again, the regulations should require the certificate to meet the statutory standard (not as effective or adverse effects or both) rather than include information why the "preferred drug" is not acceptable for the enrollee. The criteria should recognize a physician's experience in evaluating whether the statutory standard is met.

- For dosing exceptions, the regulation states the standard is a showing that the number of doses that is available under a dose restriction for the prescription drug has been ineffective or based on both sound clinical evidence and medical and scientific evidence the drug regimen is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. The standard should include "or cause an adverse reaction or other harm to the enrollee".

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, et.) and packaging, such as bubble wraps for long-term care facility residents.

423.578(b)(4), Certification requirement.
Again this section says a PDP sponsor "may" require a written certification. The language should be that the sponsor "may only require the written certification to include the following information." Again, the standards are very high. The list of information is too long and is repetitive; the doctor should only need to explain why the drug that is the subject of the exception request is needed for the enrollee [(b)(5)(iv)(D)], and not all of the previous provisions.

423.578(c)(2) Continuation of drug pending review.
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 they could show the decision needed to be made more quickly because of their condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

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 want to stress the importance of drug coverage and ensuring no gaps in the uptake 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.

Notice.
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 deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise the 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)).

Section 423.580, Right to a redetermination and Section 423.584(a), Expediting certain re-determinations.

The enrollee's authorized representative should also be able to request a re-determination or an expedited re-determination (See also Section 423.584).

These 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 then disallow an enrollee's representative from pursuing 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".

Section 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, the right to submit evidence in person and orally.

Also, see Section 423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

Section 423.586, Evidence for a re-determination.

The regulations should establish clear criteria for informing the enrollee and the doctor that they can submit evidence in person, as well as clear procedures for in-person review.

Section 423.590, Timeframes.

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).

We renew our 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.

Section 423.600, Reconsideration by the IRE.

Role of the 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 (**pg. 46721**) 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 of 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.

Requesting the reconsideration.
Since the Part D process is supposed 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, we dispute 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 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), Requirement to solicit view of treating physician.
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 Medicare Advantage independent contractor is often reluctant and often 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, face-to-face meeting.

423.600(d),Timeframe.
The regulations need to establish a set time frame 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. 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.

Section 423.602, Notice of reconsideration.

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.

Section 423.610, Right to an ALJ Hearing.

Congress recognized the special needs of the low income, and how even small copays 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.

We are 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?

Section 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 ALJs 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, including any doctor's statements, statements by the enrollee, and other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that contracting entities, including Medicare Advantage plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

Section 423.634, Reopening and revisions determinations and decisions & Section 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. That's totally unacceptable, since further delays may cause increased health consequences to people who foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart O—Intermediate Sanctions

Overarching concerns

- CMS describes in the preamble (69 Fed. Reg. 46724) a potential conflict between the statutory requirement that each region have at least two PDP sponsors and its goal of using consistent policies and procedures across regions when imposing sanctions. This conflict can be resolved, with both the statutory requirement and CMS' goal retained and implemented to ensure the highest quality of care. If a region has only two PDP sponsors, CMS can nevertheless terminate one sponsor, as appropriate, and fulfill its statutory obligation to assure that a fallback plan serves as a second PDP sponsor.

- The proposed rules establish four types of sanctions – civil money penalties and enrollment, payment, and marketing sanctions. They also identify six bases for imposing sanctions. However, the rules do not describe any process or methodology for CMS to use in deciding which sanction (or sanctions) to impose in any particular set of circumstances. In addition, the fact that *all* sanctions are permissive increases the likelihood that none will actually be imposed. CMS needs to develop a process and methodology to use in determining when to impose sanctions.

- While sanctions can be imposed only when noncompliance is determined, it is not clear from the rules how CMS will determine that PDPs are not complying with the requirements of the laws. The proposed rules describe Quality Improvement Organization activities, but QIOs are not regulatory bodies and their work is confidential. The proposed rules describe deemed status for accrediting organizations, but deemed status is granted when the standards and survey process are found to be equivalent to CMS' standards and process. What is the CMS process? The proposed rules describe the contracting process, which includes, among other things, a compliance plan, an obligation to self-report quality problems, and maintenance of records that are subject to audit and review by CMS or its designee. A contract-based system is passive and relies on PDP's disclosure. Finally, the proposed rules say that CMS retains authority to enforce standards against a PDP that does not meet standards as determined by "its own survey" or an accreditation survey. Where is the further description of what this survey would be?

- CMS should make public – through press releases, statements in the Federal Register, annual report, etc. – deficiencies it cites against PDPs

and any sanctions it imposes against a PDP. Such information could be important to beneficiaries' decisions about which PDP to join.

Section 423.752, Basis for Imposing Sanctions.

423.752(a), All intermediate sanctions.
The regulations do not implement the preamble's explicit statement that one or more sanctions may be imposed at any one time. Accordingly, we suggest amending this section as follows:

(a) *All intermediate sanctions*. For the violations listed below, CMS may impose ~~any~~ one or more of the sanctions specified in §423.750 on any PDP sponsor that has a contract in effect.

Section 423.756, Procedures for imposing sanctions.

423.756(e), Termination by CMS.
The proposed rules say that the enrollment, payment, and marketing sanctions may be used in addition to non-renewal or termination. They also suggest that civil money penalties are available in situations where the PDP terminations its contract without following the appropriate process.

We suggest that CMS amend §423.756(e) as follows to provide for the availability of civil money penalties in all instances when it declines to renew or terminates a contract:

> "In addition to or as an alternative to the sanctions described in paragraph (c) or this section and civil money penalties authorized by sections 423.750(a) and 423.758…"

Section 423.758, Maximum amount of civil penalties imposed by CMS.

The definition of when a civil money penalty for a deficiency may be imposed is too narrow and limiting. It fails to reflect the various types of noncompliance that are the bases for imposing sanctions, § 423.952(a)(1)-(6). It requires that harm occur, or be very likely to occur, to PDP enrollees before CMS can impose a financial penalty. It fails to recognize that a benefit of civil money penalties as sanctions is their ability to be varied in amount to reflect the extent and seriousness of the noncompliance. Although the rules

establish $25,000 as the outer limit of a civil money penalty, such penalties can be lower.

CMS should establish a range of civil money penalties, and vary the amount of penalties in each category to reflect the nature and extent of the PDP's noncompliance with requirements.

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

Section 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 self-attest to the status of dependents, without providing further documentation.

Full subsidy eligible individual.
The definition of full subsidy eligible individual should refer to the language of 423.773(b) *and* (c), in order to avoid ambiguity.

Income.
The definition of income 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 ICFs-MR 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 proposed regulation's limitation of countable resources to liquid assets only. 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 (see Preamble at 46,726). 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. As noted above, life insurance should not count towards assets, and this question should be eliminated.

Section 423.773, Requirements for Eligibility

General comments.

We strongly 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 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) that 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(c), Clear meaning of automatic eligibility.
Section 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 the extent 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.

423.773(c)(3): Ensuring equitable enrollment for all MSP-eligible beneficiaries.
We support the decision reflected in proposed regulation 423.773(c) to deem Medicare Savings Program ("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 rules, 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 should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy, 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 increased disregards under 1902(r)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. We urge SSA to apply also state income disregard rules. If a statutory change is necessary to implement such a rule, the Secretary should seek appropriate legislative authority.

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 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 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.

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).

423.773(c)(3), Notification for automatically eligible beneficiaries. Proposed §423.773(c)(3) states that a state Medicaid agency must notify full benefit duals 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 should develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. As mentioned above, 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.

423.773(c), Eligibility for spenddown beneficiaries.
The proposed rule does not 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 section 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.

Section 423.774 Eligibility determinations, redeterminations, and applications

423.774(a), Notification of new applicants.
Section 423.774(a) 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 beneficiaries' being able 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. A similar system has been used effectively by several states in their Medicaid and State Children's Health Insurance Program (SCHIP) programs as a means of increasing enrollment and speeding beneficiaries' access to needed services. 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.[6] 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.

We believe 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 in § 423.774(c) applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs can be of vital interest for Medicare beneficiaries, 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.

423.774(c), Redetermination Periods.

[6] Rachel Klein, "Creative Solutions: Presumptive Eligibility" *The Future of Children* 13, no. 1 (Spring 2003): 230-237.

The regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will lead to beneficiaries dropping 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.

Coordination with spenddown/medically needy programs.
As we mention in our comments to section 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.

Section 423.782, Cost-sharing subsidy.

As noted in our comments to Subpart F, section 423.265(d)(2)(iv), the rule should specify that plans cannot use an alternative benefit design to charge cost sharing to low-income beneficiaries that exceeds the amounts set out by

the statute. This applies to both the co-payments established in section 423.782(a) and the co-payments and co-insurance established in section 423.783(b).

Section 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.

423.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The reimbursement provisions of § 423.800(e) are also inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess co-payments and premiums 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 in our comments to section 423.774(b) 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 Q: GUARANTEEING ACCESS TO A CHOICE OF COVERAGE (FALLBACK PLANS)

Sections 423.851-875, Entirety of Subpart Q.

The requirements this Subpart imposes on those who would be interested in providing a 'fallback plan' to serve an area not served by at least two plans (one of which may be a MA-PD) are so severe that fallback plans will not, in fact, be available. The requirements exceed the statute and basically sabotage this provision of law; they make it entirely possible that some rural areas may have no service except regional PPOs and HMOs.

Congress clearly did not intend that seniors would have to join a managed care plan for all their health care services in order to get the prescription drug benefit. The additional contracting restrictions and other policies proposed in the regulation that would make it less viable for a plan to bid as a fallback plan should be eliminated to ensure that fallback plans will bid and participate.

Plan negotiations: fallback and non-fallback plans.
We support CMS's position that it has authority to negotiate with plans to ensure a good price for beneficiaries. As the Preamble states (46734) "if the price reference points appear to be particularly high (or low), we may request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids." We note that these pricing dangers may also occur in areas where there is no fallback plan, but just one MA-PD and one PDP. Therefore, we urge CMS to apply the same authorities to plans in non-fallback situations. In fact, the Preamble states that "we are contemplating tying the performance payments of fallback entities to the average discounts they are able to negotiate, including discounts from manufacturers." This is a higher requirement than is being imposed on non-fallback plans.

Given the tremendous potential for price collusion and price fixing in non-fallback regions, we believe a similar requirement should be imposed on all plans. If that requirement is not extended to non-fallback plans, it should be deleted for the 'fallback plans' so that there is a more level 'playing field.'

SUBPART R—PAYMENTS TO SPONSORS OF RETIREE PRESCRIPTION DRUG PLANS

Section 423.882, Definitions.

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 Fed Reg 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**.

Section 423.884, Requirements for qualified retiree prescription drug plans.

423.884(a). 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, given the significant and unprecedented employer subsidy established under the MMA, it would be wise to provide 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.
In addition, 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. (See also our comments on sections 423.46 and 423.56.)

Section 423.888, 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.

Section 423.890, Appeals.

To provide further protection against improper payment of the employer subsidy, third parties (such as employee 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.

Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

Section 423.902, Definitions

Full benefit dual eligible.
"Full benefit dual eligible" is defined, for 2003 baseline calculations, to be those individuals having Medicaid drug benefit coverage and Medicare Part A or Part B. This definition appears to include some individuals not receiving full Medicaid benefits, but receiving drug coverage under a Pharmacy Plus waiver. The preamble does not discuss this definition; it is unclear what the intention of the language is.

Section 423.904, Eligibility determinations for low-income subsidies

423.904(a), General Rule.
The provision directs states to make eligibility determinations in accordance with the provisions of 423.774. It 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 noted in our comments to Subpart P, a similar provision should be included in 423.774 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, proposed § 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 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 Section 1935(a)(3) established in Section 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 explain 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 recommend that CMS should direct those states that currently rely on the SSI methodology for determining resources for their MSP programs to instead apply the definitions of resources used in Subpart P section 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 confusing beyond repair 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.

Screening and enrollment for full Medicaid.

We believe that 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 (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program (SCHIP) 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 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.

Screening for other public benefits.

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. In particular:

- Outreach materials that SSA and CMS/State Medicaid programs design should contain information about other major benefits for which applicants may be eligible;

- Applications that are filed and other information that applicants provide should be easily shared between SSA, state agencies, and CMS so that it is available to all agencies and duplication of effort can be avoided;

- The federal agencies involved (USDA, CMS, and SSA) should make it a priority to enroll all eligible applicants in all benefit programs. In addition, these agencies should seek to simplify federal program rules so that Medicare beneficiaries can easily 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 additional questions and are certified automatically for food stamps based on their SSI applications.

423.904(c)(3), Notification.
The section refers to 423.34(d) with reference to notifying individuals deemed subsidy eligible, but 423.34(d) discusses automatic enrollment of full benefit dual eligibles in Part D plans. Notification of deemed subsidy eligible individuals of their entitlement to a subsidy is a different matter from enrollment in a Part D plan. This reference appears inapt. As discussed in our comments to section 423.773, those who are deemed subsidy eligible need immediate notification of that status and of the fact that they need do nothing more with respect to their subsidy, but that they need to enroll in a Part D plan in order to use the subsidy.

423.904(d)(3), The application process and States.
As written, the rule permits states to impose more burdensome documentation requirements on beneficiaries than could SSA. This is counter to the principle of simple enrollment underlying the statue. In addition, states should not be permitted under the cost-effectiveness provisions of section (d)(3)(ii) to transfer the costs of verification to beneficiaries by requiring visits to state Medicaid offices and production of additional documentation. Section (d)(3)(i) should be changed to read: "States may require submission of statements from financial institutions for an application for low-income subsidies to be complete *only if the applicant or personal representative is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information"* (suggested additional language in italics).

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.

SUBPART T—CHANGES TO PARTS 403, 411, 417, 460 and 442.

Changes to Part 403, 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 (page 46760) 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. Information about the new Medicare drug benefit will be readily available from a variety of sources including CMS, and introducing it in this disclosure notice detracts from important information consumers must have to understand and exercise their rights concerning their Medigap coverage.

- Delete statements about the value of Part D benefits. These statements are irrelevant to the issue of changes to Medigap. They also may not be accurate for certain individuals who have employer-sponsored or other drug coverage. The language introduces this information before consumers will understand they have important decisions to make about their Medigap coverage.

- Include at the beginning of the letter the statement that beneficiaries may call 1-800-Medicare for help understanding the disclosure notice.

- 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 adds to the length of the letter.

- Delete the information concerning enrollment issues about Medicare Part D. The language 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 **Section 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.

Changes to Part 411, Physician Self-Referral Rules.

Section 411.351, Physician Referral laws must apply to Part D drugs.
In Subpart T, Section 411.351, relating to physician referral, we strongly support the extension of the so-called Stark physician referral law to ensure that "outpatient prescription drugs" includes "all drugs covered under Medicare Part B and Part D."

A review of other nations' health systems where doctors make money on the prescriptions they write will show a much higher utilization of drugs per patient encounter than in the United States. A review of the abuse of the Average Wholesale Price (AWP) spread in Medicare Part B will show that the type of drug prescribed and the quantity increases as the spread (profit to the doctor) increases. Not to apply the physician referral laws to the Part D drugs would be a financial disaster for the program.

Respectfully submitted,

Ron Pollack
Executive Director
Families USA

CMS-4068-P-1070

Submitter : Mr. Leon Galehouse **Date & Time:** 10/04/2004 06:10:02

Organization : John Deere Pharmacy Group, Inc

Category : Pharmacist

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 plan'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 and that our patients will be able to continue to use our pharmacies.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirement on the number of preferred pharmacies a plan must have in its network. 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 met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress' intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

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

I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide an Anti-Coagulation Service (since 1997) in my practice as well as starting smoking cessation programs in December of this year. Plans should be encouraged to use my services--to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to:
1. Require plans to meet TRICARE access requirements on a local level
2. Require plans to offer a standard contract to all pharmacies
3. Recognize pharmacists as the healthcare provider who consistantly sees and interacts with the patient and is therefore the provider best suited to provide the necessary medication therapy management program for their patients.
4. Require that community pharmacy be allowed to extend the same quantity benefits to the patients that a mail order pharmacy would without the beneficiary having to be penalized with higher copays to use the community pharmacy.

CMS-4068-P-1071

Submitter : Mr. Kevin Liebkemann **Date & Time:** 10/04/2004 06:10:10

Organization : New Jersey Protection & Advocacy, Inc.

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file from the disability community.

CMS-4068-P-1071-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: Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632

Dear Sir/Madam:

The following comments on the proposed regulations "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632 are submitted by New Jersey Protection & Advocacy, Inc., the designated protection and advocacy system for individuals with disabilities in New Jersey, pursuant to the Developmental Disabilities Assistance and Bill of Rights Act of 2000, 42 U.S.C. §§ 5041 to 15045; the Protection and Advocacy for Mentally Ill Individuals, 42 U.S.C. §§ 10801 to 10807, the Client Assistance Program of the Rehabilitation Act, 29 U.S.C. § 732; the Protection and Advocacy for Individual Rights of the Rehabilitation Act, 29 U.S.C. § 794(e); and the Technology Related Assistance for Individuals with Disabilities, 29 U.S.C. § 2201.

NJP&A endorses the comments submitted by Families USA, the National Association for Protection & Advocacy Systems, and the Arc of New Jersey. NJP&A is particularly concerned about the effect of the legislation and regulations on individuals eligible for both Medicare and Medicaid benefits. As proposed, dual eligible individuals in New Jersey will be worse off as a result of the changes to the Medicaid prescription program. People with severe and chronic disabilities, particularly people with developmental disabilities, are likely to be prescribed many different medications. It is not unusual for these individuals to be on as many five, six, or seven medications. At a recent meeting of family members of people with developmental disabilities, several families indicated that their family members were taking ten or more prescribed medications. For those individuals who are prescribed multiple medications, the imposition of co-payments is likely to impose a significant barrier to continued access to the medication. While the income for dual eligibles is virtually identical to recipients of SSI only, the SSI recipients have no co-pay requirement. The imposition of preferred drug lists is also likely to

cause extraordinary difficulties for this population. There is already considerable concern that no one list will contain the specific medication that is most effective for any one individual.

In addition, NJP&A wishes to also express concern about how these regulations could impact individuals seeking to return to work after receiving Social Security Disability Income.

Part D

NJP&A is concerned that as written the proposed regulations will adversely affect individuals who are using Social Security's Work Incentive programs. The current rule provides that Medicaid beneficiaries pay nothing for most prescriptions in New Jersey. The proposed rules seem to provide favorable treatment for low-income dual eligibles receiving Medicare and Medicaid. However, the proposed rules are less clear on how dual eligibles earning over 150% of the federal poverty level will be treated, and clarification is requested.

Social Security Title II beneficiaries who only get Medicare will receive some prescription benefits under the proposed rules where none existed before. However, the proposed rules may build in a disincentive for these beneficiaries to return to work. The proposed rules provide that low income Medicare beneficiaries will pay little or nothing for prescriptions, while those earning over 150% of the federal poverty level may have to pay as much as 50% of their prescription costs. This may create a financial disincentive for these beneficiaries to attempt a return to work if they have significant prescription expenses. For instance, in some cases the extra income realized by work activity might be completely offset by the additional prescription costs resulting from earning over 150% of the federal poverty level. NJP&A urges CMS to consult with the Social Security Administration about removing this potential disincentive.

NJP&A is also concerned about the method used to calculate whether a beneficiary is over or under the 150% federal poverty rate threshold. Income for people with disabilities who are attempting a return to work can fluctuate significantly or abruptly cease due to unsuccessful work attempts, sickness, and numerous other factors. Medicare recipients who will have to pay a high contribution rate for prescription costs in months when their income stops due to a failed work attempt can face an immediate financial emergency that threatens their ability to receive needed prescription medication. The proposed rules need to be flexible enough to provide immediate solutions for these individuals.

Finally, NJP&A urges consultation with the Social Security Administration and interested parties to plan and provide appropriate training for those individuals and programs who provide assistance to beneficiaries. Social Security has created two nationwide programs that provide planning and advice to beneficiaries on work incentive programs and how work-related income and other circumstances can effect their cash benefits and Medicare and Medicaid eligibility. Those two programs are the Protection and Advocacy for Beneficiaries of Social Security (of which NJP&A is a member) and the Benefits Planning Assistance and Outreach programs. The proposed rules will affect the analysis and advice that these programs give to beneficiaries. These programs should receive training in the operation of the proposed Medicare prescription drug benefit, so that they can continue giving accurate and much-needed assistance to beneficiaries considering a return to work.

The Ticket to Work and Work Incentives Improvement Act embodies a popular bipartisan goal that SSDI and SSI beneficiaries should be encouraged to attempt work when possible, and not unfairly penalized for doing so. NJP&A urges consultation with the Social Security Administration and interested parties, so that the proposed regulations can be modified to embrace that goal and retain incentives for people with disabilities to return to work.

Sincerely,

Kevin B. Liebkemann
Senior Staff Attorney

Submitter : Mr. John Young **Date & Time:** 10/04/2004 07:10:42

Organization : RI Department of Human Services - Medicaid

Category : State Government

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Data and Coordination

Though several sections of the proposed rule establish the need for coordination between Part D plans and other plans that provide prescription drug coverage, we do not believe these requirements are well defined. Of particular concern is the lack of guidance about data sharing. In Rhode Island, we are committed to providing the highest quality care for Medicaid beneficiaries and have invested heavily in care management type activities. Since Medicaid will retain responsibility for other health care services for the dual eligibles, we believe that it is crucial for us to have access to real-time clinical data for these individuals. Without timely data on pharmacy utilization for dual eligibles, our ability to properly coordinate all health care services and improve wellness within our populations will be compromised. We assert that the Part D sponsors and/or CMS should have responsibility for sharing clinical and enrollment data with state Medicaid agencies.

We propose that the more efficient and appropriate way to ensure coordination of care and benefits for dual eligibles would be to enable state agencies to become a Part D plan sponsor if they so desired.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Eligibility Determinations for Low-Income Subsidies

Pursuant to the statute, section 423.774 establishes that determinations for eligibility for the Part D low-income subsidy, as well as redeterminations, will be made by either the state under its Medicaid state plan if an individual applies through a Medicaid agency or by the Social Security Administration (SSA). Recent guidance from CMS has indicated that states would be able to simply take applications for the low-income subsidy and then pass them on to SSA for processing. However, the proposed rule does not indicate that such a process would be permissible. We would like clarity as to whether states have the ability to delegate determinations for the low-income subsidy to another entity, such as the SSA or a private sector vendor.

While realizing that this requirement is established in the MMA statute, it is our contention that taking on this new administrative process essentially results in an unfunded mandate. It is illogical that state Medicaid agencies should have to assume a major business function for a program that we hold no responsibility for administering. Establishing a new eligibility process will require significant information systems modifications, staffing, and other administrative resources. ?432.906 specifies that states will only receive their regular federal matching rate for this operation. Given that the eligibility function remains outside of the MMIS, we will only be able to obtain 50 percent FMAP for this new requirement. It is our contention that if CMS would like states to take on administrative responsibilities for the Medicare program, then such activities should be funded with 100 percent federal dollars. At the least, we propose that state Medicaid agencies be able to fulfill their statutory obligation by offering and taking Part D low-income subsidy applications. Applications that come in through the Medicaid agency could then be sent on to the SSA for processing. Since SSA will be already be establishing an eligibility processing system, it seems that utilizing a centralized system would be the most efficient approach.

In Subpart S, ?423.904 establishes that those making eligibility determinations and redeterminations will be responsible for sharing data with CMS. We would like more details on the process CMS will use to collect data from state Medicaid agencies. Again, we hope that CMS will be mindful of the great complexity and cost that states incur when they have to make changes to their information systems.

Issues 11-20

SPECIAL RULES FOR STATES

Subpart S ? Special Rules for States

Under Subpart S, ?423.906, it is specified that no federal Medicaid funds are available to provide Part D covered drugs for full benefit dual eligibles. Therefore, we will be required to amend our Medicaid state plan when Part D is implemented. Given restrictions on limiting state plan services for certain populations, we hope that CMS plans to clarify how we are to proceed in pursuing the necessary state plan amendments since it is not addressed in the proposed rule. We strongly recommend that CMS provide states with a template to take into account changes to the state plan that will result from implementation of Part D.

We thank you for your consideration of our comments and look forward to continuing to work in partnership with CMS on the full implementation of the Medicare Modernization Act.

Phased-Down State Contribution

Under the statute, states are required to subsidize the majority of the Part D costs for dual eligibles. The formula proposed in ?423.910 to determine the amount of each state?s contribution raises significant questions and concerns. According to our analysis of the phased-down state contribution, it will actually cost Rhode Island money to have Medicare assume drug coverage for the dual eligible population. At the same time, our purchasing power will be greatly diminished as dual eligibles account for roughly two thirds of our drug spending for seniors and adults with disabilities. This loss of purchasing power will impede Rhode Island?s ability to continue to control costs in our remaining pharmacy expenditures.

The proposed methodology for calculating the clawback payments is problematic on several fronts. We strenuously object to the baseline figure based on FY 2003 expenditures. As you are aware, a number of states made cuts in their pharmacy benefits during this time period, thus greatly lower their spending. Other states, like Rhode Island, that did not reduce benefits will have to pick up a greater amount of the cost according to the baseline calculation. We also question whether MSIS is the most accurate source of data for the baseline calculation. MSIS extractions are from paid claims and do not reflect any cash receipts from third party health insurance recoveries. These recoveries, which are offsets to expenditures, will not be part of the phased-down state contribution. In addition, the adoption of a national inflator will unfairly impact those states that have been successful in containing growth in pharmacy costs. In Rhode Island, we have adopted a number of mechanisms such as prior authorizations that have contained our pharmacy growth which is projected to be 10.86 percent in FY 2005. This is notably lower than national inflation rates.

In light of the complexity of the proposed formula, there are still a few areas that we would like CMS to clarify. First, we are unclear as to how member months are being counted. Secondly, we are still unclear on how people in Medicare Advantage plans will be counted for the clawback payment. Finally, we have some dual eligibles individuals enrolled in our family planning waiver. We do not believe this issue has been addressed and propose that we be able to include them in our state contribution.

CMS-4068-P-1072-Attach-1.doc

CMS-4068-P-1072-Attach-1.doc

CMS-4068-P-1072-Attach-1.doc

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

Dear Dr. McClellan:

On behalf of the Rhode Island Department of Human Services, I welcome this opportunity to offer our comments on proposed rule CMS-4068-P implementing the new Medicare Part D Prescription Drug benefit. While the Medicare Modernization Act is a sweeping piece of legislation, full implementation, particularly of Part D, will require state Medicaid agencies to commit substantial administrative and financial resources at a time when they are still facing budgetary concerns.

There are three major areas within the proposed rule that we have identified as most challenging and burdensome: eligibility determinations for the low-income subsidy, the phased-down state contribution (clawback), and issues surrounding data coordination. Our concerns and questions on these areas are addressed below.

Eligibility Determinations for Low-Income Subsidies

Pursuant to the statute, section 423.774 establishes that determinations for eligibility for the Part D low-income subsidy, as well as redeterminations, will be made by either the state under its Medicaid state plan if an individual applies through a Medicaid agency or by the Social Security Administration (SSA). Recent guidance from CMS has indicated that states would be able to simply take applications for the low-income subsidy and then pass them on to SSA for processing. However, the proposed rule does not indicate that such a process would be permissible. We would like clarity as to whether states have the ability to delegate determinations for the low-income subsidy to another entity, such as the SSA or a private sector vendor.

While realizing that this requirement is established in the MMA statute, it is our contention that taking on this new administrative process essentially results in an unfunded mandate. It is illogical that state Medicaid agencies should have to assume a major business function for a program that we hold no responsibility for administering. Establishing a new eligibility process will require significant information systems modifications, staffing, and other administrative resources. §432.906 specifies that states will only receive their regular federal matching rate for this operation.

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eligibility function remains outside of the MMIS, we will only be able to obtain 50 percent FMAP for this new requirement. It is our contention that if CMS would like states to take on administrative responsibilities for the Medicare program, then such activities should be funded with 100 percent federal dollars. At the least, we propose that state Medicaid agencies be able to fulfill their statutory obligation by offering and taking Part D low-income subsidy applications. Applications that come in through the Medicaid agency could then be sent on to the SSA for processing. Since SSA will be already be establishing an eligibility processing system, it seems that utilizing a centralized system would be the most efficient approach.

In Subpart S, §423.904 establishes that those making eligibility determinations and redeterminations will be responsible for sharing data with CMS. We would like more details on the process CMS will use to collect data from state Medicaid agencies. Again, we hope that CMS will be mindful of the great complexity and cost that states incur when they have to make changes to their information systems.

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In light of the complexity of the proposed formula, there are still a few areas that we would like CMS to clarify. First, we are unclear as to how member months are being counted. Secondly, we are still unclear on how people in Medicare Advantage plans will be counted for the clawback payment. Finally, we have some dual eligibles individuals enrolled in our family planning waiver. We do not believe this issue has been addressed and propose that we be able to include them in our state contribution.

October 4, 2004

Data and Coordination

Though several sections of the proposed rule establish the need for coordination between Part D plans and other plans that provide prescription drug coverage, we do not believe these requirements are well defined. Of particular concern is the lack of guidance about data sharing. In Rhode Island, we are committed to providing the highest quality care for Medicaid beneficiaries and have invested heavily in care management type activities. Since Medicaid will retain responsibility for other health care services for the dual eligibles, we believe that it is crucial for us to have access to real-time clinical data for these individuals. Without timely data on pharmacy utilization for dual eligibles, our ability to properly coordinate all health care services and improve wellness within our populations will be compromised. We assert that the Part D sponsors and/or CMS should have responsibility for sharing clinical and enrollment data with state Medicaid agencies.

We propose that the more efficient and appropriate way to ensure coordination of care and benefits for dual eligibles would be to enable state agencies to become a Part D plan sponsor if they so desired.

Subpart S – Special Rules for States

Under Subpart S, §423.906, it is specified that no federal Medicaid funds are available to provide Part D covered drugs for full benefit dual eligibles. Therefore, we will be required to amend our Medicaid state plan when Part D is implemented. Given restrictions on limiting state plan services for certain populations, we hope that CMS plans to clarify how we are to proceed in pursuing the necessary state plan amendments since it is not addressed in the proposed rule. We strongly recommend that CMS provide states with a template to take into account changes to the state plan that will result from implementation of Part D.

We thank you for your consideration of our comments and look forward to continuing to work in partnership with CMS on the full implementation of the Medicare Modernization Act.

Sincerely,

John R. Young, C.P.M.
Associate Director

CMS-4068-P-1073

Submitter : Dr. Janice Patten **Date & Time:** 10/04/2004 06:10:39

Organization : Pathways Home Care

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-4068-P-1073-Attach-1.doc

Pathways Home 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.

As a hospital-based, Medicare-certified home health agency with home infusion services, clinicians at Pathways Home Care see many patients in the Medicare population. In telling our elderly population that their physician has ordered an infusion drug therapy for which they will need to pay out-of-pocket, we have heard heartbreaking responses. Indeed, many are ultimately hospitalized for the therapy, which is the costliest alternative. Others simply refuse the drug, then progress to costlier sequalae such as amputation, respiratory arrest, renal shutdown, etc.

We strongly feel that treating these patients adequately at home will reduce the need for nursing home care and hospitalizations in the long run. As an added bonus, patients can remain in their homes and continue leading productive lives. Our patient satisfaction surveys, performed by an independent research firm, run 92-99% of patients giving us a 5 on a 0-5 scale. Home infusion has enormous patient acceptability. It does, however, require significant pharmacist and nurse care planning and involvement. Teaching patients about their disease state, the drug, potential problems and side effects, how to self-administer, care of the IV line, pump operation, supply storage/disposal, delivery, and communication to other providers require time and expense far beyond that of filling a prescription.

Pathways Home 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 of 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 .

- 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,

Janice K. Patten PharmD
Director of Infusion Therapy
Pathways Home Care

CMS-4068-P-1074

Submitter : Ms. Cindy Kirk **Date & Time:** 10/04/2004 06:10:36

Organization : State & Local Government Benefits Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Attached File

CMS-4068-P-1074-Attach-1.doc

State and Local Government Benefits Association
Comments on Proposed Regulations
Medicare Modernization Act
Prescription Drug Benefit
File Code: CMS-4068-P

Introduction

I am Cindy Kirk, President of The State and Local Government Benefits Association (SALGBA). Our Association includes over 40 states and 144 local jurisdictions with a total association membership of 289. Our members cover more than 5 million employees, and control a gross health benefits expenditure of more than $14 trillion each year. Our members have over a million retirees enrolled in their programs with over half being Medicare eligible.

The federal Department of Health and Human Services' Center for Medicare and Medicaid Services (CMS) has released regulations on the prescription drug benefit. The SALGBA Board of Directors and I want to take this opportunity to express what concerns public sector employers have with the Medicare Modernization Act regulations.

The regulations pertain to Medicare eligible individuals as well as to employers and union welfare funds. I will restrict my comments to the regulations particular to the public sector employers that offer retiree Medicare prescription drug coverage.

CMS has given all stakeholders until October 4th to submit their comments on some 200 pages of regulations. Obviously that is not enough time to digest all the regulations and make cogent comments. The regulations are just murky enough that multiple readings still lead to a need for further explanation and clarity.

The proposed timeframe for implementation (January 1, 2006) will also strain most plan sponsor's resources once a decision is made to pursue the subsidy, or adopt one of the other alternatives which will likely lead the employer to redesign the prescription drug benefits it offers to eligible retirees. The federal Department of Health and Human Services' assumption that sponsors will generally lean toward the subsidy option does not recognize employer's uncertainty as to how much it will cost them directly and indirectly to obtain the subsidy.

The proposed regulations present possible alternative approaches as to how sponsors might be able to obtain the subsidy, however the regulations fail to offer clear guidance regarding the specific level of detailed claims information that will have to be provided to CMS, and the frequency of the payments of the subsidy to

sponsors. The absence of clear guidance, coupled with the erosion of the subsidy due to the cost to comply with the rules to obtain the subsidy, make this option less attractive. States and other public employers will inevitably be faced with having to make new and potentially contentious policy decisions.

The Regulations

Basically the regulations offer three possible alternatives to employers:

Subsidy

1. A subsidy of up to 28% of current cost to be returned to employers if their retirees do not opt for the Medicare prescription drug benefit called Part D and Prescription drugs are only provided through the employer. The maximum subsidy that will be paid to an employer-sponsored retiree prescription drug plan will be $1,330 per year, per retiree.

2. Use of Medicare Advantage-Prescription Drug plans (MA-PDs). These are Medicare approved plans that will offer all Medicare benefits including a wrap-around prescription drug benefit. These are similar to the old Medicare risk plans or Medicare + Choice plans. These plans basically failed when premium offered to the plans by CMS became so unattractive that companies abandoned the program. Premium levels could again be a problem for these plans in future years. Past experience with these type programs makes them initially unattractive.

3. Use of Prescription Drug Plans (PDPs). Enter into an agreement with a PDP that will apply for, and hopefully be granted a waiver from Medicare to offer an enhanced prescription drug plan, or adopt an arrangement that wraps around a PDP. Wrap around programs will not eliminate the donut hole and retirees will have out-of-pocket expenses.

All of the above options have positive and negative aspects.

Subsidy - Cost of Compliance

The cost of compliance will not be a one-time expense as many of the activities will be ongoing, and include, but will not be limited to:

- Retaining of the services of an actuary, who is a member of the American Academy of Actuaries, who must annually attest that the sponsor's retiree prescription drug plan(s) are at least actuarially equivalent to the standard Medicare prescription drug benefit, and certify that the values have been calculated according to CMS actuarial guidelines;

- Developing eligibility reporting systems that separate the sponsor's Medicare eligible retirees and their Medicare eligible spouses from their respective retirees and their spouses who are not eligible for Medicare;

- The potential need for the development of claims reporting systems that will extract prescription drug claims submission and payment data only for the Medicare retiree population;

- The need to combine prescription drug data streams from different health plans (HMOs) and prescription drug plans. Public sector employers especially large employers like states generally have multiple plans options with multiple prescription drugs benefits and PBMs;

- Incurral of increased administrative expenses charged by the sponsor's many prescription drug plan claim managers because of the need to develop claim reporting systems mentioned above,

- Incurral of additional internal administrative expenses resulting from the need to develop new retiree notification and compliance materials and procedures; and

- The possible need to eliminate certain prescription drugs from those currently covered under the retiree prescription drug plans because they will not be recognized by CMS, thus resulting in a reduction in benefits; or to develop bifurcated retiree prescription drug plan designs, one for retirees and spouses who are not eligible for Medicare, and another for Medicare eligible retirees and spouses.

All of the above are costly and will erode the savings that may accrue from the subsidy

The Subsidy - Issues

- You must be able to report to CMS your drug costs. There are several options on reporting but the bottom line is you must have the ability to combine drug costs of multiple plans, multiple groups, plans with retiree contributions, plans without, etc. This process can be tedious, costly and time consuming.

- There may be some privacy issues with turning over the data.

- Retiree contributions, discounts, charge-backs, rebates, and administrative expenses must be removed from cost thereby further reducing the potential subsidy.

- Retirees need to be urged <u>not to enroll</u> in a Medicare PDP or MA-PD plan since, if they do so the employer will not be eligible to receive a subsidy

for that retiree. This concept is difficult to communicate although CMS appears to be willing to offer notification sent to such retirees that will ask, "are you sure you want to enroll in Part D".

Our Questions

1. Will an employer-sponsored plan that manages retiree prescription drug benefits for multiple employers under a common umbrella arrangement be permitted to aggregate all of the plans for purposes of obtaining the CMS subsidy? If the employers have different plan years will the administrator be permitted to aggregate only the plans that have identical plan years or will it be permitted to aggregate all of the plans for purposes of obtaining the CMS subsidy?

2. Will employer-sponsored retiree plans that provide prescription drug coverage as a fully integrated part of their retiree medical plans that require retirees cost sharing (medical and prescription drug combined) be permitted to treat the prescription drug component as fully subsidized by the employer, if it is reasonable to presume that the cost of medical (non-prescription component) is equal to or greater than the cost of the retirees' contributions?

3. How frequently will employer-sponsored retiree plan be permitted to modify their plans, administrative agreements with PDPs, and the Medicare Part D interface?

4. Will an employer-sponsored retiree plan be permitted to enter into agreements with multiple PDPs that have been granted waivers in order to satisfy current program designs and the needs of various retiree groups?

5. Will a qualified PDP be fully at risk for the portion of the claims payments that exceed the established CMS risk corridors and reinsurance limit?

6. Will a qualified PDP be obligated to disclose to the plan the contents of its filings, including the CMS approved bid filing, and all subsequent reports and attachments filed with CMS?

7. Will a qualified PDP be obligated to apply the underlying discounts contained in its Medicare Part D bid to the enhancements requested by the retiree plan sponsor?

Comments

Subsidy- this process must be greatly simplified by CMS for large employers in order to make it more attractive. CMS needs to be aware that large employers may have multiple plans, multiple plan years, multiple groups and therefore

multiple data streams. The ability to provide reams of data in a short period of time becomes very costly and the subsidy savings therefore begins to become quickly eroded. If this becomes a poor choice, then large employers are faced with major plan design revisions and, in many cases because employers cannot fill in the donut hole, more out-of-pocket costs for retirees than they currently enjoy from their public sector coverage. More out-of-pocket costs and plan revisions would require union bargaining and likely add additional cost to health benefits programs through givebacks. A plan design solution that would please everyone would be very difficult especially in this time frame.

Suggestion – Simplify. For the subsidy, an actuarial determination should be done and then that actuary should report an annual, estimated cost. Costs would be captured in a calendar year (or fiscal year depending on the plan sponsor) regardless of the plan years of the respective plans. CMS should make a payment based on that estimate. Actual cost will be submitted once after the year is completed (within four months to allow time to accumulate the data). If the actual calculation is within a reasonable margin of the estimated cost, payments should continue although they should be adjusted if needed. This process would be more palatable for employers and allow for less expenditure.

Use of Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug plans (MA-PDs). Again purchasing canned programs or redesigning current prescription drug plans to meet the requirements of the legislation would be very difficult in this time frame. Also if you use these plans and try the wrap-around approach, the legislation prevents the filling of the $3600 donut hole therefore, for many plans, retirees would have a diminution of benefits leading to difficult labor discussions.

Suggestion - the legislation should be amended to allow filling in the gaps of drug coverage, without extending the attachments, similar to how Medicare Parts A and B work for medical and hospital services. If an amendment were done to allow employers to simply fill the gaps, it would be a relatively easy transition for employers, since we are used to supplementing Medicare and we would not have to change our designs. Coordinating would also likely save employers at least as much money and a subsidy. Without such an amendment, this option becomes more onerous than the subsidy.

Medicare Advantage Plans- the distrust and past poor track record of CMS in maintaining the viability of the Medicare (risk and Type C) programs make public employers uneasy in choosing this option. The failure of CMS to maintain proper levels of premium that caused such programs to fail in the past or become so difficult to manage that many HMOs dropped the options may, if CMS handles the Medicare Advantage programs in a similar manner, cause these program to fail down the road. This distrust of not having any control of the offerings makes this option even less attractive.

There are no easy option choices for public employers. Because it will be difficult to make a decision, the lead-time for implementation becomes problematic and thought should be given to an extension of the lead-time.

CMS-4068-P-1075

Submitter : Ms. Barbara Knowlen **Date & Time:** 10/04/2004 06:10:01

Organization : Ms. Barbara Knowlen

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-1075-Attach-2.doc

CMS-4068-P-1075-Attach-1.doc

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:

We welcome the opportunity, as two people with disabilities who would be personally affected ("devastated" might be a better word) by these proposed rues, to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. We are especially concerned with the 7 million dual eligible who will lose all Medicaid prescription drug benefits they now have. This legislation and its proposed rules are NOT a benefit. They are a frontal attack on the benefits we now have. The following are critical recommendations:

DELAY 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. 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, these 7 million people with disabilities the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into nursing homes and mental institutions to get needed medications that have become unaffordable in the community, contrary to the Olmstead and the Freedom initiative supported by CMS. Hundreds of thousands of people with psychiatric disabilities will not be able to afford the medication they need to remain stable. Many others will be easily persuaded to stop taking their medication if it costs a substantial part of their income.

Having personally worked with colleagues with the National Council on Disability in 1994 – 1996 to develop the Ticket to Work/Work Incentives Improvement Act, and having advocated for its passage through Congress, and gone to Washington to watch our dreams and hard work signed into law just days before the millennium, We are personally appalled that the Part D Program, touted as a benefit, could, as it is written, negate our ten years of hard work.

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM UNTIL ITS IMPACT ON TWWIIA (Ticket to Work/Work Incentives Improvement Act), PASS (Plan for Achieving Self Support) AND OTHER SOCIAL SECURITY WORK INCENTIVES IS DETERMINED.

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. In the research we did, we found that almost all and SSD beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. The work incentives we crafted, and Congress passed, solved much of that problem, offering continuing health care through te Medicaid Buy-in, which we both use to enable us to work, and still keep health care benefits, including personal attendant care, for which Medicaid is the only third party payer. Having been able to earn and save money. we were able to buy a home as joint tenants. We paid off our lift equipped van. We do not deend on the system for housing, food, or transportation, only for health care. The Medicaid Buy-in allowed us to achieve this level of independence.

As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years. Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need. We, ourselves, will not only lose the level of independence we have achieved, but we will also be unable to get the medication we need to maintain health and stability. We will have to stop working to afford what little medicine we can get then. We, and others, will lose productivity, freedom from pain, good health, and mental stability. But we're the lucky ones. Implementation of these rules will kill many people whse survival needs were not considered in writing them. You must not let this destructive program go forward.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress. Implementing these extremely poorly conceived rules would irreparably damage the lives, including ours, of millions of people with disabilities who are already finding it difficult to survive.

Thank you for your consideration of my views.

Yours sincerely,

Barbara Knowlen
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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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Thank you for your consideration of my views.

Yours sincerely,

Barbara Knowlen
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CMS-4068-P-1076

Submitter : Mr. Tom Wildsmith **Date & Time:** 10/04/2004 06:10:18

Organization : The Hay Group

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the Hay Group, I would like to submit the attached comment letter regarding the proposed rule (CMS-4068-P) for implementing the Medicare prescription drug benefit established by the Medicare Prescription Drug, Improvement and Modernization Act (MMA).

CMS-4068-P-1076-Attach-1.doc

Hay Group. Inc.
Suite 500
4301 North Fairfax Drive
Arlington, VA 22203
USA

October 3, 2004

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

HayGroup®

Dear CMS:

The Hay Group appreciates this opportunity to comment, on behalf of our clients, on the proposed rule (CMS-4068-P) for implementing the Medicare prescription drug benefit established by the Medicare Prescription Drug, Improvement and Modernization Act (MMA).

The Hay Group is one of the world's largest human resources consulting firms providing service to organizations in both the private and public sectors throughout the world. Hay's Benefit Division provides a full range of health & welfare and pension services, including actuarial consulting, benefit plan design, total remuneration analysis, executive benefits, regulatory compliance, administration & outsourcing advice, and employee communications. Our consultants embody a wide range of expertise and industry experience. Huggins and Company, one of the predecessor organizations to the Hay Group, was founded in 1911, making it one of the first consulting organizations in the United States to provide independent actuarial services.

Hay works with employers of all sizes. For over 35 years, the Hay Group has collected detailed plan design and cost information for a large number of employers in the government, industry, and service sectors, and integrated it into the world's largest benefits comparison database. The 2004 the Hay Benefits Report (HBR) has data on 1,003 employers – including information on the prevalence, design and cost of post-retirement medical benefits.

We also help our clients manage their post-retirement medical benefits, assisting with plan design and contribution strategies, and providing actuarial valuations of their post-retirement medical liabilities in accordance with FAS 106 and GAS 45. Currently, we are working with clients to help them understand the impact of the new Medicare drug benefit on their post-retirement medical programs, the choices facing them as plan sponsors, and the impact of those choices on their current cash costs and financial liabilities. Hay is well positioned to address the likely impact of the proposed rule on employers, the concerns employers have in managing post-retirement medical benefits, and their likely responses to the new rule.

We have comments in the following specific areas:

- The actuarial equivalence test for the 28 percent employer subsidy;
- The treatment of cost-management programs in actuarial equivalence calculations;
- Rebating the Part D premium to retirees, covered by employers, who enroll by mistake;
- Allowing prescription drug plans under Medicare Part D (PDPs) to provide a "private label" Part D plan to multiple employers by making a single filing for that plan design, and the need for clearer rules on employer sponsorship of Part D plans;
- Coordination with employer-sponsored "wrap-around" plans; and
- The impact of induced demand in populations with employer-sponsored coverage.

Actuarial Equivalence Test for the Employer Subsidy
(Section 423.884 – Requirements for qualified retiree prescription drug plans)

According to the 2004 *Hay Benefits Report*, based on a survey of more than 1000 employers, a little less than half of all employers (45 percent) currently offer post-retirement medical benefits to individuals over age 65. Of those, almost a third (29 percent) are "access only" plans where the retiree pays the entire premium. Such plans provide an important coverage option to retirees. Benefits parallel those available to younger workers, and retirees benefit from group purchasing.

We do not yet know what benefits, beyond the standard package, Part D plans will offer, and many retirees may be reluctant to sign up for an unfamiliar program when it first becomes available. Paying a higher premium to stay with an access only plan that provides richer benefits may be a rational decision for many. Precluding that choice by applying an actuarial equivalence test that would result in employers discontinuing "access only" drug coverage (e.g., a two-prong test) would harm Medicare eligible retirees who currently benefit from access only programs.

We believe the term "actuarial equivalence" in the MMA should and does refer to gross benefits. That interpretation is consistent with its use for creditable coverage and in the bid submissions of PDP plans, and would suggest a "one prong" test. The Preamble to the proposed rule suggests that one of the goals for the definition of "actuarial equivalence" is that it not result in a windfall to employers who qualify for the employer subsidy but who do not pay for any part of the retirees' prescription benefit. Avoiding employer "windfalls" is a legitimate concern. However, it is important to carefully consider what constitutes a windfall in this context, and whether the equivalence test is the correct mechanism for preventing windfall payments.

Regardless of the definition of actuarial equivalence chosen, employers will see a reduction in the cost of their post-retirement drug benefits. Some will discontinue their programs, others will coordinate with or "wrap around" Part D, others will sponsor Part D plans for their retirees, and still others will claim the 28 percent employer subsidy. In some cases – such as a wrap-around plan – the subsidy provided by the employer may be less than the subsidy provided by the Medicare program through the Part D benefit. This is neither unexpected nor inappropriate.

Given this background, we believe that an inappropriate "windfall" should be understood as an employer plan sponsor receiving the 28 percent employer subsidy, applying less than the amount

received through that subsidy towards the cost of the retiree drug benefit, and pocketing the difference. Thus, we recommend a single prong test of actuarial equivalence, with the requirement that if the amount of Part D employer subsidy exceeds the employer's contribution towards the plan, any excess subsidy payments must be used by the employer to reduce the cost of the program to enrollees.

Allowing this option will not harm retirees – enrollment in an access only plan is voluntary, and they will still have the option of enrolling in a Part D plan instead. Retirees will only enroll if they believe the combination of cost and benefits available under their employer-sponsored plan is superior to the other alternatives available to them. Using our proposed definition of "actuarial equivalence" will not increase Medicare costs. If fact, if retirees enroll in a Part D plan or Medicare Advantage plan instead, the cost to Medicare will be much larger. Because participation would be voluntary, one might initially be concerned about gaming by retirees or employers with higher than average costs; the concern is unjustified in this case. Because the subsidy base excludes catastrophic claims, it provides protection against adverse selection inflating the size of the employer subsidy.

As an alternative to the above proposal, we ask that CMS consider using our approach as a transition for one or two years, while employers evaluate their options. This would ease the transition for retirees currently covered under employer-sponsored plans.

Cost-Management & Actuarial Equivalence
(Section 423.56 – Procedures to determine and document creditable coverage status of prescription drug coverage; Section 423.884 – Requirements for qualified retiree prescription drug plans)

The cost of a pharmacy benefit program depends on more than the benefit provisions (the definition of covered expenses and cost sharing requirements); it also depends on the population covered, negotiated discounts and rebates, and cost-management programs such as formularies. The definition of creditable coverage and the qualification standards for receiving an employer subsidy are based on the standard Part D benefit as specified by the MMA, and not on any particular Part D plan. A generally recognized actuarial principle is that when testing whether two plan designs are actuarially equivalent, the same underlying population should be used for both benefit packages. Extending this principle to the context of determining if coverage is creditable, and of the first prong of the actuarial equivalence test for qualifying for the 28 percent employer subsidy, we believe that discounts and cost-management efforts should also be held constant.

Some negotiated savings and cost management programs will be completely invisible to the beneficiary – such as drug manufacturer rebates. While these affect the cost of providing benefits, they do not affect the value of those benefits to the beneficiary. Thus, they clearly should be held constant when measuring the actuarial equivalence of alternative benefit designs. Others, such as negotiated prices, may have an indirect effect on beneficiary out-of-pocket costs. For instance, the difference between a 20 percent discount and a 25 percent discount on a $40 drug will reduce the patient cost under a deductible or coinsurance requirement (but not under a

$10 co-payment requirement). However, because the test is against the statutory definition of the standard Part D benefit, rather than any particular Part D plan, there is no clear benchmark for the discount, formulary or cost-management practices to assume. Furthermore, the purpose of the test is to measure the coverage and cost-sharing provisions of another plan against those of the standard Part D benefit package, rather than the cost of providing those benefits. Thus, we believe that discounts and other cost-management features should be held constant also.

Rebating Part D Premiums for Retirees Enrolling by Mistake
(Section 423.884 – Requirements for qualified retiree prescription drug plans)

Medicare eligible retirees will be faced with a confusing variety of new coverage options in 2006, when Medicare prescription drug coverage first becomes available. Some will erroneously enroll in both Part D and an actuarially equivalent employer-sponsored program, resulting in duplicative coverage and unnecessary premium costs. In addition to increasing premium costs for retirees, this unnecessary, duplicitous coverage will create a serious problem for employers. Because they will be unable to claim the 28 percent employer subsidy for retirees who also enroll in Part D, employers will be forced to choose between coordinating with Part D plans on a claim-by-claim basis, or incurring higher costs on those enrollees. Duplicative coverage will also increase the cost to the Medicare program, since the federal subsidy for Part D coverage will exceed the average value of the employer subsidy.

We recommend that the rule permit retirees who have erroneously enrolled in a Part D plan, and have actuarially equivalent coverage from another source, to voluntarily disenroll from Part D and receive a premium refund. This would prevent retirees from paying Part D premiums unnecessarily, simplify plan administration for employers, and reduce the cost to the Medicare program.

We suggest that CMS permit a retroactive disenrollment from a PDP for up to 12 months of premiums, provided that during the period no claim has been filed with that PDP and the enrollee was continuously enrolled in another plan providing creditable prescription drug coverage. A PDP would not be required to permit retroactive disenrollment more than once for any person. Also, a PDP would be allowed to charge a nominal processing fee beginning in 2007, thereby allowing for a reasonable transition period.

Importance of "Private Label" Part D Plans and Need for Clearer Rules on Employer Sponsorship of, or Contracting with, Part D Plans
(Section 423.458 – Application of Part D rules to MA-PD plans on and after January 1, 2006)

Employers will undoubtedly appreciate the opportunity to sponsor a Part D prescription drug plan (PDP) either directly or through contract with a PDP. We believe that the final rule should facilitate employer sponsorship of Part D plans. Employer-sponsored Part D plans would provide an attractive option to many retirees. Enrollment could be coordinated with the rest of an employer's post-retirement benefit program. Allowing employers to sponsor their own PDPs would provide employers with an attractive way to supplement the standard Part D benefit

package. Unlike a "wrap-around," any supplemental or enhanced prescription drug benefits would be integrated with the standard Part D benefits into a single comprehensive program. The result would be simpler for retirees to understand and use, and has the potential to be easier for employers to administer.

Only the very largest employers or union plans, however, will have enough retirees to directly sponsor a Part D plan. (And most of them will not want to administer a drug program – just as most employers with self-funded medical benefit programs choose to use third party administrators.) For most employers, sponsoring a Part D plan will only be a viable option if done through a contract with a commercial Part D plan sponsor.

Most employers are very unlikely to sponsor a Part D plan for their retirees if the employer has to go through the same bid submission process required of a local or regional Part D plan. Rather, they are likely to look for packaged solutions. We recommend that commercial Part D plan sponsors be allowed to submit bids for packaged "turnkey" Part D products that they may then market to employers – much as an insurer or HMO will file a health policy with a state insurance department once, and then market it to multiple employers.

This approach would allow for detailed review of Part D plans marketed to employers without unduly burdening those employers – and would significantly streamline the CMS bid review and approval process. Employers would be able to evaluate this option on the same basis that they do any other health benefit plan – based on benefit design, cost, and the administrative capabilities of the vendor – without taking on bid requirements more appropriate for a health plan itself. A commercial Part D sponsor considering entering this market would have bid requirements commensurate with that for offering a local or regional Part D plan.

It should be expressly stated in the rule that once the PDP obtains approval for a particular plan design, an employer that contracts with the PDP for that plan design is not required to seek further CMS or other approvals. An employer should be able to contract with a PDP for a limited group of Medicare-eligible retirees, subject to any applicable non-Medicare law.

For either direct employer sponsorship or sponsorship through a turnkey product to be of significant use, CMS should issue more specific guidance (whether in the preamble or the rule itself) about what employers will have to do to take advantage of these opportunities. Following are examples of further guidance we think would be very helpful to employers.

The final rule should provide safe harbors for the types of waivers that will be available to an employer that wants to sponsor its own PDP; such as: permission for an employer to cover exclusively all retirees (or all retirees in a particular geographic region or from a particular business unit, such as a subsidiary or division), wherever they reside; permission for an employer to contract to a third party PDP compliance while the employer retains ultimate responsibility and liability for compliance; and automatic permission for an employer that sponsors a PDP to undergo a merger, acquisition or other business reorganization that does not necessitate re-applying for PDP status, provided the terms of the transaction expressly require ongoing compliance with the PDP requirements by the successor organization.

With respect to the waiver process, we support the final rule containing expedited waiver procedures whereby an applicant may cite to two or more previously granted, publicly available, waivers, which have the same fundamental facts as those represented in the applicant's submission. The rules could provide that the grant of the waiver is dependent upon the applicant's representation that all relevant facts are the same.

Coordination with Employer-Sponsored "Wrap-Around" Plans
(Section 423.464 – Coordination of Benefits with Other Providers of Prescription Drug Coverage)

We are concerned that employers that want to provide a "wrap-around" plan which supplements the retiree's Part D coverage will have difficulty administering this type of plan in 2006 and perhaps longer because necessary computer systems are not yet working. To accommodate these employers and PDPs, we suggest CMS consider a transition rule that would allow an employer (directly or through a third party) to accumulate all Part D claims and submit them electronically for reimbursement on behalf of the Part D enrollee. Depending on how the technology develops, CMS could terminate the transition rule or modify it as necessary.

Impact of Induced Demand in Employer-Sponsored Populations
(Section 423.56 – Procedures to determine and document creditable coverage status of prescription drug coverage; Section 423.104 – Requirements related to qualified prescription drug coverage; Section 423.884 – Requirements for qualified retiree prescription drug plans)

The proposed rule requires the "increased cost over the average" from the availability of enhanced or alternative drug coverage to be included in the cost of the supplemental coverage, rather than in the cost of the standard coverage.

While many actuaries have experience with pricing health care costs for different drug benefit designs, few have experience with measures of induced demand. Further, unless a standardized method for measuring induced demand is included in the final rule, this requirement will lead to a wide variation in bid costs for very similar plan designs.

The Hay Group has extensive experience with health actuarial measurements and with the Medicare Current Beneficiary Survey data, which CMS has determined is the best available resource for measuring prescription drug utilization among Medicare beneficiaries. Using the Hay MCBS-based health actuarial model, we have estimated the cost of the standard Part D benefits in 2006 using (a) the full MCBS database, (b) just those records identified as having employer insurance, and (c) the full MCBS database excluding those records that are identified as having employer insurance. The following table shows the actuarial values in 2006 of the standard Medicare Parts A and B benefits, Parts A, B, & D, and therefore by subtraction the value of the Part D benefit coverage. The table also shows the demographic characteristics of the group included in each measurement, and illustrates the difficulty of allocating the "induced demand" measurement in the cost between the standard benefit and an alternative or enhanced benefit.

Group Included in the Measurement	Actuarial Value of Parts A & B	Actuarial Value of Parts A, B, & D	Estimated Cost of Part D	Average Age	Percent Female
All Medicare Beneficiaries	$8,519	$10,345	$1,826	73.1	**57%**
Just those with Employer Insurance	$8,538	$10,862	$2,324	73.9	**53%**
Excluding those with Employer Insurance	**$8,466**	**$10,043**	**$1,577**	**72.7**	**59%**

- The table shows that there are slight differences in the demographic characteristics among the groups. Those Medicare beneficiaries who also have employer insurance can be expected to be slightly older and have more males than the overall Medicare population.

- The differences in the value of Medicare Parts A & B benefits are very small -- $8,519 for the overall population, and under one-half percent higher for those with employer insurance. This is consistent with the general observation that the "induction" effect for hospitalization benefits is quite small. In the Hay model we typically use an induction parameter of 30% for hospitalization benefits and 70% for outpatient benefits.

- There is, however, a significant difference in the cost of the Part D benefits for the different groups. Based on the underlying prescription drug usage collected in the MCBS survey, for those Medicare beneficiaries who have employer coverage, and only measuring the cost for the portion of these expenditures covered by Part D, the estimated cost is 27 percent higher than the all-Medicare average and 47 percent higher than the cost for those Medicare beneficiaries who do not have employer insurance.

Thus, based on the MCBS data, we observe that the availability of employer insurance (equivalent to the availability of enhanced coverage) has a significant effect on overall prescription drug usage – such that the value of just the Part D coverage is almost 50 percent higher for those with such coverage compared to those without such coverage.

We believe it would be incorrect for an actuary preparing a bid using prescription drug experience from plans which had broad coverage (i.e. current employer plan designs) to assign the cost of $1,577 to the standard Part D plan, when the current underlying claims experience indicates it is $2,324. Similarly, if the actuary had access to a health actuarial model similar to the Hay model based on the MCBS data, it would be wrong for the actuary to assume that the availability of prescription drug coverage would have no effect on expected expenditures, and therefore use of $1,577 cost would be inappropriate.

We believe it is inappropriate for the rule to require an allocation of the induced demand cost between the Part D benefits and enhanced benefits.

That said, if it is decided to include this requirement in the final regulations, we believe that the competitive bid process would be enhanced if all bidders had access to the Hay MCBS-based health actuarial model so that the induced demand costs can be determined from a common base.

The model allows for the selection of parameters to reflect induced demand, so bidders would be able to choose their own assumptions, however as the underlying data would be common, the results of the allocation of costs more equitable. The model was developed initially for the Congressional Research Service, and as such is in the public domain.

* *

Thank you for the opportunity to comment on this proposed rule. We believe the implementation of the new Medicare prescription drug benefit in a way that broadens seniors' access to prescription drugs, rather than undermining access to existing coverage, is a significant challenge. Successfully meeting that challenge will require careful consideration of the impact of the program on employer-sponsored post-retirement medical plans. If you have any questions about these comments, please contact Adam Reese (703-841-3119 or Adam_Reese@haygroup.com) or Tom Wildsmith (703-841-3135 or Tom_Wildsmith@haygroup.com).

Sincerely,

Adam Reese, FSA, MAAA, EA
Senior Consultant

Tom Wildsmith, FSA, MAAA
Consultant

Submitter : Dr. Douglas Miller **Date & Time:** 10/04/2004 06:10:11

Organization : Grady Health System

Category : Local Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

As Chief of Pharmacy and Drug Information at Grady Health System ? Atlanta, Georgia (GHS), I would like to first thank you for the opportunity to submit comments on the proposed regulation to implement the Medicare prescription drug benefit. At Grady Health System, our mission is to improve the health of the community by providing quality, comprehensive health care in a compassionate, culturally competent, ethical and fiscally responsible manner. Grady maintains its commitment to the underserved of Fulton and DeKalb counties, while also providing care for residents of metro Atlanta and Georgia. Grady provides leadership to the healthcare community through its clinical excellence, innovative research and progressive medical education and training.

Recently, the Centers for Medicare & Medicaid Services published comment regarding the deeply discounted prices available to 340B disproportionate share hospitals (DSH) and health systems that are dispensing outpatient prescriptions to largely indigent and underserved populations. This allows 340B entities to extend affordable drug coverage to their patients, many of whom are Medicare beneficiaries without other insurance.

BENEFITS AND BENEFICIARY PROTECTIONS

Medicare Approved plan sponsors should not be allowed to require beneficiaries to use mail order pharmacies, nor should they be allowed to promote such pharmacies if they have an ownership interest. There are not only safety concerns, but medication management and compliance are hard to address when the patient?s profile is not easily accessible. Since DSH institutions are able to provide prescription medications at a reduced cost, mail order should only be offered as an additional benefit without a co-payment incentive.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

CMS discusses permitting State Pharmaceutical Assistance Programs (SPAPs) and other drug plans, such as Medicaid, group health plans, federal employee and military health plans to coordinate coverage with private and Medicare Advantage prescription drug plans (PDP and MA-PD), but again makes no concession for DSH institutions. DSH institutions generally provide care to Medicare beneficiaries at reduced out of pocket costs, including prescription medications. There is no wording in the proposed guidelines encouraging PDPs and MA-PDs to allow DSH institutions as part of the pharmacy network, which disrupts the continuity and high quality patient care we are currently providing. Currently, there are only two Medicare Drug Card approved sponsors that will work with DSH institutions, limiting our options to participate to an almost discriminatory level.

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

I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. At Grady Health System, we currently provide clinical pharmacy services for patients in our Geriatrics, Diabetes, Hepatitis C, HIV / Infectious Disease, Urgent Care, and General Medicine Clinics. Plans should be encouraged to continue to use our services and to help our patients make the best use of their medications.

Pharmacists are also the ideal health care professionals to identify Medicare beneficiaries with multiple disease states and chronic care issues that need medication management for their drug therapies. CMS needs to ensure that referral for MTM is not limited by the plan. CMS also needs to guarantee that pharmacy service providers are not limited to licensed pharmacies, nor tied to a specific pharmacy or a written prescription. Due to the clinical nature of pharmacy services offered by many institutions and health systems, MTM services should be able to be administered with or without filling a prescription.

CMS should include guidelines for plan sponsors for minimum requirements for MTM services. To further ensure quality care, CMS should consider a program to accredit plans offering MTM services to meet basic knowledge competencies. This will help to lower costs and offer quality care by a pharmacist. Programs at minimum should include: diabetes management and education, anticoagulation services, asthma education, cholesterol monitoring, HIV therapy management and education, osteoporosis screening, and pharmacotherapy programs for chronic diseases.

I believe it is important for CMS to allow for all pharmacists to be considered providers of MTM services, and that plans should be directed to allow for such services, regardless of the practice setting. CMS should also guarantee that providers of MTM services are reimbursed at the same rate, regardless of provider status. Pharmacists are an integral part of the healthcare team that can make certain appropriate drug therapies are used and conditions are treated properly.

ELIGIBILITY, ELECTION, AND ENROLLMENT

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. 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 met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. It also alienates a subset of pharmacies providing care for the most vulnerable patients. CMS has failed to consider the unique situation of 340B ?Safety Net? healthcare organizations that represent five percent of the nation?s hospitals, and treat close to two million Medicare beneficiaries each year, in many cases, providing pharmaceutical coverage at substantially discounted prices. Incompatibilities with such institutions could limit, even cut-off, the very small number of approved Medicare Card vendors willing to participate with DSH institutions. CMS should require plans to offer a standard contract to all pharmacies and provide wording to require private prescription drug plans to contract with ?Safety Net? hospitals providing outpatient prescriptions.

CMS discusses permitting State Pharmaceutical Assistance Programs (SPAPs) and other drug plans, such as Medicaid, group health plans, federal employee and military health plans to coordinate coverage with private and Medicare Advantage prescription drug plans (PDP and MA-PD), but again makes no concession for DSH institutions. DSH institutions generally provide care to Medicare beneficiaries at reduced out of pocket costs, including prescription medications. There is no wording in the proposed guidelines encouraging PDPs and MA-PDs to allow DSH institutions as part of the pharmacy network, which disrupts the continuity and high quality patient care we are currently providing. Currently, there are only two Medicare Drug Card approved sponsors that will work with DSH institutions, limiting our options to participate to an almost discriminatory level.

GENERAL PROVISIONS

CMS must act responsibly by assuring that the dispensing fees are not discriminatory against DSH institutions. Because such institutions are able to access 340B pricing, average wholesale pricing is not used as part of our billing equations, thus putting us at a disadvantage if the dispensing fee is limited. If an institution is billing at actual acquisition, a dispensing fee structure should be provided such that overhead costs are covered.

CMS-4068-P-1078

Submitter : Mr. R. Dale Tinker **Date & Time:** 10/04/2004 07:10:05

Organization : New Mexico Pharmaceutical Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Practitioners are defined in most state statutes as: a healthcare provider with the authority to prescribe, dispense and administer medications.

Under New Mexico law, pharmacists can:
1. prescribe under the supervision of a physician to provide medication therapy management, limited only to the scope of the physician?s practice.
2. prescribe based on protocols approved by the Board of Pharmacy, the Board of Medicine and the Board of Nursing. Currently approved protocols are for prescribing vaccinations for emergency contraception. Tobacco cessation protocols are expected to complete the last step in approval after the Board of Nursing meeting in November.
3. dispense medications.
4. administer medications.

We make the following recommendations for successful implementation of the program, leading to improved patient care.

It is our position that CMS should include in the rules:
1. definition of a qualified provider, and that pharmacists should be granted primary provider status within the regulations.
2. Under-use of medications often is as serious a drug-related problem as is over-use. Based upon this, targeted beneficiaries should not be limited, except to patients with at least one chronic disease condition.
3. Reimbursement rates must be determined by CMS, using a national standard, any willing provider guidelines and ensuring appropriate coverage areas.
4. The patient must have freedom of choice of providers.
5. CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas.

Access to Care.
Long-term Care, Home Care, Assisted services, etc.:
CMS states in its proposal: ?It is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient pharmacies.?

Tri-Care Standards:
?Averaging? access: require MA-PDs and PDPs to calculate access on a local basis in each state, not regionally.

?Preferred? and ?Non-Preferred? Networks: require all plans to offer all pharmacies of a similar nature (e.g. institutional, retail, rural, urban, suburban) the same contract terms.

Indian Health Service and tribal pharmacies: require MA-PDs and PDPs to include IHS and tribal pharmacies in their networks, in addition to other pharmacies, under the same terms and conditions, adjusted for the lower acquisition costs reflected in the FSS.

?Level playing field? between retail and mail order pharmacies: Clearly state that no PDP may create any incentive for the use of mail delivered benefits over community delivered benefits. Prohibit requiring the use of pharmacies in which PDP has an ownership interest, consistent with Medicare rules for other health services.

MTMP - CMS must:
Develop a descriptive requirement for MTMP so all PDP will incur approximately the same MTMP costs. Develop oversight procedures to ensure that MA-PDs and PDPs actually engage in a reasonable process to determine MTMS payment rates that are sufficient to allow pharmacists to provide face-to-face MTMS.

MA-PDs and PDPs should:

1. reimburse pharmacists for immunization services at the same rates paid to other immunization providers under Part B.
2. be required to adopt the NCPDP-approved patient claim card format.
3. be required to establish pharmacy and therapeutics (P&T) committees, comprised of equal numbers of pharmacists and physicians.
4. be required to maintain 24/7 help desk access for pharmacists and patients.
5. count out-of-network pharmacy expenses toward total out-of-pocket expenses.
6. ensure that ?dual eligible? patients don?t suffer an interruption in their drug therapies.

Sincerely, R. Dale Tinker
Executive Director
New Mexico Pharmaceutical Association

CMS-4068-P-1078-Attach-1.doc

New Mexico Pharmaceutical Association
4800 Zuni S.E.
Albuquerque, New Mexico 87108

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

Re: CMS-4068-P

Dear Sir or Madam:

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.

Practitioners are defined in most state statutes as: a healthcare provider with the authority to prescribe, dispense and administer medications.

Under New Mexico law, pharmacists can:

1. prescribe under the supervision of a physician to provide medication therapy management, limited only to the scope of the physician's practice.
2. prescribe based on protocols approved by the Board of Pharmacy, the Board of Medicine and the Board of Nursing. Currently approved protocols are for prescribing vaccinations for emergency contraception. Tobacco cessation protocols are expected to complete the last step in approval after the Board of Nursing meeting in November.
3. dispense medications.
4. administer medications.

We make the following recommendations for successful implementation of the program, leading to improved patient care.

It is our position that CMS should include in the rules:

1. definition of a qualified provider, and that pharmacists should be granted primary provider status within the regulations.
2. Under-use of medications often is as serious a drug-related problem as is over-use. Based upon this, targeted beneficiaries should not be limited, except to patients with at least one chronic disease condition.
3. Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas.
4. The patient must have freedom of choice of providers.
5. CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas.

Access to Care

Long-term Care, Home Care, Assisted services, etc.:

CMS states in its proposal: "It is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient pharmacies." This statement confuses the payment standard for dispensing and for medication therapy management.

Solution: develop a standard for product payment (to efficient pharmacies) and a standard for payment for providing medication therapy management. The standard must recognize the provision of necessary services and added costs of providing services for this patient population (unit dose packaging, working through intermediary caregivers, etc.).

Tri-Care Standards:

The proposed rules suggest several ways that MA-PDs and PDPs could avoid the strict statutory requirement to meet or exceed the Tri-Care retail pharmacy access standards, among them: "Averaging access" measurement regionally, allowing plans to develop "preferred" and "non-preferred" networks and allowing plans to use Indian Health Service and tribal pharmacies in calculating access.

"Averaging" access: The Medicare statute and TriCare set out clear standards of access. The only way that CMS can meet the requirements of the law is to require MA-PDs and PDPs to calculate access on a local basis in each state, not regionally. If a regional average were allowed, then many seniors in remote areas effectively would be denied access to Part D.

Solution: CMS should require MA-PDs and PDPs to calculate access on a local basis in each state, not regionally.

"Preferred" and "Non-Preferred" Networks: If MA-PDs and PDPs were allowed to include "non-preferred pharmacies" – where patients presumably would be forced to absorb more cost sharing – for purposes of measuring access, plans would be allowed to meet the statutorily required access standards without actually providing any access at all.

Solution: CMS should require all plans to offer all pharmacies of a similar nature (e.g. institutional, retail, rural, urban, suburban) the same contract terms.

Indian Health Service and tribal pharmacies: As CMS itself observes in its proposal, IHS and tribal pharmacies do not service the general population and purchase prescription drugs based on the Federal Supply Schedule (FSS). We agree that in some areas, such as the Navajo Nation or Apache Reservations, failing to include tribal pharmacies in MA-PDs and PDPs would effectively deny access to Part D for tribal members. But the solution to this problem is not to allow plans to count IHS and tribal pharmacies for purposes of calculating whether a plan has met the TriCare access standards; that could have the equally damaging effect of denying non-tribal patients access to local pharmacies in communities near Indian reservations. For example, the residents of communities such as Ruidoso and Gallup could be denied Part D access to their local pharmacies.

Solution: CMS should require MA-PDs and PDPs to include IHS and tribal pharmacies in their networks, in addition to other pharmacies, under the same terms and conditions, adjusted for the lower acquisition costs reflected in the FSS.

"Level playing field" between retail and mail order pharmacies: We are pleased to see that CMS intends to pursue program designs which will serve to level the playing field between community based pharmacies and mail order pharmacies, as is clear in the statute and congressional intent. However, we are concerned that the rule does not go far enough to ensure a true level playing field that favors beneficiary choice.

Solution: CMS rules should clearly state that no PDP may create any incentive for the use of mail delivered benefits over community delivered benefits.

We are greatly concerned that CMS would allow a PDP or MA-PD to both manage a network of community pharmacies and promote its own mail order operation in direct competition with that pharmacy network, and even possibly use manufacturer rebates gained from the community pharmacy network to subsidize lower patient cost-sharing through their captive mail order pharmacies. Such a conflict of interest must be recognized by CMS and prohibited in its enabling regulation. Fragmenting patient care services for the sole purpose of promoting profits should not be dismissed by CMS as an acceptable risk in exchange for promises of "cheap drugs in a bottle".

Solution: Prohibited PDP or MA-PD from promoting or requiring the use of pharmacies in which they have an ownership interest, consistent with Medicare rules for other health services.

Medication Therapy Management Services

MTMP costs and will contribute proportionally to the savings in Medicare Parts A and B. Without a stringent requirement, the bare minimum is likely to be provided and will most likely be a simple repackaging of population-based activities already performed by PDP.

Solution: A descriptive requirement for MTMP is necessary so all PDP will incur approximately the same MTMP costs.

The pharmacy benefits management (PBM) industry, which is likely to be among the PDPs, has demonstrated little consideration of provider costs or the needs of special populations such as seniors. In fact, the PBM industry's primitive focus on product cost at the expense of patient care services has resulted in diminished pharmacy access in rural areas and has impeded the adoption of pharmacy based patient care services that have been proven to be beneficial to patients and payers in numerous studies.

Solution: CMS must develop oversight procedures to ensure that MA-PDs and PDPs actually engage in a reasonable analytical process to determine MTMS payment rates and that those rates are sufficient to allow pharmacists to provide face-to-face MTMS

General Administration Issues:

- CMS should consider requiring MA-PDs and PDPs to reimburse pharmacists for immunization services at the same rates paid to other immunization providers under Part B. Pharmacists have become a major source of immunization services in recent years, and CMS should take advantage of the claims processing efficiencies of Part D to increase immunization rates among the elderly.
- MA-PDs and PDPs should be required to maintain 24/7 help desk access for pharmacists and patients.

- MA-PDs and PDPs should be required to establish pharmacy and therapeutics (P&T) committees, comprised of equal numbers of pharmacists and physicians including both pharmacy and physician specialists.
- MA-PDs and PDPs should be required to adopt the NCPDP-approved patient claim card format, as CMS suggests.
- When patients must or choose to use an out-of-network pharmacy, expenses should be counted toward total out-of-pocket expenses. Since an out-of-network pharmacy by definition will not have access to the preferred pharmacy rates for any product, a pharmacy's "usual and customary" pricing structure should be recognized. We support the proposed requirement that pharmacies inform patients of the cost of a comparable, lower-cost generic drug if a generic drug is not being dispensed.
- We are extremely concerned that the transition of "dual eligible" patients from state-based Medicaid to the new Part D is fraught with peril for our nation's most fragile patients. CMS must take great care to ensure that "dual eligible" patients don't suffer an interruption in their drug therapies. MA-PDs and PDPs must be required to provide benefits information to patients, their caregivers and their involved physicians and pharmacies at least 45 days in advance of the changeover in order to provide adequate time to make the necessary adjustments in drug therapies without putting patients' lives at risk.

Sincerely,
R. Dale Tinker
Executive Director

CMS-4068-P-1079

Submitter : **Date & Time:** **10/04/2004 06:10:08**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The proposed regulation that allows plans to establish preferred and nonpreferred pharmacies, could affect the pharmacists ability to serve his/her patients. Allowing plans to distinguish between preferred and nonpreferred pharmacies, has the potential to drive patients to certain pharmacies, which goes against Congressional intent. Congress wants to ensure that patients can go to their pharmacy of choice.

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

CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacisits should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill directly for the services.

Plans must be required to pay the same fee for MTMS to all providers. CMS must carefully evaluate each plans application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

CMS-4068-P-1080

Submitter : Mr. Mike Godino **Date & Time:** 10/04/2004 06:10:19

Organization : Queens Independent Living Center, QILC

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please find the attached comments from the Queen Independent Living Center, QILC.

CMS-4068-P-1080-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:

The Queens Independent Living Center, QILC welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632.

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:

DELAY 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. 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 sheer implausibility 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 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.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

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.

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 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:

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

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. 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 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.

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 a truly independent review by an administrative law judge (ALJ) and 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; 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:

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.

Best Regards,

Mike Godino
Systems Advocacy Coordinator, QILC

CMS-4068-P-1081

Submitter : Maxine Johnson **Date & Time:** 10/04/2004 07:10:19

Organization : Albertsons

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Albertsons supports the attached NACDS SPOCS proposal and would encourage CMS to utilize this model for eligibility, coordination of benefits, and TrOOP maintenence. Without on-line, real-time management of these processes, Medicare Recipients will not receive the benefits they anticipate or the service they expect from their managed care organization and their local pharmacy.

CMS-4068-P-1081-Attach-1.doc

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

IssueBrief

Expanding CMS' Option 2 to Include Pharmacies Would Allow a More Efficient COB and an Accurate Calculation of TrOOP that Would Reduce the Medicare Beneficiaries Waiting Time for Prescription Medication and Supply Services.

NACDS offers a proposal that will allow CMS to attain its self–defined goals of maximizing the efficiency and effectiveness of a COB–TrOOP system by the MMA deadline of January 1, 2006. This proposal simply builds on CMS' Option 2, as described on FR page 46706, by including pharmacies in the single point of contact system. NACDS refers to this online real time COB–TrOOP system as SPOCS (Single Point Of Contact System), which is described below.

SPOCS would have two major advantages over CMS' proposed Option 2. Those advantages are that both Medicare recipients and pharmacies would also enjoy the benefits of a single point of contact system, not only payors. This increase in functionality maximizes the efficiency and effectiveness of a COB–TrOOP real time system.

NACDS offers CMS this SPOCS Proposal to assist CMS in its efforts to establish, before July 1, 2005, procedures and requirements that will promote the effective COB between a Part D plan and a State Pharmaceutical Assistance Program (SPAP), Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage CMS may specify in the future.

Most importantly, Medicare recipients will find SPOCS to be the easiest system to understand and the most convenient system to obtain their prescription medication and supply services.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

(703) 549-3001
Fax (703) 836-4869
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PROPOSAL
Single Point Of Contact System (SPOCS)
for
Medicare Part D COB and TrOOP

Overview of the Proposed COB–TrOOP Process:

- Medicare recipient needs only to present Medicare card and prescription(s) at the pharmacy.
- Pharmacy submits ALL Medicare recipients prescription claims (e.g., SPAP, Medicaid, group health plan, FEHBP, TRICARE) to the "SPOCS".
- SPOCS has ALL of the Medicare recipient's insurance eligibility information and the correct billing order in its electronic files.
- SPOCS, after receiving a prescription medication or supply payment claim from the pharmacy, identifies the Medicare recipient in its electronic file and sends the payment claim to that Medicare recipient's primary payor, the primary payor responds back to the SPOCS with the necessary COB and TrOOP information and the SPOCS repeats the process with the Medicare recipient's secondary payor, etc. until all of the responsible payors are billed.
- SPOCS sends the claim with a "separate response payment segment" for each payor back to the pharmacy so the pharmacy knows what each payor has paid and who to expect payment from.
- SPOCS receives the final TrOOP calculation for that claim and sends this information to the appropriate parties.

Advantages:

- Medicare recipient only needs to present Medicare Card at the pharmacy… no other insurance cards are necessary because of the single point of contact with the SPOCS.
- Medicare recipient's claims will go through the SPOCS and can be accessed for Medicare eligibility determination, TrOOP management, physician billed Part B claims updates, claims reversal communications, and inquires by appropriate parties about the TrOOP.
- CMS will only need to work with the SPOCS for eligibility and TROOP management.
- Pharmacy knows where to send ALL of the Medicare recipient's prescription claims reducing dispensing time so that the Medicare recipient obtains prescription medications and supplies more quickly than she/he otherwise would if the pharmacy was required to make eligibility inquires or to try to determine the correct billing order of the Medicare recipient's payors.
- A prescription ID card is not required to be sent to Medicare recipient… the Medicare recipient's Medicare Card is all that is necessary.
- SPOCS will be able to manage ALL* payment claims real-time, including Medicare Complementary Cross Over Claims.
- SPOCS is an independent entity that acts as a switch for real–time COB and TrOOP information that does not have a potential conflict of interest managing patient identifiable health care information and pharmacies' confidential payment rates.
- Separate response payment segments from the SPOCS will eliminate the current confusion in those cases when the DMERCs do not let the pharmacy know the secondary payor information on Medicare Complimentary Billings.
- Each payer is responsible for its own payments, which are reflected in the SPOCS's separate response payment segments back to the pharmacy.

*ALL – Need to have pharmacy Medicare Part B claims process on-line, real-time. See below.

SPOCS' System Requirements:

- Claims processing at PBM's must have a separate and enforced Bin Number for all Medicare claims processing at their site to assure that claims go through the SPOCS with the proper routing.
- All Medicare recipients' billing information and billing order must be on file at SPOCS and continually updated.
- Must have separate "response payment segments" for each payor billed through the SPOCS.
- To process COB claims, the processors would need to follow one of the NCPDP COB billing standards. The processor would elect to process the payment information by electing to use the 5.1 COB segment and accepting the "Other Payer Amount Paid", OR, not use the 5.1 COB segments but use the 5.1 pricing segment and accept the "Copay Billing" which would be populated with the Gross Amount Due.
- SPOCS treats all pharmacy claims and information as proprietary and confidential.
- Pharmacy maintains ownership of submitted claims data to dissuade the unauthorized uses and further disclosures of patient identifiable health care information as prohibited by the HIPAA privacy regulations.
- Pharmacies and Payers would need to make appropriate software changes that would allow them to: interact with SPOCS as the central point of contact for Medicare billed claims, receive multiple payment response segments, and receive TrOOP accumulator information. These changes for the Medicare recipients' claims would allow the SPOCS system to identify the eligible Medicare recipient, bill their claims to responsible payors in the proper billing order, send the information back to the pharmacy in an identifiable payment reconciliation format, and communicate the TrOOP back to the appropriate parties. The system should also allow for easy update of physician billed Part B claims.
- Medicare Part B pharmacy claims must process on-line, real time through SPOCS. This is required to allow for proper and accurate TrOOP calculation for the Medicare recipient. It is necessary to know the Medicare Part B paid amount (which by today's use of paper claims can takes weeks to obtain) to do any wrap around or additional COB billings and obtain a real-time calculation of Medicare recipient's TrOOP.
- Medicare Part B claims processing requirements would need slight modifications to make them as streamlined as pharmacy commercial payment claims and Part B would need to move to NCPDP 5.1 online, real time claims management.
- COB claims submission process would need to be accomplished within the industry standard claims submission time–out window of approximately 12 seconds.
- Preferable that all Medicare Prescription Plans use the Medicare recipient's Medicare ID number (or one ID number designated by CMS) as the Medicare recipient's ID number for all the various prescription programs the Medicare recipient may be enrolled. If not, the SPOCS would need to maintain the alternate ID billing numbers for the Medicare recipient to cross reference and COB bill.
- Work towards using common claim identifier values for physicians (NPI) and for drugs (NDC numbers).

Submitter : Mrs. Beth Martin **Date & Time:** 10/04/2004 07:10:40

Organization : University of Wisconsin School of 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. As both an pharmacy educator and pharmacy practitioner, I am especially grateful to have this opportunity to share my suggestions for your consideration as CMS develops the final regulation.

SUBPART C: Benefits and Beneficiary Protections
I recommend revising the pharmacy access standard to require plans to meet the standard on a local level to ensure that all benficiaries have convient access to a local pharmacy that is qualified. I am concerned that the proposed regulations allow plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. I have seen this system abused in our current third party system, and where my patients lacked proper care due to pharmacies who were contracted on their 'lowest bid.'

SUBPART D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I am most appreciative that CMS recognizes pharmacists as primary providers, but am concerned that leaving the decision of provider status to the plans may allow them to choose less qualified providers to provide MTM services. Pharmacists and students I work with have embraced patient care services and render quality, cost-efficient care to the patients they assist. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently teach and provide tobacco cessation, hypertension, lipid management, asthma, osteoporosis, and complex regimen services to patient groups.

It is also important to provide providers a reasonable payment for MTM services. Too often I see quality care denied to patients due to the small pool of providers who must limit their access because of less-than break-even payment for services rendered. The system must recognize the billions of dollars spent annually on drug-related problems -- a portion of those monies that could be paid for MTM services to PREVENT such problems.

In conclusion, I urge CMS to consider accepting all pharmacies as providers (basic requirements upheld), to pay for quality services (not discounted to the lowest bidder) and to recognize the special skills and training that make pharmacists an ideal health professional to provide MTM services.

Thank you and most sincerely,
Beth A. Martin, MS, RPh
Clinical Assistant Professor
University of Wisconsin School of Pharmacy
777 Highland Ave
Madison WI 53705-2222

CMS-4068-P-1083

Submitter : **Date & Time:** **10/04/2004 07:10:45**

Organization : **Medicare Consumers Working Group**

Category : **Consumer Group**

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

see attached

BACKGROUND

see attached

BENEFITS AND BENEFICIARY PROTECTIONS

see attached

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

see attached

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

see attached

ELIGIBILITY, ELECTION, AND ENROLLMENT

see attached

GENERAL PROVISIONS

see attached

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

see attached

PAYMENTS TO PDP AND MA-PD PLANS

see attached

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

see attached

Issues 11-20

COLLECTION OF INFORMATION REQUIREMENTS

see attached

EFFECT OF CHANGE OF OWNERSHIP OR LEASING OF FACILITIES DURING TERM OF CONTRACT

see attached

FALLBACK PLANS

see attached

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

see attached

INTERMEDIATE SANCTIONS

see attached

MEDICARE CONTRACT DETERMINATIONS AND APPEALS

see attached

PART D PROVISIONS AFFECTING PHYSICIAN SELF-REFERRAL, COST-BASED HMO, AND PACE REQUIREMENTS

see attached

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

see attached

REGULATORY IMPACT ANALYSIS

see attached

SPECIAL RULES FOR STATES

see attached

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MEDICARE Consumers Working Group

October 4, 2004

The U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services

Comments on Proposed Regulations
File Code [CMS-4068-P]

The Medicare Consumers Working Group, a coalition of health care and consumer organizations, has jointly developed the following comments on the above referenced Proposed Regulations. Members of this group include:

AFL-CIO
Center for American Progress
Center for Budget and Policy Priorities
Center for Medicare Advocacy, Inc.
Epilepsy Foundation
Families USA
Health Policy Institute, Georgetown University
Medicare Rights Center
National Committee to Preserve Social Security and Medicare
National Council on Aging
National Health Law Program
National Mental Health Association
The Arc and UCP Public Policy Collaboration

Together, our organizations represent a wide range of Medicare beneficiaries and a cross-section of interests and expertise: consumer and Medicare beneficiary advocacy organizations; organizations addressing the needs of individuals with specific diseases or disabilities; legal services; unions; and research and policy institutes. We bring to the comment process significant experience and expertise in health care policy, and an in-depth understanding of the specific health care needs and issues confronting Medicare beneficiaries, particularly those who are eligible for both Medicare and Medicaid. And we share many issues and concerns—several quite serious—with the Proposed Regulations.

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The organizations listed below, and listed again at the conclusion of this letter, join in submitting these comments:

AFL-CIO
AIDS Alliance for Children, Youth & Families
AIDS Foundation of Chicago
AIDS Institute
AIDS Legal Council of Chicago
Alliance for Retired Americans
American Association of People with Disabilities
American Association on Mental Retardation
American Congress of Rehabilitation Medicine
American Council of the Blind
American Dance Therapy Association
American Diabetes Association
American Federation of State, County & Municipal Employees
American Federation of Teachers
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Network of Community Options and Resources
American Public Health Association
Association of Academic Physiatrists
Association of University Centers on Disabilities
Bazelon Center for Mental Health Law
Brookdale Center on Aging, Hunter College
Brooklyn Wide Interagency Council for the Aging Educational Fund
California Health Advocates
Catholic Charities USA
Center for Advocacy for the Rights and Interests of the Elderly
Center for American Progress
Center for Health Care Rights
Center for Independence of the Disabled
Center for Medicare Advocacy, Inc.
Center on Budget and Policy Priorities
Center on Disability Issues and the Health Professions
Coalition of Wisconsin Aging Groups
Disability Law Center of Alaska
Easter Seals
Epilepsy Foundation
Families USA
Family Voices
Fiscal Policy Institute
Gay Men's Health Crisis
Greater Upstate Law Project
Health and Disability Advocates

Helen Keller National Center
HIV Medicine Association
International AIDS Empowerment
Jewish Federation of Metropolitan Chicago
Joint Public Affairs Committee for Older Adults
Legal Services of Eastern Missouri
Lutheran Services in America
Medicaid Matters New York
Medicare Advocacy Project, Greater Boston Legal Services
Medicare Rights Center
National Academy of Elder Law Attorneys
National Alliance of State and Territorial AIDS Directors
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities
National Association of County Behavorial Health Directors
National Association of Protection and Advocacy Systems
National Association of Social Workers
National Citizens' Coalition for Nursing Home Reform
National Coalition on Deaf-Blindness
National Committee to Preserve Social Security and Medicare
National Fragile X Foundation
National Health Law Program
National Mental Health Association
National Multiple Sclerosis Society
National Respite Coalition
National Senior Citizens Law Center
National Women's Law Center
New Hampshire Department of Health and Human Services, Division of Family
New York Immigration Coalition
New Yorkers for Accessible Health Coverage
Northeastern Illionois Area Agency on Aging
NY State Alliance for Retired Americans
NY StateWide Senior Action Council
Paralyzed Veterans of America
Poverty Law Project at Vermont Legal Aid
San Francisco AIDS Foundation
Senior Citizens Law Project of Vermont Legal Aid
Service Employees International Union
Tennessee Protection and Advocacy, Inc.
The Arc of the United States
Title II Community AIDS National Network
United Cerebral Palsy
United Senior Action of Indiana
United Spinal Association
USAction

Vermont Disablity Law Project
Vermont Long Term Care Ombudsman Project
Vermont Office of Health Care Ombudsman
Volunteers of America
Westchester Disabled on the Move Inc.
World Institute on Disability

Organization of Comments

Our comments begin with introductory observations that outline our general concerns. These are followed by more specific comments addressing the following Subparts and specific sections within those Subparts. In addition to the specific sections on which we have comments, in many cases we have noted overriding concerns with some or all of the sections in a Subpart.

INTRODUCTORY COMMENTS

These Introductory Comments reflect our overarching concerns and relate to the entirety of the Proposed Regulation.

Use Authority to Ensure Access to Affordable Medications. The law gives the Secretary broad discretion to set policy for many aspects of the prescription drug benefit. However, the proposed regulation does not, in many areas, suggest that the Secretary will use that authority to ensure that all Medicare beneficiaries have access to affordable medications. The detailed comments include a number of provisions that should be added to the final regulation to ensure that the law fulfils its promise.

Many Pro-Consumer Comments in the Preamble Do Not Appear in the Proposed Regulations.
We are concerned that many statements in the Preamble that we support do not appear to be reflected in the proposed regulation. We urge that more be done to reflect the Preamble's good intentions in the actual body of the regulation. 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 just says that notice should be provided, without specifying 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 when an enrollee's plan does not contract with the long-term care pharmacy which an enrollee in a nursing home must use. The regulatory language does not include the examples CMS discusses in the preamble.

While specifying beneficiary protections in the Preamble is well and good, they bear no weight unless captured in the regulation.

Need for Second Round of Comments Given Large Number of Issues Not Addressed.
We are also surprised at the large number of issues that are not addressed and for which only the vaguest suggestion of the final regulation is offered. We fear that the final regulation will include a number of errors and provisions that result in unintended consequences because so much of the final

regulation will not have been seen by the public. We urge that CMS 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 regulation is more fully drafted will create some serious problems in the fall of 2005 when the program is launched.

Need for Technical and Corrective Amendments.
There are clearly a number of areas where the law is unclear or contradictory and these areas are creating serious problems for the regulation-writers. We urge the Department to 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.

Cost Reductions in the Future.
In its Preamble/Regulatory Impact Statement, CMS notes:

> "We are very interested in developing further evidence on the best ways to encourage outcome improvements and overall health care cost reductions through drug coverage…."

In response, we urge that the Department fund the MMA Section 1013 "Research on Outcomes of Health Care Items and Services." The law authorized $50 million for this in FY 2004, but no funds were requested and Congress provided none. But the law says "such sums as may be necessary for each fiscal year thereafter." Adequate funding of this research could achieve enormous savings, in lives and money, in the years to come, and we urge the Department to make this a funding priority.

We also urge the Department to seek the legislative repeal of the MMA section 622 ban on Medicare considering functional equivalence in its payment for drugs under Part B. This ban is anti-consumer and anti-taxpayer and will prevent the Department from saving hundreds of millions of dollars in the years to come.

Simplify as Possible.
The sheer size and complexity of these regulations is also a testament to the fact that this new law is terribly confusing to most Medicare beneficiaries—and confusion will make enrollment and use of the new program very difficult, particularly for the lower income, the sicker, and those with English literacy problems. In general, whenever it is possible and whenever it is not anti-

consumer, CMS should seek to simplify the new program. In most cases, simplification will be the pro-consumer position.

SUBPART B—ELIGIBILITY AND ENROLLMENT

Overarching Concerns Regarding the Enrollment Process.

We are very concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries, beneficiaries with mental illness, and other populations with special needs.

Officials at the Centers for Medicare and Medicaid Services (CMS) have indicated that they will rely heavily on State Health Insurance Assistance Programs (SHIPs) to assist with enrollment. SHIPs have played a critical role in helping Medicare beneficiaries navigate the Medicare drug discount cards and will continue to play an important role helping Medicare beneficiaries as enrollment begins for the new prescription drug benefit. However, additional funding is critical if SHIPs are to continue to successfully serve the Medicare population and help diverse Medicare beneficiaries navigate the complicated new law's provisions (the need to augment SHIP funding is discussed in greater detail in section 423.48).

While SHIPs will be critical to education and enrollment efforts, other community-based groups with historical expertise working with the unique needs of and issues for beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs, will also need to be integral to education and enrollment strategy development and implementation. These groups also must be engaged and provided funding if all beneficiaries are to identify and enroll in the best plan available. The potential for new partnerships between these groups and SHIPs should be explored and supported.

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. For example, 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, including but not limited to schizophrenia, bipolar disorder, depression,

anxiety disorder, dementia, and attention deficit/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes." [Report No. 108-391, pp. 769-770.] Experience implementing Medicaid managed care programs over past 10 years shows that to successfully enroll individuals with mental illness, cognitive impairments (like Alzheimer's disease) and disabilities, outreach, education, and enrollment opportunities must be incorporated at multiple points within the health communities.

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries with special needs, CMS must partner with community-based organizations focused on addressing the needs of people with special disease and disability conditions, (such as mental illness) and state and local agencies that coordinate benefits for these individuals. Beneficiaries with disabilities know and trust these organizations, and it is to these organizations that they will likely turn 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 disabilities about the new benefit. CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (§423.48). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. 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 disabilities in each region. This plan must incorporate collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. In addition, in their bids, PDPs and MA-PDPs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness.

Overarching Concerns Regarding Enrollment of Dual Eligibles in Medicare Part D.

Enrollment of Dual Eligibles: Coordinating and Timing Transfer from Medicaid.
Our specific comments on enrollment of dual eligibles and our recommendations appear in our comments on Sections 423.34, 423.36, 423.48 and in Subparts P and S. Much that is outlined below is repeated in those sections. However, this is such a critical and overriding concern with the enrollment process that it merits special attention.

The NPRM fails to adequately address how drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the dual eligibles) will be transferred to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of operationalizing the enrollment process. The NPRM does not address either in any way that will ensure that these 6.4 million beneficiaries do not confront a loss of benefits or a gap in drug coverage, either of which could have disastrous health consequences for these individuals,

Timing. Automatic enrollment of dual eligibles will not begin until the end of the initial enrollment period on May 15, 2006. However, states' Medicaid drug benefit for dual eligibles will end on January 1, 2006. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education (outlined above), 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 automatic enrollment. This completely foreseeable situation is untenable, and directly in conflict with Congress' and the Administration's promise that dual eligibles will be better off under Medicare Part D (see below). The transfer of drug coverage from Medicaid to Medicare Part D must be delayed.

Operationalizing automatic enrollment. CMS requests 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; therefore, we recommend that states have the option of performing automatic enrollment. However, this added responsibility must include sufficient administrative payments (see our discussion in Section 423.34).

Continuity of Care for Dual Eligibles.
We are extremely concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. (For a more detailed discussion of formulary requirements, the need for different formulary treatment of specific populations, and recommendations regarding defining those populations, see our comments on Subpart C, Section 423.120.)

In our following discussion of concerns regarding continuity of care for dual eligibles, and for others with special health care needs, we frequently illustrate the problem with foreseeable situations that could arise related to treatment of mental illness. A disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications: According to MedPAC, 38% of all duals have cognitive or mental impairments. These issues and concerns, however, apply equally to all dual eligibles, and particularly to those with special health care needs, as well as to other populations with specific needs (again, see our comments in Subpart C, Section 423.120 for a discussion of populations with special needs).

As proposed in the NPRM, duals would be forced 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 in states that have restricted access to drugs in Medicaid programs with preferred drug lists and prior authorization requirements, most of these states have exempted selected conditions, such as mental illness, from these restrictions.

Without access to the coverage they need, dual eligibles will be forced to switch medications. In the treatment of HIV/AIDS, such switches can be deadly. As another example, in a letter to Dr. Mark McClellan, Michael Hogan, former Chair of President Bush’s New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, advises that “[a]ppropriate continuity of care provisions for psychiatric medications for dual eligibles are critical and need to be considered in the development of this program. It has been shown that once a patient has evidence of successful response to a particular medication or treatment regimen, switching the treatment without clear clinical indication is deleterious.”

We believe the same is true for a number of other illnesses and categories. To use just one disease group as an example of the problem in many sectors, we cite the danger of changing psychiatric medications. It can take up to 6-12 weeks to determine if a medication works and almost as long to wash a

medication out of a consumer's system. Abrupt changes in psychiatric medications bring the risk of serious adverse drug interactions. Moreover, each failed trial results in suffering and possible worsening of a person's condition. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who do not and their treatment typically costs about 50 percent more than it would have if they had been allowed to continue taking a medication that had already been deemed appropriate.[1]

Not ensuring continuity of care for dual eligibles will greatly increase costs. In his letter to Dr. McClellan, Dr. Hogan states that "[p]atients who are not adequately treated, or treated with the wrong therapeutic agent, tend to utilize more costly crisis intervention, inpatient hospital, and intensive case management services. They also will tend to be less adherent to prescribed medications from that point forward, even when a more clinically appropriate treatment regimen has been prescribed." A study of the overall medical costs and use of services among people who had mental illnesses and were uninsured revealed that continuity of medication therapy resulted in a 65 percent reduction in inpatient costs, a 55 percent reduction in emergency costs, a 23 percent increase in outpatient care and an overall mean cost savings of $166 per patient per month.[2] Fewer prescriptions are needed when access to medications is not limited, but increased restrictions are associated with more physician and emergency room visits, hospitalizations and prescriptions which become increasingly costly each year.[3]

Moreover, it is clear that Congress was concerned with ensuring access to psychiatric medications under the new Part D benefit. The conference report states 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]

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[1] Hensely, PL and Nurnberg, H.G. (2001). Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls. *Pharmacoeconomics*, Vol. 19, No. 10, pp. 973-982.

[2] Del Paggio, D., Finley, P., and Cavano, J. (2002). Clinical and economic outcomes associated with Olanzapine for the treatment of psychotic symptoms in a county mental health population. *Clinical Therapeutics*, 24.5, 803-817.

[3] Horn, W. Unintended Costs and outcomes: The Fiscal Case for Open Access. *Drug Benefit Trends*, Vol. 15, Supplement 1.

This type of cost to the system can be cited in disease after disease category. It is clear that CMS needs to find a way to ensure continuity of care for all of those with pharmacologically complex conditions.

The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§ 423.36). However, as noted in more detail below in the discussion of that section, this provision as written is inadequate to meet the special needs of dual eligibles.

In the preamble to the proposed regulations, CMS points to an exceptions process as a means of securing coverage of off-formulary medications (Section M, Appeals and Grievances; our concerns with specific language related to appeals and grievances are addressed in our comments on that Subpart). But the process proposed is extremely complex and 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 extremely 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. Again, using comments citing treatment for mental illness as just one example, Michael Hogan, former chair of the President's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, stated in a letter to Dr. McClellan, "patients with significant psychiatric illness, especially those that are disabled as a result of their illness, have an extremely limited capacity to navigate [grievance and appeals] procedures." Dr. Hogan also urges CMS not to rely on the existence of grievance and appeal processes as a substitute for open formulary access to medications.

Honoring Congress and the Administration's Promise to Dual Eligibles. Congress and the Administration have promised that dual eligible beneficiaries will be better off with this new Part D drug benefit than they are 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 just as a number of states (e.g., WI, OR, KY, TX, CA) have done in implementing preferred drug lists for their Medicaid programs. For the very vulnerable dual eligible population, for those with life-threatening diseases, such as HIV/AIDS, mental illness, cancers, and other extreme conditions (groups which could be classified as having pharmacologically complex conditions), drug plans must be required to cover their existing medications. At a minimum this protection should be given to dual eligibles because they have so few financial resources. Higher reimbursement for this coverage could be based on "allowable and allocable

costs" as CMS has proposed to pay fallback plans. Increased federal payments are warranted as coverage of the full array of medications by these drug plans will prevent increased utilization of more costly inpatient and outpatient services and resulting increases in Medicare Part A and B costs.

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. Again, increased payments for drug plans based on "allowable and allocable costs" as proposed for fallback plans is warranted to account for the savings to Medicare Parts A and B that will result from ensuring access to needed medications. A more detailed discussion of this alternative flexible formulary proposal can be found in our comments on section 423.120, Access to Covered Part D Drugs.

Section 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 should 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), Operationalizing enrollment of 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. States opting to conduct auto assignment should receive full federal financing for this function given the MMA's explicit directive for the Secretary to accomplish this function. *See* 1860D-1(b)(1)(A) and (C). CMS should not require all states to perform the auto-assignment task, however, because some states may lack

the capacity to complete it in an acceptable manner. CMS will therefore have to develop its own systems to automatically enroll dual eligibles in states that do not elect to perform the autoenrollment.

However, this is an additional and considerable burden on the states that perform autoenrollment, and the structure of the program with its "clawback" provision builds in a financial disincentive for states to maximize enrollment in Part D. Under the law, the "clawback payment" will be based on the number of dual eligibles enrolled in the new Part D benefit: the fewer enrolled, the smaller the giveback to the Federal government. To blunt that disincentive and to maximize enrollment, administrative payments to the states for autoenrollment must be adequate and must be sufficient to counter the built in financial disincentives inherent in the "clawback" provision. We urge CMS to reimburse the states for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.

In addition, regardless of which entity performs the auto-enrollment, strong accountability measures and oversight from CMS will be essential. The regulations should specify that after beneficiaries are automatically enrolled in plans, they must be clearly informed via telephone, mail, and other means about the plans in which they have been enrolled, as well as their right to choose a different plan and where they can get assistance to do so.

Finally, because the proposed rule left unanswered key questions about who will conduct automatic enrollment of dual eligibles and how it will occur, we reiterate that, as we have stated in the introduction to these comments, 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), Enrollment requirements for full benefit dual eligibles, timing between end of Medicaid's benefit and automatic enrollment.
The NPRM 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.

CMS's 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 would be a considerable hardship and could have serious health consequences for this vulnerable population. (see our discussion of Overarching Concerns at the beginning of our discussion of Subpart B, above).

To prevent catastrophic consequences for dual eligibles, we believe the transition of drug coverage for dual eligibles must be delayed by a year, or at a minimum six months. MEDPAC indicates that six months is needed for a successful transition in private sector drug plans. MEDPAC, June *2004 Report to Congress*. Dual eligibles will need a longer transition period given their higher drug use, increased incidence of cognitive impairment, and need for personalized counseling and assistance to select the most appropriate Part D coverage. This extension may require a statutory change. If so, the Secretary should request the appropriate legislative action.

In the absence of a delayed transition for drug coverage, we believe the least harmful approach would be for dual eligibles to 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 (see our proposed definition of "random" in section 423.34(d)(2), below). 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 to educate them about their new drug coverage before January 1, 2006.
To make this process work more smoothly, even before plan information is released on October 15, 2005, states can begin profiling individuals' drug history to prepare for random auto-assignment among plans that are appropriate for the individual. Additionally, it is critical that CMS must fund a massive campaign of individualized counseling and assistance both before and after auto-enrollment to a) explain to individuals their choices and how to enroll in a plan, b) if applicable, explain how to get benefits under the plan to which they have been auto-assigned and c) 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 (see also our suggestions on information and outreach for dual eligibles under section 423.48).

423.34(d)(1)(ii), Enrollment requirement for full benefit dual eligibles in MA plans.
It is essential that CMS develop an adequate solution to the issue of automatic enrollment and 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. Forcing a dual eligible to choose between continued MA enrollment, paying added premiums, or foregoing drug coverage is inherently disruptive.

Although absent a statutory change we do not have a comprehensive solution to the problem, we have suggestions to assist some beneficiaries. For institutionalized duals enrolled in an MA-PD plan whose premium is higher than the fully-subsidized premium amount, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly share of cost to the facility. For non-institutionalized duals in such situation, in states where State Pharmacy Assistance Programs (SPAPs) will wrap around Part D coverage and will cover duals, SPAPs should be authorized to pay the difference. Or, 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-PD back into original Medicare.

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 define "on a random basis" in this section as "among all such plans in the region that meet the beneficiary's particular drug needs."

Section 423.36, Enrollment Periods.

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 (see comments under section 423.44). 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.

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 the needs of dual eligibles. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare+Choice plans in the past. In addition, these individuals will not have the resources to pay more in premiums 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), Other special enrollment periods
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, (i.e., 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.

Section 423.44, Disenrollment by the PDP.

423.44(b)(2)(i) Required involuntary disenrollment by the PDP.
CMS stated that it was "particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area."

The disenrollment requirement in this section raises the issue of "snowbirds"—the large number of Medicare beneficiaries who move for large parts of the year. 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 (as described in the June, 2004 MedPAC report to Congress), 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.

We suggest several ways that CMS can better address this issue:

- **Require traveler benefits policies.** We believe the disruption and paperwork involved in this issue is so severe that we urge CMS to require as a condition of participation that plans have a system of visitor or traveler benefits.

- **Allow PDP exceptions.** We ask CMS to consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement. At a minimum, beneficiaries must have a clear understanding of how a plan will serve people temporarily out of the service area.

- **Require plans provide information on traveler benefits.** In addition to requiring traveler benefit policies, we urge that CMS require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies." In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. Beneficiaries who are traveling and need emergency pharmaceutical services need to know how their plan will (or will not) reimburse for those services.

- **Define time period.** The regulations should also clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area." This should be defined to accommodate seasonal travelers who maintain a residence in the service area.

423.44(d)(2), Disenrollment for disruptive or threatening behavior*.* General concerns with/comments on this section.
We have a number of very serious 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" (§ 423.44). These provisions create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's disease, 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.

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 minimal beneficiary protections are as follows:

Lower involuntary disenrollment standard. CMS has proposed to lower the standard for involuntary disenrollment in these Part D regulations (as well as the proposed regulations for the new Medicare Advantage (MA) program) from that provided in similar provisions in the Medicare+Choice (M+C) program regulations (after which these regulations were clearly modeled). The preexisting M+C regulation allowing for disenrollment for disruptive behavior states that M+C plans may not disenroll an individual if the behavior at issue is "related to the use of medical services or diminished mental capacity." The NPRM for Part D plans (and the new requirements for MA plans) would lessen the degree of protection for beneficiaries against involuntary disenrollment for disruptive behavior. The proposed regulations state that "disruptive behavior may not be based on noncompliance with medical advice." This standard would unfairly deny protection for beneficiaries who complied with medical advice, for example, by trying an on-formulary drug instead of the drug needed, and as a result experienced a bad reaction causing their disruptive behavior.

Although the proposed regulations would also require that the behavior be committed by someone with "decision making capacity", this standard is not as broad as protections for people with diminished mental capacity as previously provided under the M+C program. It is patently unfair and discriminatory to deny protections for those whose allegedly disruptive behavior is a result of diminished mental capacity. Moreover, this lower standard would impose unacceptable risks to the health and well-being of these beneficiaries many of whom are likely have very low incomes with no way to access needed medications during the extended period when they would have no drug coverage as a result of being involuntarily disenrolled.

Addition of “threatening” to list of behaviors. The proposed regulations also add "threatening" to the list of behaviors that could merit disenrollment under the M+C program, in addition to disruptive, abusive, unruly, and uncooperative. Under the preexisting regulations, a beneficiary had to have at least taken some action to merit disenrollment. Moreover, the highly subjective term of "threatening" is not defined.

We strongly urge that CMS not include in the final regulation this lower standard for involuntary disenrollment for disruptive behavior that it has proposed in the NPRM.

Expedited disenrollment. We are alarmed by CMS's 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. The proposed expedited disenrollment process is itself undefined, and provides no standards, requirements or safeguards. Moreover, the NPRM 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. We strongly oppose the inclusion of this expedited disenrollment process in the final rule.

Reenrollment. 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. These 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. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify beneficiaries, and may in fact be an indication that they are in need of medical assistance. Congress clearly intended for all Medicare beneficiaries to have access to this benefit as evidenced by the fact that the Medicare Modernization Act requires that there be fallback plans available in areas where there are not at least two private drug plans.

The stigma that continues to surround mental illness and other cognitive impairments that could manifest in disruptive behavior all but assures that where these regulations open the door, such discrimination will occur. Congress' clear concern in the conference report for assuring access to needed medications for individuals with mental illness argues for exercise of the greatest care in the development of these regulations to ensure that avenues for potential discrimination are barred. Absent such steps here, the disenrollment processes proposed in the NPRM will have a disproportionate impact on individuals with disabilities particularly those with mental illness and Alzheimer's disease, either because they will be used purposefully to discriminate against these individual or 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.

In the preamble, CMS states that PDPs must apply policies for involuntary disenrollment consistently among beneficiaries enrolled in their plans, "unless we permit otherwise" and must comply with laws against discrimination based on disability. We question under what circumstances would CMS permit plans not to apply these policies in a consistent manner. There is already a significant and highly troubling risk that these provisions will be used to discriminate against certain individuals, and we urge CMS to review plans' requests for approval with the utmost scrutiny and to strictly require consistency in the applications of these provisions.

Individuals that 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 in the first place and given the high risk of discrimination presented by these provisions.

Protections to include. At the very least, 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. In addition, we strongly recommend the following protections be included in the regulations implementing the Part D benefit and the Medicare Advantage program to lessen the grave risks inherent in authorizing sanctions on "disruptive behavior":

- PDPs and MA-PDPs must be prohibited from disenrolling an enrollee 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;

- PDPs and MA-PDPs may not disenroll an enrollee 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 enrollee must include documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities, if applicable, in accordance with the Americans with Disabilities Act; and

- Documentation that the plan provided the enrollee with appropriate written notice of the consequences of continued disruptive behavior or written

notice of its intent to request involuntary disenrollment;

- PDPs and MA-PDPs 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.

Section 423.46, Late enrollment penalty.

General concern/comment on this section.
We urge CMS to delay implementation of this section for all enrollees for two years. The drug benefit is a new 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 know from experience with the Medicare-endorsed prescription drug discount card that reaching beneficiaries is challenging—for example, even with significant outreach, the majority of individuals eligible for the drug discount card's low-income subsidy have not yet taken advantage of the $600 available to them.

After the first two years, CMS should require plans to allow individuals with disabilities, as well as other specific population with special health care needs, a grace period if they miss an enrollment deadline. (See our comments under Subpart C, section 423.120(b) for our discussion of populations with special needs and see also our comments below in this section under the heading "Omissions in this section.")

Additionally, we recommend that the late enrollment penalty not apply to individuals eligible for the low-income subsidy. Subsidy-eligible 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. Beneficiaries should not be penalized because of program complexity.

Omissions in this section.
Beyond that general comment, we have several more specific concerns regarding omissions in this section.

- **Add appeals opportunity.** There should be an opportunity for enrollees to appeal late enrollment penalties. This should be noted in this section and should be incorporated as part of the general system for appeals outlined in Subpart M.

- **Coordinate with "special enrollment periods."** Late enrollment penalties should be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties. The exemption of time during special enrollment periods from late penalties should be stated in this section.

- **Exemption for individuals involuntarily disenrolled.** Unless CMS adds special enrollment opportunities for individuals who are involuntarily disenrolled—as strongly recommended under our comments on section 423.36(c)—those who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period. At that point, they may be subject to a late penalty and increased premiums. This is patently unfair, especially since it may be based on an arbitrary and unjustified decision by the plan to 'get rid of' high cost patients. The disruptive behavior may have resulted from denial of access to needed medications. The late enrollment penalty should be waived for these individuals as well.

- **Late enrollment penalties and people with disabilities and special health care needs**. CMS should incorporate an enrollment "grace period" for individuals with disabilities, as well as for other specific population with special health care needs (see our comments under Subpart C, section 423.120(b) for our discussion of populations with special needs). The rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to these beneficiaries, many of whom require on-going treatment for one or more conditions or illnesses. These individuals may well require additional time to make a selection and complete the enrollment process—the confusing nature of the program, coupled with their on-going treatment needs, may make plan choice and selection particularly difficult for them. Therefore, CMS should incorporate a late enrollment "grace period" for these populations.

- **Special enrollment opportunities/no penalties for incorrect notice of change in coverage status (see also Section 423.56).** 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 of a change in status of that coverage, and that coverage is not creditable, beneficiaries should not face late enrollment penalties.

Section 423.48, Information about Part D.

General concern/comment on this section: 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. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate.

SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and Area Agencies on Aging, 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.

Information plans must provide.
This section states that “each PDP and MA-PDP plan must provide …information necessary” to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient.

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. Plans should also be required to notify CMS during the year within 2 business days of any changes in a plan’s formulary, pharmacy network, drug prices, or any other aspects of

plan benefits or operation that could affect enrollees' access to prescription drugs or financial liability for drug costs. In order to ensure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance.

In addition, CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments as well. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. Furthermore, plans must be required to make information available in languages other than English, to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. CMS should continue to make the information available upon written request and through 1-800-Medicare. We urge CMS to continue to work to improve these information sources, as they sometimes are difficult to use by consumers.

Minimal information plans should be required to provide. While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on the benefit itself that potential enrollees will need in order to make a choice among plans and plan offerings. That should be specified in this section. Specifically, beneficiaries will need to understand:

- 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 copay 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. (Plans should be required to report formulary changes during the year to CMS and to update information on their websites to reflect those changes.)

- Participating pharmacies, mail order options, out-of-service options.

- Appeals and grievance processes.

- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans.

Beyond providing this information to CMS, plans should also 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 (see comments on section 423.50, below). Therefore, we urge that CMS specify the minimal information that plans will need to provide. As noted, guidance is insufficient.

Specifically, we urge CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees, who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. We urge CMS to require plans to publish, as part of their marketing materials, price information in addition to posting negotiated price information on their website.

Printed price information for marketing materials could be provided in a manageable format. For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish, in a standardized format, their negotiated price for each of those drugs, with clear information on how to get price information on additional drugs through a toll-free number (the plan's and 1-800-MEDICARE) or the Internet (referencing both the Plan's site and the Medicare website). Such a list would be easy to prepare and take only about one page in marketing materials (again, see comments on 423.50, below).

Information and outreach for dual eligibles.
In the Preamble, CMS states that "prior to [this] automatic enrollment process, a widespread education and information campaign (described later in this subpart at Section 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled" (Federal Register, Vol. 69, No. 148, Tuesday, August 3, 2004, Proposed Rules, page 46638). Such an education and information campaign targeted to dual eligible individuals and that does equip them to select among plans and enroll prior to automatic enrollment is critical. However, the proposed regulations fall far short.

In the Preamble, CMS discusses education and information materials that it will provide to beneficiaries. This discussion focuses on support through the Internet sources and the 1-800-Medicare number. Both are necessary but, as noted above, insufficient to meet the needs of the Medicare population and particularly insufficient to meet the education and information needs of dual eligibles. This is a difficult to reach population with limited Internet access and, in many cases, limited telephone access. Further, the NPRM does not outline any requirements for meeting the needs of this population in the proposed Section 423.48.

The regulations should include specific requirements for plans and states, as well 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. Extensive outreach and assistance has helped limit the need for default enrollment in Medicaid managed care programs. The states or CMS must also involve community-based organizations and providers that serve and work with dual eligibles in this enrollment process. CMS should offer grants and other resources to help these organizations and providers inform dual eligibles of their choices and what they need to do to sign up. These organizations can provide culturally appropriate outreach and assistance to help duals find the best plan available to them and let them know that they can switch plans through the special enrollment provision in § 423.36 if they have been automatically enrolled in a plan that is not the best for them.

In addition, as early as possible, and no later than October15, 2005 (assuming information is available as recommended in 423.34(d), above), CMS or the states should mail standardized, easy-to-understand notices to

dual eligibles that, among other things: (i) inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA; (ii) list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; (iii) 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; (iv) explain how they may change their drug plans if they wish at any time; and (v) 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.

Section 423.50, Approval of marketing material and enrollment forms

General Comments/Concerns
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(c) Guidelines for CMS review.
This section vaguely specifies benefit information that plans must provide in their marketing materials in subparts (i), (ii), and (iii). We urge CMS to include more specific requirements. It will be important that beneficiaries have comprehensive information on plan benefits and drug prices, since the drug co-pays, coinsurance and donut hole costs they might have to pay could be substantial. We recommend that CMS require that plans make available add to the following critical points for information —through the Internet, toll-free customer service lines, and in print—on benefits and benefits structure:

- **Information on the formulary**: What the formulary is; information on the fact that the formulary might change; what notice will be provided if there is a formulary change; and, a complete formulary list, with cost-share tier information for each formulary drug. The complete formulary list with corresponding cost-share tier information should be required on each plan's website (and should be required to be current) and in print material available to beneficiaries. Plans should be required to provide some specific formulary information in their standard print marketing materials. For print marketing materials the formulary list might be shortened, for example, to cover the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries as outlined in section 423.48, above. However,

CMS should require that all plans provide information on the same drugs so that beneficiaries can more easily make plan-to-plan comparisons. With this list, plans should be required to provide instructions on how to access information on additional drugs through the Internet, the plan's toll-free number, and 1-800-MEDICARE.

- **Information on drug prices.** A description of the "negotiated price," what it is, when it applies, how it might change, and (on the Internet and available in print through request) the negotiated price for each drug. For standard print marketing materials, plans should be required to provide some price information. For this material, the list might be shortened, for example, to price information for the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries, comparable to the suggestions for formulary information, above. In standard print marketing materials, plans should be required to provide instructions on how to access price information for additional drugs through the Internet, a toll-free number, and 1-800-MEDICARE.

- **Premium information**. Information on plan benefits and the premium (for the basic benefit and any other benefit structures offered). If a PDP offers multiple plans in a single area, marketing material should include a side-by-side comparison of the benefits for each offering. For each offering, PDPs should be required to note, clearly and conspicuously, whether individuals qualifying for the low-income subsidy will have to pay a premium and, if so, the amount that will have to be paid.

- **Information on plan performance**. After 2006, plans should be required to include in their marketing materials basic information on the plan's prior performance: number and type of appeals and grievances filed and outcome for each type, and performance on other quality measures collected by CMS.

All of the information outlined above will be critical if beneficiaries are to make informed choices among plans. It should be part of standard marketing materials; potential enrollees should not have to request this basic information.

423.50 (e), Standards for PDP marketing.
Prohibit telemarketing. Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. There have been numerous reports of

telemarketing fraud under the Medicare Drug Discount Program.[4] The Part D benefit is susceptible to even more fraudulent business practices. 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.

Prohibit marketing of other services. 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 seems to believe that this would encourage entities such as financial services firms to participate as prescription drug plans. 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. This would be unadvisable for several reasons:

- Having plans offer added services would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved plan"; the difficult task of comparing plans would become even more complex for potential enrollees; beneficiaries might mistakenly believe that they need to take an entire package of offered services when they sign up for the drug plan. This section prohibits marketing activities that could "mislead or confuse." Allowing plan sponsors to market added services is so apt to create situations that confuse and mislead beneficiaries that it is in direct conflict with the provisions of this section.

- Financial institutions claim they are exempt from the HIPAA Privacy Rule; CMS should not encourage entities that take this position 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.

Prohibit provider marketing.
CMS asked for comment on the applicability of MA marketing requirements for PDP marketing.

We recommend that marketing 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.

[4] See Lori Racki, *Medicare Scams Prey on Seniors*, Chicago Sun-Times, News Special Edition at 8 (May 24,2004).

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.

We can easily foresee such skewed marketing occurring if a pharmacy has a contract with only one PDP or has more favorable contract terms with a specific PDP. Providers with relationships with a PDP plan might market that plan more heavily. We urge CMS to consider the potential for provider and pharmacy-based marketing to steer beneficiaries into inappropriate PDPs and, in response, to make marketing requirements extremely protective of consumers. Given the high potential for abuse, we recommend that providers, including pharmacies, not be allowed to market specific PDPs or MA-PDPs. Health care providers should be a source of balanced information on the program, plan choices, and how to select a plan. They should not be allowed to verbally, or otherwise, promote a specific PDP or MA-PDP.

While we recommend against allowing providers, including pharmacies, to market individual PDPs, if providers are allowed to engage in marketing, we recommend the following minimal requirements:

- Pharmacies and any other providers displaying plan materials should be required to provide equal space and prominence to materials from all PDPs/MA-PDPs available in the area, not just those with which they have relationships;

- Marketing be limited to the display of information as outlined above. Active promotion of any specific plan by a provider should be prohibited.

Do not allow plans to use Medicare discount card enrollee and applicant information. The regulations should prohibit prescription drug plans from obtaining and using Medicare Drug Discount Card enrollee and applicant information, and information collected from any other card programs the company might sponsor.

It is foreseeable that many Discount Card sponsors will apply to be prescription drug plans. As Discount Card plans, these entities will have beneficiary-level information on drug use, creating the potential for prescription drug plans to use Discount Card information to target marketing to low-cost beneficiaries, either directly or through marketing firms.

Section 423.50(e)(2) prohibits drug plans from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." The regulations should:

- Specifically prohibit prescription drug plans from obtaining or using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor.

- Prohibit others from using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor to market on behalf of a prescription drug plan sponsor.

Specify whether and how the Secretary can provide information to prescription drug plans. The MMA added section 1860D-1(b)(4)(A) to the Social Security Act. This permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."[5]

The proposed rule does not contain any provision governing whether and how this information will be provided and in the Preamble, CMS seeks comments on a number of operational issues as well as on the provision in general.

The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair information practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. There may be some marginal benefit in the Secretary's providing information to prescription drug plans if the plans send information to eligible individuals information that would actually be useful in determining which plan to select. We recommend the following in the disclosure of identifiable information:

[5] H.R. CONF. REP. NO. 108-391, at 432 (2003).

- If the Secretary provides information to prescription drug plans, the information provided should be limited to the minimal amount necessary: the potential enrollee's name and address. No health or financial information should be disclosed.

- The Secretary should disclose identifiable information to prescription drug plans to facilitate marketing or enrollment only if the plan's marketing materials contain formulary and drug pricing information or are accompanied by an application form. This approach could help balance privacy concerns with the need for beneficiaries to obtain important plan information.

- The Secretary should not disclose telephone numbers. Telemarketing should be prohibited; there is no need for plans to have beneficiary phone numbers unless provided by the beneficiary.

- Beneficiaries should be given the choice of whether they want this information disclosed. We suggest that an opt-in approach be used to ensure that beneficiaries do, in fact, want their information disclosed. The op-in notice should be clear; written with the Medicare population in mind; state what will be shared; and clearly state that even if a beneficiary elects to opt-out, they can still enroll in the benefit, they will still receive information about the benefit from CMS, and they can still request information directly from plans.

Section 423.56, Procedures to determine and document creditable status of prescription drug coverage.

Section 423.56 (e), Notification. 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. We recommend the following as minimal notice to beneficiaries.

- **Notice in 2005.** In 2005, information on whether coverage is creditable or not should be provided in more than one mailing, and included in such valuable documents as quarterly retiree income statements, medical

billing correspondence, etc.

- **Notice after 2005.** In future years, we urge CMS to develop standard notices, through its Beneficiary Notice Initiative, to be used in this regard. The standard notices CMS has developed through this initiative have helped ease confusion about Medicare coverage in other situations.

- **Changes in status of coverage.** The most important point is that in years after 2006, when creditable status changes, special notification is needed. Individuals need to know as soon as the decision is made to reduce coverage, so that they can begin shopping for a PDP and avoid a lifetime of premium penalties. As MedPAC has reported, six months lead time in switching plans is ideal, and shorter transitions are fraught with confusion and chaos. An individual should be notified as soon as the entity's management decides to reduce coverage below the "creditable" requirement. Such a notice is too easy to miss in the wave of mail and solicitations that many households receive. Because it is a very important notification, we urge that it be sent by registered mail, or e-mail with proof of receipt.

- **Information on value of the creditable coverage benefit.** We support the CMS idea that "given the importance of knowing whether coverage constitutes 'creditable coverage'" health plan sponsors should provide information to their enrollees about the value of the benefit, the annual premium, and the amount that the beneficiary will be required to pay. More information to consumers will help them understand how their coverage compares and whether they may want to seek Medicare coverage.

In cases where individuals 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). In other words, each individual adversely impacted by the failure of the employer or other entity to adequately inform should not have to apply or appeal for a SEP. (See also comments on Section 423.46.)

In addition, in the appeals section (subpart M), it should be made clear that questions relating to creditable coverage and notice of when such coverage changes should be eligible for the full range of appeals rights.

Finally, we urge CMS to make clear to those attesting to actuarial equivalence (or non-equivalence) and creditable coverage what the penalty is for false attestation. We assume that this would be a violation of the False Claims Act or other laws.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

Section 423.100, Definitions.

Definition of "dispensing fee" to permit coverage of home infusion-related services.
We recommend that the final rule include a definition of "dispensing fee" that is 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.

We do not support option 1 for the definition of "dispensing fee" because we believe it 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 we do not support option 2 because we do not believe that the definition captures all of the true costs associated with the dispensing of a covered Part D drug.

Definition of "long-term care facility" to 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. 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 Requirements related to qualified prescription drug coverage

Definition of "person" so that family members can pay for covered Part D drug cost-sharing.
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, HRAs, and FSAs by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) do not count as incurred costs.
The proposed regulations state that contributions made by an AIDS Drug Assistance Program (ADAP) on behalf of a beneficiary will not count towards the beneficiary's true out-of-pocket costs, which is necessary to reach the catastrophic limit. We strongly recommend that the final rule count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. If a state ADAP program decides to provide cost-sharing subsidies, these subsidies must be counted as incurred costs. 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 in gaps left by other federal programs, including Medicaid and Medicare.

Federal funds for ADAP programs are appropriated by Congress on a discretionary basis. Notwithstanding the decision by a state to use ADAP funds to subsidize Part D cost-sharing, federal costs do not increase. Further, ADAP funding has not kept pace with growing need over the past decade, and this has led to increases in the number of individuals on waiting lists for ADAP services, as well as restrictions and limitations in ADAP formularies. In this environment, should a state prioritize providing Part D cost-sharing subsidies, federal policy should not create a disincentive for states to make the most prudent resource allocation decisions. Furthermore, the populations

served by ADAPs are predominately low-income and often take multiple prescription drugs. Therefore, even Medicare subsidized cost-sharing for low-income Medicare Part D enrollees could provide a significant barrier to accessing prescription drugs. This has grave implications both for the medical management of HIV/AIDS in the affected individual, but also public health implications resulting from increased risk of the development of resistance to currently available HIV-related antiretroviral medications and therefore an increased risk of transmission. Discouraging ADAPs from subsidizing beneficiary cost sharing by not counting as incurred expenses ADAP expenses spent on premiums, deductibles, cost-sharing or the amount spent filling in the donut hole, could leave people living with HIV/AIDS who receive Medicare benefits vulnerable to fall through the cracks.

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 counting state dollars 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 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 appropriated state dollars. It is inexcusable to exempt people living with HIV/AIDS from receiving this type of help from their state, while allowing people with other medical conditions to benefit from their state dollars.

Similar consideration should be given to payment from the Veterans Administration and the Indian Health Service. These programs serve disproportionately vulnerable populations who, like people with HIV/AIDS, need the extra assistance.

Maximizing savings for people needing HIV/AIDS medications under the 340B program.

The regulations encourage state ADAPs to move toward the model of purchasing their drugs directly, under the 340B program, instead of using a rebate model. We feel it is completely inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by the Health Resources and Services Administration (HRSA), the federal agency that oversees the Ryan White CARE Act and the 340B Program.

As mentioned, there are several states that use a rebate option model available to ADAPs under 340B to purchase drugs instead of the direct purchase model. These states, including California and New York, the two largest ADAPs, have carefully analyzed the cost benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study which demonstrated that after calculating rebates, they receive prices for HIV pharmaceuticals comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms.

Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size and geography and demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen. ADAPs have and will continue to use every mechanism available to receive the best prices for their HIV-related drugs, including negotiating for supplemental rebates and discounts.

Coordinating between ADAPs and Medicare Part D benefits.
Any coordination between ADAPs and the Medicare Part D PDPs is, under the proposed rules, completely voluntary on the part of the PDPs. There are several issues that would inhibit the coordination of benefits between ADAPs and PDPs. Most importantly, since ADAPs' expenditures for beneficiaries would not count as incurred costs and thereby not allowing many of the HIV-positive beneficiaries living with HIV/AIDS to reach the catastrophic limit, ADAPs would have no strong incentive to collaborate with private drug plans. Furthermore, PDPs could charge ADAPs for any coordination between the two entities. The proposed coordination would not result in any significant amount of cost savings and would not be cost-effective for the ADAPs. Finally, it could potentially be very difficult for ADAPs to coordinate with multiple PDPs participating in the Medicare program in a given area. Under these proposed rules, it is not feasible for ADAPs to coordinate with PDPs. However, if CMS would allow payments made by ADAPs to count as incurred costs, coordination between ADAPs and PDPs could result in substantial costs savings and therefore provide incentive for ADAPs to collaborate with PDPs.

We are interested in exploring methods of collaboration between ADAPs and PDPs that could allow beneficiaries living with HIV/AIDS to benefit from the 340B pricing. We understand that several 340B entities have begun entering into partnerships with various state and local government programs to provide more individuals access to 340B pricing. However, there are so many

complexities and unknowns about the Medicare Part D prescription drug program and its effects on ADAPs that we are not prepared to comment on the details of any such collaboration at this time.

423.104(e)(2)(ii), 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 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. In another section, we also comment on what we view as a wholly inadequate exceptions process.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would place Medicare Part D enrollees in 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% 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).

423.104(g), Basic alternative benefit designs that go beyond actuarially equivalent standard coverage.
We are strongly opposed to the provisions of § 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 § 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. We further recommend that 423.104(e)(2)(i)(B) (re: actuarially equivalent cost sharing) should be moved and should be included as an option under the description of alternative coverage at 423.104(f), re-numbered as 423.104(f)(2).

423.104(h), Access to negotiated prices when the beneficiary is responsible for 100 percent cost-sharing.
We strongly oppose allowing any plan 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.

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.

Section 423.120, Access to covered Part D drugs.

423.120(a), Access standards must be met in each local service area.
We support the inclusion in the final rule of the provision in the proposed rule that requires 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. A key principle of the MMA is that Medicare beneficiaries will have convenient access to a local pharmacy. By permitting plans to meet the access standards across more than one local service area could only lead to individuals in some local service areas to not have convenient access to a local pharmacy.

Counting only retail pharmacies as part of their networks for the purpose of meeting access standards.
We support the inclusion in the final rule of the provision in the proposed rule that only counts retail pharmacies for the purpose of meeting pharmacy access standards. Because of the principle that Medicare beneficiaries should have convenient access to a local pharmacy, it would undermine this principle 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.

Counting Indian and Tribal pharmacies as network pharmacies for the purpose of meeting access standards.
We recommend that the final rule 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.

If the final rule requires plans to offer a standard contract to I/T/U pharmacies, then we are supportive of counting these pharmacies for purposes of meeting

network access standards. We believe it is an important national policy goal and an important treaty obligation to preserve and protect access to programs providing health services to American Indian/Alaska Native populations through I/T/U programs. Further, I/T/U programs should be fully reimbursed for all costs associated with providing prescription drugs through the Medicare Part D program.

Requiring prescription drug plans and MA-PD plans to offer their standard pharmacy contracts to some or all long-term care pharmacies in their service areas.
We recommend that the final rule 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.

Balancing convenient access with appropriate payment for long-term care pharmacies.
We believe 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 prescription drug plans to contract with all LTC pharmacies;

- Alternatively, the final rule could require prescription drug plans to make available a standard contract to all LTC pharmacies, and 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.

Permissible ways to assure Part D enrollees' access to FQHC and rural pharmacies, among others.
Federally qualified health centers (FQHCs) and rural health centers play a critical role in bringing doctors, basic health services and facilities into the nation's neediest and most isolated communities. These programs operate in over 3,600 communities - spanning urban and rural communities in all 50 states, the District of Columbia, and all territories. We recommend that the final rule require prescription drug plans to offer to contract with all FQHC and rural pharmacies and make available a standard contract. Should the final rule not contain this requirement and in situations where an FQHC or rural 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.

423.120 (a)(4), Requiring PDP sponsors and MA organizations to make available a standard contract for participation in their plan's network.
We recommend that the final rule require plans to make available to all pharmacies a standard contract for participation in their plan's network. Section 1860D-4(b) of the MMA requires plans to permit the participation of any willing pharmacy, and also requires prescription drug plans to provide for convenient access for network pharmacies. We believe that these requirements are best achieved by requiring plans to make available a standard contract for participation in their plan's network. We also believe that this also has other important advantages in terms of ease of administration and expanded beneficiary access.

423.120 (a)(5), Permitting lower cost-sharing for preferred pharmacies through higher cost-sharing for non-preferred pharmacies or as alternative prescription drug coverage.
We recommend that the final rule permit lower cost sharing for preferred pharmacies only when the plan's network of pharmacies exceeds the minimum regulatory requirements for network adequacy. In addition, as recommended previously, enrollees who are required or who have specialized needs that make it desirable to use specialized pharmacies, including I/T/U pharmacies and LTC pharmacies, should not be penalized by having to pay higher cost-sharing.

423.120(a)(6), Counting the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy (vs. a network mail-order pharmacy) as an incurred cost.
We recommend that the final rule ensure that beneficiary costs paid out-of-pocket used for the purchase of covered Part D drugs count as incurred

costs. A key principle of the MMA is that Medicare beneficiaries will have convenient access to a local pharmacy. We believe that 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. 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: use authority to review plan design to ensure non-discrimination.

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.

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, cost sharing for covered chemotherapy drugs that are utilized by people with chronic and acute care needs.

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), Requiring P&T committee decisions regarding the plan's formulary to be binding on the plan.

We strongly recommend that the final rule ensures that 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 rationale for 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.

We also believe 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, we will make clear that we have 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 plan financial considerations and it must reinforce the independence and broad-based clinical expertise of P&T committees.

423.120 (b)(1), Requiring certain P&T committee members to be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers.
We support the proposal in the proposed rule to ensure that the final rule interprets the requirement that certain P&T members be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers. The essential function of the P&T committee 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.** We strongly recommend that the final rule include far stronger provisions than are found in the proposed rule 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 expand on the MMA's requirements for independent expertise in the care and treatment of the elderly and people with disabilities. Because of their unique experience at serving institutionalized populations, a significant subset of the Part D eligible population, the final rule should expand the P&T committee requirement to also include members who are independent LTC pharmacists.

  At a minimum, 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.

  Notwithstanding the size of the committee, it will not be possible for any committee to have adequate expertise in all areas. Therefore, 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.

- **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 public. The final rule should require P&T committees to hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies. The final rule should specify that meetings of the P&T committee should be open to the public. Further, 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 disabled populations.

- **Timely Review:** The final rule must require P&T committees to meet at least quarterly, and have processes for making formulary revisions between regularly scheduled meetings when new clinical information or FDA approval of medications occurs that could be used for the treatment of life threatening conditions.

423.120(b), Formulary requirements.
We have many concerns related to formulary requirements.

Ensuring continued access to accepted "off label" use.
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 prescribers to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

While we understand concerns by CMS that certain pharmaceutical manufacturers may violate federal law by marketing drugs for off-label uses, 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 strongly 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.

- **Recommendations for preventing access barriers to covered Part D drugs for off label uses.** We strongly recommend that the final rule include a clear prohibition that prevents plans from denying coverage for a covered part D drug solely because it is prescribed for an off-label indication. We are deeply concerned that while the MMA clearly permits plans to cover covered Part D drugs for off-label indications, financial incentives could lead plans to inappropriately restrict coverage for off-label uses. As stated previously, off-label prescribing has become a common practice across a broad spectrum of clinical conditions. In enacting the MMA, Congress did not carefully consider issues related to off-label prescribing and it would be improper to implement the MMA in a way that removes the ability of treating physicians to prescribe the full pharmacopoeia of FDA-approved medications when medically necessary.

Standards and criteria for determining that a PDP sponsor or MA organization's formulary does not discriminate against certain classes of Part D eligible beneficiaries when using a classification system not based on the USP model guidelines.
In a CMS Discussion Paper, *The Role of USP Draft Model Guidelines for Formulary Classification in Determining Formulary Adequacy for the Medicare Drug Benefit*, CMS states the following:

> Our formulary review standards and processes are under development and will be released in draft form in the Fall for public comment. We are seeking preliminary comments at this time on the factors to include in this guidance and on how our formulary assessments should interact with formulary classification systems…CMS will evaluate formularies at a more granular level than described by the Model Guidelines to make sure they include sufficient choices of clinically significant drugs…CMS also will not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. For example, plans will not be allowed to price all antiretroviral drugs in the highest tier. However, this does not mean that these beneficiary groups cannot be subject to tiered cost sharing, just that such tiering cannot be designed to discourage enrollment of that specific beneficiary group…Finally, CMS will review drug plan prior authorization requirements, exceptions criteria and appeal policies. We

> understand that prior authorization techniques include clinically appropriate step therapies or diagnosis-related restrictions. Nevertheless, our focus will be to determine if specific beneficiary groups are disproportionately affected by such requirements. CMS will examine the drugs that are subject to prior authorization and the associated criteria for obtaining approval.

We are supportive of many of the intentions stated in this discussion paper. Nonetheless, we strongly believe that any review standards developed by CMS must be published as legally-enforceable regulations, and not as guidelines. Moreover, the standards for public comment on these critical standards must meet the requirements of the Administrative Procedures Act.

However, we object to some of CMS' stated intentions. In particular, the example provided in the text highlighted above illustrates a major concern with CMS' planned review process. CMS stated that, "plans will not be allowed to price all antiretroviral drugs in the highest tier. However, this does not mean that these beneficiary groups cannot be subject to tiered cost sharing, just that such tiering cannot be designed to discourage enrollment of that specific beneficiary group." We assert that the treatment of antiretrovirals is a clear example when tiered cost-sharing should be prohibited, and is per se discrimination. This is because directing utilization to particular antiretroviral drugs on the basis of cost (or other plan criteria) is in every instance clinically inappropriate and irresponsible. In this context, there are serious public health implications in shifting prescriber behavior away from providing the most efficacious treatment regimen based on highly individualized criteria and the experience of an HIV treating physician consistent with Federal clinical practice guidelines. This is true of many other disease categories.

CMS has stated that it will not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. We urge CMS to interpret groups to extend beyond health status. In particular, there is a growing body of evidence that highlights racial and ethnic differences in responses to specific drugs. We urge CMS to ensure that they evaluate plan formularies for their impact on racial and ethnic groups, in addition to other "groups" for whom group status may be unrelated to health status.

As stated above, CMS has acknowledged that, "prior authorization techniques include clinically appropriate step therapies or diagnosis-related restrictions." We also strongly recommend that CMS publish in the final rule a list of conditions for which it is clinically inappropriate to require step therapies. For

guidance on developing such a list, we recommend that CMS consider the experience of many state Medicaid programs. In most states employing fail-first or step therapy requirements, clinical experience has led many states to exempt certain conditions, including mental illness and HIV/AIDS.

Special treatment for specific populations and defining which specific populations to include.
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 that could create insurmountable access barriers. ***We recommend that the final rule must provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs with a valid prescription.*** 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 income except 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. According to a Metlife survey, in 2002, the average monthly cost of a private room in a nursing home was $5,110 and the average monthly cost of a semi-private room was $4,350. By July/August of 2004, Metlife reported that for a private room, the average monthly costs had risen to $5,840—a 14 percent increase over 2002.

- **Persons with Life-Threatening Conditions:** Persons with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening need to have unrestricted and affordable access to the full range of available treatments. Protections in the MMA intended to ensure that beneficiaries will have access to all needed medications are inadequate for persons with life-threatening conditions. For example, the MMA requires P&T committee 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. For example, research shows that different antipsychotic medications affect different portions of the brain. The Report of President Bush's New Freedom Commission on Mental Health states that "any effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services" (New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in American; Final Report*, p. 26).

  We recommend 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 require access to an affordable and flexible alternative formulary. This category should encompass:

  - Persons with conditions that are recognized for their pharmacological complexity. At a minimum, the list must include 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 critical dose drugs and 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.

Require plans to accept evidence of prior documented therapy failures.

If, prior to enrolling a specific PDP, an enrollee has tried a preferred therapy under medical supervision and the enrollee or enrollee's physician can document that preferred drug is not appropriate, the PDP should be required to accept the prior medical record as proof that the therapy is inappropriate, rather than requiring the enrollee to try and again fail on the preferred drug. The prior medical record should be sufficient evidence for coverage appeals and requests for formulary exceptions (see comments on section 423.578(b).

Minimum timeframes for periodic evaluation and analysis of protocols and procedures related to plan formularies.
We recommend that the final rule require plans to evaluate and analyze their protocols and procedures related to plan formularies at least quarterly. For many conditions, every month brings significant advances in the clinical management of disease, making it essential that the final rule require regular ongoing and timely review of their formulary protocols and procedures.

Notification requirements for enrollees directly affected by a formulary change.
The proposed rule provides notification provisions regarding formulary changes that are inadequate 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 the 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.

Recommendations for limitations on mid-year formulary changes.
We 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. 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 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, we strongly recommend that plans 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

Broader out-of-network standards as an alternative to emergency access standards.
We support inclusion in the final rule of provisions that establish out-of-network access standards. Nonetheless, this requirement is insufficient to provide for emergency access to covered Part D drugs. 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 that 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.

Out-of-network access requirements.
We recommend that the final rule 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:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;

- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;

- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her plan's pharmacy network; and

- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly

from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail order pharmacies.

Definition of usual and customary price.
We recommend that the final rule define "usual and customary price" to be, "the maximum price that a pharmacy would charge a customer who is a Medicare beneficiary participating in an in-network Part D plan."

Counting the cost differential for receiving a covered Part D drug at an out-of-network pharmacy at the usual and customary price (vs. a network pharmacy) as an incurred cost.
We recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs. Therefore, if the final rule permits Part D participants to be charged the cost differential for receiving a covered Part D drug at an out-of-network pharmacy versus at a network pharmacy, then the rule must require that this differential is counted as an incurred cost.

Proposed payment rules at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.
We recommend that out-of-network pharmacies that are outside of an individual Medicare beneficiary's local service area be required to charge beneficiaries no more than the maximum charged to any in-network plan that they participate in. Further, we recommend that pharmacies be permitted to charge out-of-network customers who are out of their local service area prices as low as the deepest discounted price for in-network participants in any Part D plan accepted by the pharmacy.

Section 423.128, Dissemination of plan information.

423.128 (d), 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.

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:

- **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. (See our comments in Subpart B, Section 423.48, Information about Part D.) 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% 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.

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. With today's technology, this information should be available at each point of the sales transaction. The notice should also tell people how to appeal or to request an exception.

In addition, information on a beneficiaries' annual out-of-pocket and total spending to date should be available at the point of sales. Since the standard benefit includes a benefit "gap", it will be especially important for a senior to know how much each prescription will cost as well as whether the next prescription filled will have higher or lower cost sharing due to the beginning or end of the benefit gap.

Section 423.132, Public disclosure of pharmaceutical prices for equivalent drugs.

Costs to nursing home patients.
The law requires that in general a person be told about the lowest cost generic available under a plan at the time they pick it up at a network pharmacy (or receive it in the mail). The Secretary is given discretion to waive that disclosure requirement, and the Preamble discusses (p. 46665) whether such information should be given to long term care residents, given the special ways in which medicines are delivered in nursing homes. We believe that many nursing home residents, their families, or their representatives would like to know if savings are possible, and we urge that such information be made available.

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.

We have serious concerns that the proposed regulation 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 regulation 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.

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." 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.

We also strongly recommend that the final rule 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. 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.

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.

For example, after the state of Michigan implemented a restrictive preferred drug list for its Medicaid program, a hotline was established for consumers and providers to report their experiences: sixty-six percent reported medication delays or said they had suffered negative consequences after being forced to switch medications (*Report on Prescription Access Hotline, April 22 – June 14, 2002,* Mental Health Association in Michigan and Michigan Association for Children and Families, February 2003). 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, and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, 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 consumers who have been stabilized on a particular psychiatric medication to switch to another medication can be very dangerous for the consumer 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.

In a very recent report entitled "Psychiatric Medications: Addressing Costs without Restricting Access" (August 20, 2004), CMS encourages State Medicaid Directors to implement innovative approaches to controlling costs without restricting access. CMS must encourage Part D prescription drug plans implementing the Medicare drug benefit to implement these same cost management techniques as alternatives to the more common approaches that restrict beneficiary access to medications. 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). They 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.

Section 423.153, Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

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.

More needed in quality assurance.
In the preamble, CMS lists the elements that are "desirable" for quality assurance programs (electronic prescribing, clinical decision support systems, educational interventions, bar codes, adverse event reporting systems, and provider and patient education.) but then says "We do not expect PDPs and MA-PD plans to adopt all of these elements." This is insufficient. We recommend that the final rule require all plans to operate quality assurance programs with all of the listed elements.

In addition to the listed elements described above, the final rule must require plans to include clinical decision support systems and educational interventions including –

- Programs that use claims data and physician referral triggers to identify treating-physicians and consumers who have specific diseases such as asthma, diabetes, schizophrenia, depression, and substance abuse/addiction disorders and provide educational tools and materials to

these providers to encourage more coordinated care for these consumers;

- Programs that 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 and provide educational interventions designed to align these physicians prescribing practices with best practice guidelines;

- Closer scrutiny of utilization data to manage cases of polypharmacy; and,

- Algorithms and other practice standards that promote appropriate prescribing based on clinical data and evidence-based practice.

These interventions not only serve to contain drug costs as discussed above, but also improve the quality of patient care.

The public needs to know about a plan's quality.
The preamble notes that "In the future, we may require quality reporting that includes error rates." This is a key quality indicator that should shape consumer selection of plans. We urge that data on plan error rates, even if just a sampling in 2006, be made public in the first year of the program and all in future years.

Medication Therapy Management Programs: The need to stress quality improvement and let the public know the outcomes.
We urge that the financial incentives in MTMP (423.153(d)(5)) encourage quality outcomes and not reduced costs. Payment for reducing costs without regard to quality will lead to creative and devious forms of rationing. The preamble says that CMS "may provide a mechanism for plans to demonstrate" the value of their MTMPs to the public. We urge CMS to make it clear that such a mechanism shall be developed.

The preamble to the proposed rule states that "MTMPs can lead to improved overall health for individuals while at the same time decreasing overall healthcare costs resulting from improper medication use and adverse drug events". States are using many of these components in their Medicaid programs for individuals with mental illness and other chronic illnesses and are observing improvements in treatment outcomes, reductions in polypharmacy, and successful efforts to contain costs. CMS should look to provider education interventions programs in Pennsylvania and Missouri and the Texas Medication Algorithm Project for best practices that should be implemented by drug plans in their MTMPs.

In the preamble, CMS states that plans should have discretion to design or "customize" their MTMPs because the best approach is to let the market shape these programs. We disagree with this reliance on the market to set required parameters for the MTMPs. We do not believe that stand alone prescription drug plans have sufficient incentives to devote significant resources and attention to developing MTMPs that would improve overall health.

The proposed rule proposes to delegate to private prescription drug plans authority to set an annual cost threshold and invites comments on how to set this level and what persons with multiple chronic diseases to include. Although the types of activities described by CMS as components of MTMPs would save drug costs in the long run, in the short term there will be added costs in implementing these activities and thus PDPs and MA-PDs will have a disincentive to identify enrollees as qualifying for this additional benefit. Therefore, it would be highly inappropriate for CMS to delegate to these plans authority to determine the annual cost threshold to qualify for this benefit. Furthermore, plans will not be interested in attracting enrollees who would qualify for these benefits and thus they would naturally want to set the threshold drug cost amount very high. We recommend that you look to Medicaid claims data for dual eligibles to develop estimates of annual drug costs of beneficiaries with multiple medications and multiple chronic diseases.

In the preamble to the proposed rule, CMS suggests that it may be appropriate to go beyond the statute's requirement that pharmacists provide MTMP services. We agree. MTMP services cannot all be appropriately delivered by a pharmacist. Many of these activities will require complex interactions with a trusted provider and will require face-to-face consultations that cannot be adequately performed over the telephone – e.g., health status assessments, monitoring patient response to drug therapy, and coordination with other case management. As discussed in the preamble, to ensure the effectiveness of their MTMPs, plans must develop and maintain on-going beneficiary-provider relationships and enable beneficiaries to choose providers of these services. Having services delivered by a trusted provider is critical to successful medication therapy.

CMS proposes to leave it up to plans to determine whether to pay other providers to perform MTMP services. Given the importance of the beneficiary-provider relationship that CMS acknowledges and the fact that they state that all MTMP services should not be performed by pharmacists (e.g., developing drug treatment plans for complex and comorbid conditions), CMS must specify in the final rule that MTMPs are to incorporate the services of physicians, as well as pharmacists, and that beneficiaries shall be able to

choose the providers from whom they would receive MTMP services. The final rule should also require that, to the greatest extent possible, beneficiaries may receive MTMP services from their current providers. To ensure that MTMP services are readily available to those beneficiaries who qualify for them, adequate fees must be provided to the pharmacists and physicians offering these services. Adequate fees are also critical to ensuring that beneficiaries have a meaningful choice among pharmacist and physician providers of the MTMP benefit.

Section 423.156, Consumer Satisfaction Surveys.

Consumer satisfaction surveys: start in 2006.
We urge that the first surveys be conducted starting in 2006 with the results available before the fall 2006 open season. The preamble and the proposed rule do not describe an effective date.

Section 423.159, Electronic Prescription Program.

Electronic Prescription program: Initiate as soon as possible.
We support and commend CMS's efforts to expedite, in every way possible, the development and widespread use of e-prescribing. The life-saving safety and quality improvements from such a system will be enormous.

Section 423.165, Compliance deemed on the basis of accreditation.

Compliance deemed on the basis of accreditation.
We do not support the proposed deeming requirements in the proposed rule. We believe that deeming compliance significantly diminishes the beneficiary protections in the MMA and serves only to protect certain organizations from having to comply with key provisions of the statute. We strongly recommend that the final rule delete the provisions in § 423.165.

SUBPART F, SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUM; PLAN APPROVAL

Section 423.265, Submission of bids and related information.

423.265 (a), Eligibility for bidding.
There is nothing in paragraph (a) that precludes a prescription drug plan (PDP) from being owned by or affiliated with a drug manufacturer. The recent history of drug manufacturer and drug delivery firm cooperation shows that this type of relationship invariably leads to the products of the manufacturer being promoted, regardless of whether they are the best product, or the lowest cost. It will be nearly impossible for CMS to prevent such abuses of beneficiaries, and therefore we urge that the regulations prevent groups affiliated with manufacturers from providing the Part D benefit. As the Preamble states in the discussion of fallback plan negotiations, CMS "would also ensure that there is no conflict of interest leading to higher bids." Banning financial relationships between manufacturers and PDPs is the best way to prevent such a conflict.

423.265(d)(2)(iv), Actuarial value of bid components: ensuring that low-income beneficiaries pay no more than the cost-sharing specified by law.
Prescription drug plans are allowed to vary the cost sharing from the standard benefit if the resulting benefit design is actuarially equivalent. As reflected in our comments in Subpart C, section 423.104, we have serious concerns about plans' use of actuarial equivalence to create benefit designs that, in effect, discriminate against high-cost enrollees. We also have serious concerns regarding the use of "actuarial equivalence" and the low-income benefit.

If plans are allowed to claim "actuarial equivalence" to increase the upper-end of the low-income cost-sharing amounts beyond what was specified in law, plans could effectively place all but the lowest tier drugs completely out of the financial reach of low-income enrollees. For low-income individuals, plans should not be allowed to have a higher cost-sharing amount than the upper-end of the range specified in the law. The proposed regulation should clarify that prescription drug plans cannot use an alternative benefit design to charge cost sharing to low-income beneficiaries that exceeds the amounts set out by the statute.

Section 423.272, Review and negotiation of bid and approval of plans

423.272 (b)(2), Approval of proposed plans, plan design.
The NPRM in (b)(2) states that "CMS does not approve a bid if it finds that the design of the plan and its benefits….are likely to substantially discourage enrollment by certain Part D eligible individuals under [in?] the plan." We urge that the regulation drop the word 'substantially.' Any cherry picking is an abuse of beneficiaries, the Medicare program, and taxpayers in general.

Elsewhere, we and others comment on the many deficiencies in the formulary proposal and the weaknesses in the proposed model formulary developed by the USP. We hope that the USP model becomes more detailed and offers more classes and subclasses. But assuming that the USP model does not become less granular (less detailed) and stays approximately as it is, then CMS should make it known that it will not approve any plan application which develops its own formulary that has fewer classes and categories than the USP model. Any plan which spends money and P&T effort to develop its own formulary that is likely to cover fewer essential, high technology medicines should be presumed to be trying to avoid HIV/AIDS, mental health, complex cancer, and other cases. The potential for abuse of the program by cherry-picking is so enormous that CMS needs to be much stronger in its advice in this subsection.

SUBPART J—COORDINATION UNDER PART D WITH OTHER PRESCRIPTION DRUG COVERAGE

Section 423.464 Coordination of Benefits with other providers of Prescription Drug Coverage.

Recognize AIDS Drug Assistance Programs as State Pharmaceutical Assistance Programs (SPAPs).
We urge that AIDS Drug Assistance Programs (ADAPs) be recognized as State Pharmacy Assistance Programs and be allowed to wrap around the Medicare Part D drug benefit and that ADAP expenditures be counted as true out-of-pocket costs. We see nothing in the law that prohibits ADAPs as being designated as SPAPs and they certainly serve the same function and purpose as traditional SPAPs, for the low income HIV/AIDS population.

Let State Pharmacy Assistance Programs help their residents pick the best plan.
The NPRM Preamble prohibits SPAPs 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*. But despite the Preamble language, the 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 Preamble language be dropped and 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.

423.464 (e), Coordination with State Pharmaceutical Assistance Programs.
We are hopeful that existing SPAPs and new SPAPs will be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance.

In order 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.

SUBPART K –APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Section 423.504, General provisions.

While we strongly support the strong new anti-fraud provisions in this section, we also hope that CMS will make it clear that this program **will**—not "may"—be subject to extensive annual audit. The history of providers in this sector (for example, the $1.1 million settlement of Omnicare of Maine with the State of Maine announced August 25 as a penalty for switiching patients from lower cost forms of a generic to a more expensive form), coupled with the billions of dollars at stake, make this a very high risk program.

Section 423.507, Non-renewal of Contract.

423.507(a)(2) and (a)(3), Timeframes.
In light of the MedPAC's June, 2004 report to Congress on the importance of long-lead times in transferring files, we believe the timeframes in this section are too short and should be lengthened if at all possible. We also note that MedPAC reported a case where one provider refused to cooperate with another provider in file and data transfer. As a condition of participation in the program or recovery of surety bonds, PDPs and MA-PDs should be required to cooperate in a timely manner in all file and data transfers, including in cases where the PDP is leaving the market.

Section 423.512, Minimum enrollment requirements.

We are concerned that some of the minimum enrollment standards being set (5,000 and 1,500 in rural areas) are too low. We do not believe that plans with this small an enrollment base can obtain adequate discounts, maintain 7/24 advice and information lines, and employ the expertise needed for pharmacologically complex condition patients. We support small businesses, but in this case, too small a business may not be good for the health of those enrolled. CMS should carefully evaluate minimum enrollment requirements; minimum enrollment should be sufficiently high to ensure that every PDP will have the ability to both negotiate adequate discounts and provide the level of service beneficiaries will require.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS AND APPEALS

Overarching concern and general comments.

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution and 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 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 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.*** 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. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 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 timeframes, the paperwork, and the processes should be simplified into one course of action that beneficiaries may hope to understand.

Section 423.560, Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines authorized representative as someone authorized by 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 also act on behalf of an enrollee in exceptions and grievances.

Section 423.562, General provisions.

423.562 (c)(1), Appealing when enrollee has no further liability.
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.

423.562 (c)(2), Challenging non-network coverage determinations.
This subsection may preclude an enrollee from challenging a plan's determination that it has no obligation to cover a drug received from a non-network pharmacy and should be deleted. As stated elsewhere in these comments, the actual regulatory language in 423.124 does not establish clear criteria as to when a plan must cover drugs received from non-network pharmacies. Thus, there is no guarantee that plans will interpret the regulation as CMS describes in the preamble. Taken together, proposed 423.124 and 423.562(c)(2) place at risk vulnerable individuals such as those in institutions whose purchases from long-term care pharmacies are treated as if they are from a non-network pharmacy.

Section 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. We refer CMS to the website of the Florida Agency for Health Care Administration, http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/multi_source.shtml, for an example of information Florida pharmacies must provide when they deny a prescription under the Florida Medicaid program.

Section 423.568, Standard timeframes and notice requirements for coverage determinations.

Timeframes.

Section 423.568(a), Timeframe for request 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.

Section 423.568(b), Timeframes for request for payment.
This section should be eliminated, per our opening comment about the need to simplify these regulations and provide more uniform timeframes, etc.

There should be no distinction in time frames when an enrollee requests payment.

Notice.

Section 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 situations 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. See our previous comment about the Florida Medicaid program.

Content of the notice (Applies also to 423.572(d)).
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 the following:

- Notice about exceptions and appeal rights should be presented immediately upon denial (including upon determination that a drug is not covered on formulary and including denials issued by the pharmacist) and should explain why coverage was denied and options for obtaining necessary medications as well as appeal procedures.

- Notice should include clinical or scientific basis for denial.

- Notice should be available in multiple languages and the availability of language services noted (see below).

- A recently settled Florida class action lawsuit filed on behalf of Medicaid recipients determined that the state had not provided written notification to people whose prescription coverage was denied of their right to appeal the decision. The settlement's provisions require the state to provide:

    - Written notification that explains why the coverage request was denied
    - Information on how to resolve the issues that triggered the rejection
    - Instructions that explain how consumers can request an appeal
    - Steps 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).

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. We support the August, 2000 HHS OCR guidance on how programs can meet their Title VI obligations to provide written materials in 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.

Section 423.570, Expedited consideration.

423.570(a), Requests for expedited determinations.
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 time frames 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.

Section 423.572, Times frames and notice requirements for expedited coverage determinations.

(See comments above re content of notice.)

Section 423.572 (b), Timeframe.
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 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.'

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 NPRM what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. (This is also discussed in the next section.) The statute says plans

must make the change in information available on the internet, the Preamble discusses a mailed notice, and the NPRM 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.

Section 423.578, Exceptions process.

Overall, the exceptions process does not comply with the statutory requirements or meet the basic elements of due process.

Notice.
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 (pg 46661), the regulatory language just says that notice must be given, and the statute requires posting on the Internet.

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 reasons why a drug is not included on/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), Plan criteria.
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 regulations propose 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, for example :

- Consideration of the cost of the requested drug compared to the cost of the preferred drug has no bearing on whether a drug would not be as effective or would have adverse effects and should not be a consideration.

- Consideration of whether the formulary includes a drug that is the therapeutic equivalent also is not relevant to the statutory standard. The FDA requires that 80 percent to 125 percent of the medication be the same to be considered "therapeutically equivalent." Treatment for certain conditions, including mental illness, is highly individualized given the non-interchangeability of many medications even within the same class, the high degree of variability in how these diseases present themselves in terms of symptoms, and the many other factors that must be taken into account, including overdose lethality in light of heightened risk of suicide. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the deciding factor.

- Consideration of the number of drugs in the plan's formulary that are in the same class as the requested drug, for the reasons stated above, also is not relevant to the determination of the treating physician that the requested drug is needed.

Inadequate guidance for physicians.
The proposed rules fail to provide adequate guidance concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or cause adverse effects has been met.

- The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug would not be as effective or cause adverse effects. The statute does not support allowing 'fail first.' In fact, for many enrollees, a fail first requirement in and of itself would cause adverse effects. A fail first standard might apply if the statute required—which it does not—the doctor to certify that the drug is not as effective or causes adverse effects.

- The regulation says that the plan sponsor "may require the written certification to include only the following information…" Given that the statute requires a determination by the doctor that the preferred drug would not be as effective, would cause adverse consequences, or both, plans are going to require some kind of written statement. However, the regulation should limit the statement only to the statutory standard. It should read "The sponsor may only require the written certification to include the following information."

- The preamble states that a PDPs exceptions process also would have to describe how a determination on an exception request would affect the enrollee's cost-sharing under the PDP's tiering structure. 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 criteria, which were omitted:

- Rule permitting continued access to a drug at given price when there is a mid-year formulary change.

- 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.

Exceptions involving nonformulary drugs

423.578(b), Defining formulary use, 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 ".(p. 46720). ***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" (p. 46721).*** 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 criteria and process described in 423.578(b)(2) will make it impossible to get an exception. The process is not transparent, as is stated in the preamble (pg 46720), because it is left totally to the discretion of each plan. We urge CMS, and not each individual plan, to establish the criteria for evaluating the request. 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.

The regulations must also establish standard criteria that plans must use in evaluating a prescribing physician's determination that any on-formulary drug would not be as effective or would cause adverse effects. In addition, independent review entities must be charged with reviewing plan criteria to ensure that they comply with these federal standards and implement the statutory standard requiring that the prescribing physician determine that all on-formulary drugs would not be as effective or have adverse effects.

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.

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.

The regulations need to establish fixed criteria for evaluating the prescribing doctor's determination that using all formulary drugs would not be as effective or would cause adverse consequences to the enrollee. Requiring this amount of evidence would make it impossible to meet this standard. Instead the regulation 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 plan 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 older people, people with disabilities, and people with co-morbidities. While some such evidence exists, there may not be this level of evidence for all drugs and conditions. Again, the regulations should require the certificate to meet the statutory standard (not as effective or adverse effects or both) rather than include information why the "preferred drug" is not acceptable for the enrollee. The criteria should recognize a physician's experience in evaluating whether the statutory standard is met.

- For dosing exceptions, the regulation states the standard is a showing that the number of doses that is available under a dose restriction for the prescription drug has been ineffective or based on both sound clinical evidence and medical and scientific evidence the drug regimen is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. The standard should include "or cause an adverse reaction or other harm to the enrollee".

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, et.) and packaging, such as bubble wraps for long-term care facility residents.

423.578(b)(4), Certification requirement.
Again this section says a PDP sponsor "may" require a written certification. The language should be that the sponsor "may only require the written certification to include the following information." Again, the standards are very high. The list of information is too long and is repetitive; the doctor should only need to explain why the drug that is the subject of the exception request is needed for the enrollee [(b)(5)(iv)(D)], and not all of the previous provisions.

423.578(c)(2) Continuation of drug pending review.
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 they could show the decision needed to be made more quickly because of their condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

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 want to stress the importance of drug coverage and ensuring no gaps in the uptake 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.

Notice.
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 deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise the 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)).

Section 423.580, Right to a redetermination and Section 423.584(a), Expediting certain re-determinations.

The enrollee's authorized representative should also be able to request a re-determination or an expedited re-determination (See also Section 423.584).

These 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 then disallow an enrollee's representative from pursuing 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".

Section 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, the right to submit evidence in person and orally.

Also, see Section 423.580 regarding allowing an individual's authorized representative to request an expedited re-determination.

Section 423.586, Evidence for a re-determination.

The regulations should establish clear criteria for informing the enrollee and the doctor that they can submit evidence in person, as well as clear procedures for in-person review.

Section 423.590, Timeframes.

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).

We renew our 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.

Section 423.600, Reconsideration by the IRE.

Role of the 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 (**pg. 46721**) 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 of 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.

Requesting the reconsideration.
Since the Part D process is supposed 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, we dispute 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 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), Requirement to solicit view of treating physician.
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 Medicare Advantage independent contractor is often reluctant and often 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, face-to-face meeting.

423.600(d),Timeframe.
The regulations need to establish a set time frame 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. 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.

Section 423.602, Notice of reconsideration.

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.

Section 423.610, Right to an ALJ Hearing.

Congress recognized the special needs of the low income, and how even small copays 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.

We are 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?

Section 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 ALJs 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, including any doctor's statements, statements by the enrollee, and other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that contracting entities, including Medicare Advantage plans, often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

Section 423.634, Reopening and revisions determinations and decisions & Section 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. That's totally unacceptable, since further delays may cause increased health consequences to people who foregone medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

Subpart O—Intermediate Sanctions

Overarching concerns

- CMS describes in the preamble (69 Fed. Reg. 46724) a potential conflict between the statutory requirement that each region have at least two PDP sponsors and its goal of using consistent policies and procedures across regions when imposing sanctions. This conflict can be resolved, with both the statutory requirement and CMS' goal retained and implemented to ensure the highest quality of care. If a region has only two PDP sponsors, CMS can nevertheless terminate one sponsor, as appropriate, and fulfill its statutory obligation to assure that a fallback plan serves as a second PDP sponsor.

- The proposed rules establish four types of sanctions – civil money penalties and enrollment, payment, and marketing sanctions. They also identify six bases for imposing sanctions. However, the rules do not describe any process or methodology for CMS to use in deciding which sanction (or sanctions) to impose in any particular set of circumstances. In addition, the fact that *all* sanctions are permissive increases the likelihood that none will actually be imposed. CMS needs to develop a process and methodology to use in determining when to impose sanctions.

- While sanctions can be imposed only when noncompliance is determined, it is not clear from the rules how CMS will determine that PDPs are not complying with the requirements of the laws. The proposed rules describe Quality Improvement Organization activities, but QIOs are not regulatory bodies and their work is confidential. The proposed rules describe deemed status for accrediting organizations, but deemed status is granted when the standards and survey process are found to be equivalent to CMS' standards and process. What is the CMS process? The proposed rules describe the contracting process, which includes, among other things, a compliance plan, an obligation to self-report quality problems, and maintenance of records that are subject to audit and review by CMS or its designee. A contract-based system is passive and relies on PDP's disclosure. Finally, the proposed rules say that CMS retains authority to enforce standards against a PDP that does not meet standards as determined by "its own survey" or an accreditation survey. Where is the further description of what this survey would be?

- CMS should make public – through press releases, statements in the Federal Register, annual report, etc. – deficiencies it cites against PDPs

and any sanctions it imposes against a PDP. Such information could be important to beneficiaries' decisions about which PDP to join.

Section 423.752, Basis for Imposing Sanctions.

423.752(a), All intermediate sanctions.
The regulations do not implement the preamble's explicit statement that one or more sanctions may be imposed at any one time. Accordingly, we suggest amending this section as follows:

(a) *All intermediate sanctions*. For the violations listed below, CMS may impose ~~any~~ one or more of the sanctions specified in §423.750 on any PDP sponsor that has a contract in effect.

Section 423.756, Procedures for imposing sanctions.

423.756(e), Termination by CMS.
The proposed rules say that the enrollment, payment, and marketing sanctions may be used in addition to non-renewal or termination. They also suggest that civil money penalties are available in situations where the PDP terminations its contract without following the appropriate process.

We suggest that CMS amend §423.756(e) as follows to provide for the availability of civil money penalties in all instances when it declines to renew or terminates a contract:

> "In addition to or as an alternative to the sanctions described in paragraph (c) or this section and civil money penalties authorized by sections 423.750(a) and 423.758…"

Section 423.758, Maximum amount of civil penalties imposed by CMS.

The definition of when a civil money penalty for a deficiency may be imposed is too narrow and limiting. It fails to reflect the various types of noncompliance that are the bases for imposing sanctions, § 423.952(a)(1)-(6). It requires that harm occur, or be very likely to occur, to PDP enrollees before CMS can impose a financial penalty. It fails to recognize that a benefit of civil money penalties as sanctions is their ability to be varied in amount to reflect the extent and seriousness of the noncompliance. Although the rules

establish $25,000 as the outer limit of a civil money penalty, such penalties can be lower.

CMS should establish a range of civil money penalties, and vary the amount of penalties in each category to reflect the nature and extent of the PDP's noncompliance with requirements.

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

Section 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 self-attest to the status of dependents, without providing further documentation.

Full subsidy eligible individual.
The definition of full subsidy eligible individual should refer to the language of 423.773(b) *and* (c), in order to avoid ambiguity.

Income.
The definition of income 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 ICFs-MR 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 proposed regulation's limitation of countable resources to liquid assets only. 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 (see Preamble at 46,726). 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. As noted above, life insurance should not count towards assets, and this question should be eliminated.

Section 423.773, Requirements for Eligibility

General comments.

We strongly 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 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) that 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(c), Clear meaning of automatic eligibility.
Section 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 the extent 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.

423.773(c)(3): Ensuring equitable enrollment for all MSP-eligible beneficiaries.
We support the decision reflected in proposed regulation 423.773(c) to deem Medicare Savings Program ("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 rules, 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 should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy, 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 increased disregards under 1902(r)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. We urge SSA to apply also state income disregard rules. If a statutory change is necessary to implement such a rule, the Secretary should seek appropriate legislative authority.

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 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 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.

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).

423.773(c)(3), Notification for automatically eligible beneficiaries.
Proposed §423.773(c)(3) states that a state Medicaid agency must notify full benefit duals 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 should develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. As mentioned above, 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.

423.773(c), Eligibility for spenddown beneficiaries.
The proposed rule does not 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 section 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.

Section 423.774 Eligibility determinations, redeterminations, and applications

423.774(a), Notification of new applicants.
Section 423.774(a) 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 beneficiaries' being able 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. A similar system has been used effectively by several states in their Medicaid and State Children's Health Insurance Program (SCHIP) programs as a means of increasing enrollment and speeding beneficiaries' access to needed services. 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.[6] 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.

We believe 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 in § 423.774(c) applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs can be of vital interest for Medicare beneficiaries, 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.

423.774(c), Redetermination Periods.

[6] Rachel Klein, "Creative Solutions: Presumptive Eligibility" *The Future of Children* 13, no. 1 (Spring 2003): 230-237.

The regulation refers to redeterminations and appeals under the state Medicaid plan. This is inadequate, as frequent redeterminations in place in some states will lead to beneficiaries dropping 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.

Coordination with spenddown/medically needy programs.
As we mention in our comments to section 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.

Section 423.782, Cost-sharing subsidy.

As noted in our comments to Subpart F, section 423.265(d)(2)(iv), the rule should specify that plans cannot use an alternative benefit design to charge cost sharing to low-income beneficiaries that exceeds the amounts set out by

the statute. This applies to both the co-payments established in section 423.782(a) and the co-payments and co-insurance established in section 423.783(b).

Section 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.

423.800(e), Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy.
The reimbursement provisions of § 423.800(e) are also inadequate to protect low-income beneficiaries. The proposed regulation would require plans to reimburse low-income beneficiaries for excess co-payments and premiums 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 in our comments to section 423.774(b) 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 Q: GUARANTEEING ACCESS TO A CHOICE OF COVERAGE (FALLBACK PLANS)

Sections 423.851-875, Entirety of Subpart Q.

The requirements this Subpart imposes on those who would be interested in providing a 'fallback plan' to serve an area not served by at least two plans (one of which may be a MA-PD) are so severe that fallback plans will not, in fact, be available. The requirements exceed the statute and basically sabotage this provision of law; they make it entirely possible that some rural areas may have no service except regional PPOs and HMOs.

Congress clearly did not intend that seniors would have to join a managed care plan for all their health care services in order to get the prescription drug benefit. The additional contracting restrictions and other policies proposed in the regulation that would make it less viable for a plan to bid as a fallback plan should be eliminated to ensure that fallback plans will bid and participate.

Plan negotiations: fallback and non-fallback plans.
We support CMS's position that it has authority to negotiate with plans to ensure a good price for beneficiaries. As the Preamble states (46734) "if the price reference points appear to be particularly high (or low), we may request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids." We note that these pricing dangers may also occur in areas where there is no fallback plan, but just one MA-PD and one PDP. Therefore, we urge CMS to apply the same authorities to plans in non-fallback situations. In fact, the Preamble states that "we are contemplating tying the performance payments of fallback entities to the average discounts they are able to negotiate, including discounts from manufacturers." This is a higher requirement than is being imposed on non-fallback plans.

Given the tremendous potential for price collusion and price fixing in non-fallback regions, we believe a similar requirement should be imposed on all plans. If that requirement is not extended to non-fallback plans, it should be deleted for the 'fallback plans' so that there is a more level 'playing field.'

SUBPART R—PAYMENTS TO SPONSORS OF RETIREE PRESCRIPTION DRUG PLANS

Section 423.882, Definitions.

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 Fed Reg 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**.

Section 423.884, Requirements for qualified retiree prescription drug plans.

423.884(a). 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, given the significant and unprecedented employer subsidy established under the MMA, it would be wise to provide 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.
In addition, 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. (See also our comments on sections 423.46 and 423.56.)

Section 423.888, 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.

Section 423.890, Appeals.

To provide further protection against improper payment of the employer subsidy, third parties (such as employee 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.

Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

Section 423.902, Definitions

Full benefit dual eligible.
"Full benefit dual eligible" is defined, for 2003 baseline calculations, to be those individuals having Medicaid drug benefit coverage and Medicare Part A or Part B. This definition appears to include some individuals not receiving full Medicaid benefits, but receiving drug coverage under a Pharmacy Plus waiver. The preamble does not discuss this definition; it is unclear what the intention of the language is.

Section 423.904, Eligibility determinations for low-income subsidies

423.904(a), General Rule.
The provision directs states to make eligibility determinations in accordance with the provisions of 423.774. It 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 noted in our comments to Subpart P, a similar provision should be included in 423.774 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, proposed § 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 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 Section 1935(a)(3) established in Section 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 explain 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 recommend that CMS should direct those states that currently rely on the SSI methodology for determining resources for their MSP programs to instead apply the definitions of resources used in Subpart P section 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 confusing beyond repair 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.

Screening and enrollment for full Medicaid.

We believe that 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 (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program (SCHIP) 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 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.

Screening for other public benefits.

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. In particular:

- Outreach materials that SSA and CMS/State Medicaid programs design should contain information about other major benefits for which applicants may be eligible;

- Applications that are filed and other information that applicants provide should be easily shared between SSA, state agencies, and CMS so that it is available to all agencies and duplication of effort can be avoided;

- The federal agencies involved (USDA, CMS, and SSA) should make it a priority to enroll all eligible applicants in all benefit programs. In addition, these agencies should seek to simplify federal program rules so that Medicare beneficiaries can easily 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 additional questions and are certified automatically for food stamps based on their SSI applications.

423.904(c)(3), Notification.
The section refers to 423.34(d) with reference to notifying individuals deemed subsidy eligible, but 423.34(d) discusses automatic enrollment of full benefit dual eligibles in Part D plans. Notification of deemed subsidy eligible individuals of their entitlement to a subsidy is a different matter from enrollment in a Part D plan. This reference appears inapt. As discussed in our comments to section 423.773, those who are deemed subsidy eligible need immediate notification of that status and of the fact that they need do nothing more with respect to their subsidy, but that they need to enroll in a Part D plan in order to use the subsidy.

423.904(d)(3), The application process and States.
As written, the rule permits states to impose more burdensome documentation requirements on beneficiaries than could SSA. This is counter to the principle of simple enrollment underlying the statue. In addition, states should not be permitted under the cost-effectiveness provisions of section (d)(3)(ii) to transfer the costs of verification to beneficiaries by requiring visits to state Medicaid offices and production of additional documentation. Section (d)(3)(i) should be changed to read: "States may require submission of statements from financial institutions for an application for low-income subsidies to be complete *only if the applicant or personal representative is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information"* (suggested additional language in italics).

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.

SUBPART T—CHANGES TO PARTS 403, 411, 417, 460 and 442.

Changes to Part 403, 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 (page 46760) 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. Information about the new Medicare drug benefit will be readily available from a variety of sources including CMS, and introducing it in this disclosure notice detracts from important information consumers must have to understand and exercise their rights concerning their Medigap coverage.

- Delete statements about the value of Part D benefits. These statements are irrelevant to the issue of changes to Medigap. They also may not be accurate for certain individuals who have employer-sponsored or other drug coverage. The language introduces this information before consumers will understand they have important decisions to make about their Medigap coverage.

- Include at the beginning of the letter the statement that beneficiaries may call 1-800-Medicare for help understanding the disclosure notice.

- 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 adds to the length of the letter.

- Delete the information concerning enrollment issues about Medicare Part D. The language 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 **Section 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.

Changes to Part 411, Physician Self-Referral Rules.

Section 411.351, Physician Referral laws must apply to Part D drugs.
In Subpart T, Section 411.351, relating to physician referral, we strongly support the extension of the so-called Stark physician referral law to ensure that “outpatient prescription drugs” includes “all drugs covered under Medicare Part B and Part D.”

A review of other nations’ health systems where doctors make money on the prescriptions they write will show a much higher utilization of drugs per patient encounter than in the United States. A review of the abuse of the Average Wholesale Price (AWP) spread in Medicare Part B will show that the type of drug prescribed and the quantity increases as the spread (profit to the doctor) increases. Not to apply the physician referral laws to the Part D drugs would be a financial disaster for the program.

These comments are respectfully submitted by the following organizations:

AFL-CIO
AIDS Alliance for Children, Youth & Families
AIDS Foundation of Chicago
AIDS Institute
AIDS Legal Council of Chicago
Alliance for Retired Americans
American Association of People with Disabilities
American Association on Mental Retardation
American Congress of Rehabilitation Medicine
American Council of the Blind
American Dance Therapy Association
American Diabetes Association
American Federation of State, County & Municipal Employees
American Federation of Teachers
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Network of Community Options and Resources
American Public Health Association
Association of Academic Physiatrists
Association of University Centers on Disabilities
Bazelon Center for Mental Health Law
Brookdale Center on Aging, Hunter College
Brooklyn Wide Interagency Council for the Aging Educational Fund
California Health Advocates
Catholic Charities USA
Center for Advocacy for the Rights and Interests of the Elderly
Center for American Progress
Center for Health Care Rights
Center for Independence of the Disabled
Center for Medicare Advocacy, Inc.
Center on Budget and Policy Priorities
Center on Disability Issues and the Health Professions
Coalition of Wisconsin Aging Groups
Disability Law Center of Alaska
Easter Seals
Epilepsy Foundation
Families USA
Family Voices
Fiscal Policy Institute
Gay Men's Health Crisis
Greater Upstate Law Project

Health and Disability Advocates
Helen Keller National Center
HIV Medicine Association
International AIDS Empowerment
Jewish Federation of Metropolitan Chicago
Joint Public Affairs Committee for Older Adults
Legal Services of Eastern Missouri
Lutheran Services in America
Medicaid Matters New York
Medicare Advocacy Project, Greater Boston Legal Services
Medicare Rights Center
National Academy of Elder Law Attorneys
National Alliance of State and Territorial AIDS Directors
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities
National Association of County Behavorial Health Directors
National Association of Protection and Advocacy Systems
National Association of Social Workers
National Citizens' Coalition for Nursing Home Reform
National Coalition on Deaf-Blindness
National Committee to Preserve Social Security and Medicare
National Fragile X Foundation
National Health Law Program
National Mental Health Association
National Multiple Sclerosis Society
National Respite Coalition
National Senior Citizens Law Center
National Women's Law Center
New Hampshire Department of Health and Human Services,
Division of Family
New York Immigration Coalition
New Yorkers for Accessible Health Coverage
Northeastern Illionois Area Agency on Aging
NY State Alliance for Retired Americans
NY StateWide Senior Action Council
Paralyzed Veterans of America
Poverty Law Project at Vermont Legal Aid
San Francisco AIDS Foundation
Senior Citizens Law Project of Vermont Legal Aid
Service Employees International Union
Tennessee Protection and Advocacy, Inc.
The Arc of the United States
Title II Community AIDS National Network

United Cerebral Palsy
United Senior Action of Indiana
United Spinal Association
USAction
Vermont Disablity Law Project
Vermont Long Term Care Ombudsman Project
Vermont Office of Health Care Ombudsman
Volunteers of America
Westchester Disabled on the Move Inc.
World Institute on Disability

CMS-4068-P-1084

Submitter : John Klimek **Date & Time:** 10/04/2004 07:10:03

Organization : Albertsons

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

We have been working with NACDS (National Association of Chain Drug Stores) on a Single Point of Contact System (SPOCS) concept in which pharmacies can access information such as Eligibility, TrOOP, and DUR (Drug Utilization Review), as well as having the SPOCS system run the Coordination of Benefits (COB) that is needed to calculate the TrOOP for a Medicare patient 'real-time'. We are in full support of NACDS's proposakl in the fact that it will deliver a TRUE out of pocket cost to the patient 'real-time'.

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

The proposal of the SPOCS (Single Point of Contact System) will help CMS monitor and contain costs through utlization manqagement of a single entry system, as well as help deliver appropriate therapy management to patients quickly at POS (Point of Service).

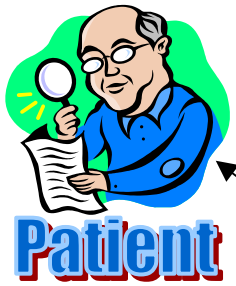
CMS-4068-P-1084-Attach-2.doc

CMS-4068-P-1084-Attach-1.doc

CMS-4068-P-1084-Attach-2.doc

CMS-4068-P-1084-Attach-1.doc

Processing Prescription Claims Today (NCPDP 5.1)



Pharmacy (Provider)

Real Time

Switch

Real Time

Insurance Card

Real Time

Processor (PBM)

- Eligibility
- Co-Pay
- DUR (Drug Utilization Review)

Some pharmacies connect directly to PBM (s) whereas others use SWITCH to route claims to PBM (s). The SWITCH is just a pass-through.
Co-Pays that report on-line today are correct and up-to-date according to benefit (s).

CMS Prescription Claim Processing
Medicare Part D

Plans

Plans

Plans

Eligibility / TrOOP
Central Database
(Updated nightly)

1st to determine order of processing

X12 270/271

Pharmacy (Provider)

Multiple cards

Switch

2nd, 3rd, 4th determine TrOOP and COB

Processor (PBM)

- TrOOP (co-pay)
- COB
- DUR (Drug Utilization Review)

The TrOOP that reports on-line with this proposal will not be up-to-date!

Proposed NACDS SPOCS
Prescription Claim Processing
Medicare Part D

Plans

Plans

Plans

Real Time
TrOOP Update

Real Time
TrOOP Update

Real Time
TrOOP Update

Pharmacy
(Provider)

Real Time

Separate Response
Payment Segments
for each payor

SPOCS

(Single Point Of Contact System)

- **Eligibility**
- **TrOOP (co-pay)**
- **COB**
- **DUR**

Medicare Card

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

IssueBrief

Expanding CMS' Option 2 to Include Pharmacies Would Allow a More Efficient COB and an Accurate Calculation of TrOOP that Would Reduce the Medicare Beneficiaries Waiting Time for Prescription Medication and Supply Services.

NACDS offers a proposal that will allow CMS to attain its self–defined goals of maximizing the efficiency and effectiveness of a COB–TrOOP system by the MMA deadline of January 1, 2006. This proposal simply builds on CMS' Option 2, as described on FR page 46706, by including pharmacies in the single point of contact system. NACDS refers to this online real time COB–TrOOP system as SPOCS (Single Point Of Contact System), which is described below.

SPOCS would have two major advantages over CMS' proposed Option 2. Those advantages are that both Medicare recipients and pharmacies would also enjoy the benefits of a single point of contact system, not only payors. This increase in functionality maximizes the efficiency and effectiveness of a COB–TrOOP real time system.

NACDS offers CMS this SPOCS Proposal to assist CMS in its efforts to establish, before July 1, 2005, procedures and requirements that will promote the effective COB between a Part D plan and a State Pharmaceutical Assistance Program (SPAP), Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage CMS may specify in the future.

Most importantly, Medicare recipients will find SPOCS to be the easiest system to understand and the most convenient system to obtain their prescription medication and supply services.

413 North Lee Street
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22313-1480

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www.nacds.org

PROPOSAL
Single Point Of Contact System (SPOCS)
for
Medicare Part D COB and TrOOP

Overview of the Proposed COB–TrOOP Process:

- Medicare recipient needs only to present Medicare card and prescription(s) at the pharmacy.
- Pharmacy submits ALL Medicare recipients prescription claims (e.g., SPAP, Medicaid, group health plan, FEHBP, TRICARE) to the "SPOCS".
- SPOCS has ALL of the Medicare recipient's insurance eligibility information and the correct billing order in its electronic files.
- SPOCS, after receiving a prescription medication or supply payment claim from the pharmacy, identifies the Medicare recipient in its electronic file and sends the payment claim to that Medicare recipient's primary payor, the primary payor responds back to the SPOCS with the necessary COB and TrOOP information and the SPOCS repeats the process with the Medicare recipient's secondary payor, etc. until all of the responsible payors are billed.
- SPOCS sends the claim with a "separate response payment segment" for each payor back to the pharmacy so the pharmacy knows what each payor has paid and who to expect payment from.
- SPOCS receives the final TrOOP calculation for that claim and sends this information to the appropriate parties.

Advantages:

- Medicare recipient only needs to present Medicare Card at the pharmacy… no other insurance cards are necessary because of the single point of contact with the SPOCS.
- Medicare recipient's claims will go through the SPOCS and can be accessed for Medicare eligibility determination, TrOOP management, physician billed Part B claims updates, claims reversal communications, and inquires by appropriate parties about the TrOOP.
- CMS will only need to work with the SPOCS for eligibility and TROOP management.
- Pharmacy knows where to send ALL of the Medicare recipient's prescription claims reducing dispensing time so that the Medicare recipient obtains prescription medications and supplies more quickly than she/he otherwise would if the pharmacy was required to make eligibility inquires or to try to determine the correct billing order of the Medicare recipient's payors.
- A prescription ID card is not required to be sent to Medicare recipient… the Medicare recipient's Medicare Card is all that is necessary.
- SPOCS will be able to manage ALL* payment claims real-time, including Medicare Complementary Cross Over Claims.
- SPOCS is an independent entity that acts as a switch for real–time COB and TrOOP information that does not have a potential conflict of interest managing patient identifiable health care information and pharmacies' confidential payment rates.
- Separate response payment segments from the SPOCS will eliminate the current confusion in those cases when the DMERCs do not let the pharmacy know the secondary payor information on Medicare Complimentary Billings.
- Each payer is responsible for its own payments, which are reflected in the SPOCS's separate response payment segments back to the pharmacy.

*ALL – Need to have pharmacy Medicare Part B claims process on-line, real-time. See below.

SPOCS' System Requirements:

- Claims processing at PBM's must have a separate and enforced Bin Number for all Medicare claims processing at their site to assure that claims go through the SPOCS with the proper routing.
- All Medicare recipients' billing information and billing order must be on file at SPOCS and continually updated.
- Must have separate "response payment segments" for each payor billed through the SPOCS.
- To process COB claims, the processors would need to follow one of the NCPDP COB billing standards. The processor would elect to process the payment information by electing to use the 5.1 COB segment and accepting the "Other Payer Amount Paid", OR, not use the 5.1 COB segments but use the 5.1 pricing segment and accept the "Copay Billing" which would be populated with the Gross Amount Due.
- SPOCS treats all pharmacy claims and information as proprietary and confidential.
- Pharmacy maintains ownership of submitted claims data to dissuade the unauthorized uses and further disclosures of patient identifiable health care information as prohibited by the HIPAA privacy regulations.
- Pharmacies and Payers would need to make appropriate software changes that would allow them to: interact with SPOCS as the central point of contact for Medicare billed claims, receive multiple payment response segments, and receive TrOOP accumulator information. These changes for the Medicare recipients' claims would allow the SPOCS system to identify the eligible Medicare recipient, bill their claims to responsible payors in the proper billing order, send the information back to the pharmacy in an identifiable payment reconciliation format, and communicate the TrOOP back to the appropriate parties. The system should also allow for easy update of physician billed Part B claims.
- Medicare Part B pharmacy claims must process on-line, real time through SPOCS. This is required to allow for proper and accurate TrOOP calculation for the Medicare recipient. It is necessary to know the Medicare Part B paid amount (which by today's use of paper claims can takes weeks to obtain) to do any wrap around or additional COB billings and obtain a real-time calculation of Medicare recipient's TrOOP.
- Medicare Part B claims processing requirements would need slight modifications to make them as streamlined as pharmacy commercial payment claims and Part B would need to move to NCPDP 5.1 online, real time claims management.
- COB claims submission process would need to be accomplished within the industry standard claims submission time–out window of approximately 12 seconds.
- Preferable that all Medicare Prescription Plans use the Medicare recipient's Medicare ID number (or one ID number designated by CMS) as the Medicare recipient's ID number for all the various prescription programs the Medicare recipient may be enrolled. If not, the SPOCS would need to maintain the alternate ID billing numbers for the Medicare recipient to cross reference and COB bill.
- Work towards using common claim identifier values for physicians (NPI) and for drugs (NDC numbers).

CMS-4068-P-1085

Submitter : Mr. Daniel Rubin **Date & Time:** 10/04/2004 07:10:22

Organization : Adheris

Category : Private Industry

Issue Areas/Comments

Issues 1-10

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

Comment attached in WORD and PDF format.

CMS-4068-P-1085-Attach-2.doc

CMS-4068-P-1085-Attach-1.pdf

October 4, 2004

BY ELECTRONIC MAIL

http://www.cms.hhs.gov/regulations/ecomments
Centers for Medicare and Medicaid Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: CMS-4068-P (Medicare Program; Medicare Prescription Drug Benefit)
Issue 5: Cost And Utilization Management, Quality Improvement, And Medication Therapy Management

Adheris, Inc. (Adheris) is pleased to submit this comment to the Centers for Medicare/Medicaid Services (CMS) on the provisions of CMS's proposed rule implementing the new Medicare Prescription Drug Benefit under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), 69 Fed. Reg. 46632 (Aug. 3, 2004). Adheris primarily directs its comments to Medication Therapy Management Programs (MTMPs), addressed in 69 Fed. Reg. at 46668-46670. As a leading provider of prescription drug compliance and adherence programs, Adheris offers these comments to guide CMS in the development of requirements for MTMPs that will benefit patients and improve their health.

Adheris

Adheris helps retail pharmacies nationwide with prescription drug compliance programs (sometimes referred to as "compliance/adherence" programs or, more narrowly, "refill reminder" programs). Adheris provides patient education and reminder programs for pharmacies to use to communicate with their patients efficiently and effectively. The communications the pharmacy is able to distribute educate patients about their prescribed drugs and the importance of completing the therapy regimen the doctor has prescribed. These messages may also provide patients with important information about the disease or condition being treated. All Adheris compliance/adherence communications comply with the requirements of the Privacy Rule promulgated by HHS pursuant to the Health Insurance Portability and Accountability Act (HIPAA).

The Problems of Patient Non-Compliance with Prescribed Medication

By mandating MTMPs, Congress and CMS are hoping to address a serious and well-documented problem – the failure of patients to comply with the doctor's orders. There are enormous costs to the patient, to public health, and to the economy when patients do not adhere to prescription drug regimens their doctors have prescribed. *See* Ernst FR and Grizzle AJ, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," 41 *Journal of the American Pharmaceutical Assn* 192 (March/April 2001) (direct and indirect societal costs to patient non-compliance estimated at $177 billion annually). *See also* World Health Organization (WHO), "Adherence To Long-Term Therapies: Evidence For Action" (2003) at 21 (increasing the effectiveness of adherence may have a far greater impact on health than any

improvements in specific medical treatments).[1] The American Heart Association has stated "the cost of non-compliance, in terms of human lives and money, is shocking" and has made prescription drug compliance management one of its key priorities. American Heart Association Press Release, April 21, 1999.

As CMS's sister agency, the Food and Drug Administration (FDA) concluded, "[p]atient noncompliance with prescribed drug regimens can be directly related to therapeutic failure."[2] Patient non-compliance can also lead to more serious and, in some cases, life-threatening complications. Missed doses of antiglaucoma medications may lead to optic nerve damage and blindness. Missed doses of antiarrhythmic medications may lead to arrhythmia and cardiac arrest. Missed doses of antihypertensive drug products may lead to rebound hypertension that can be worse than if no medication was taken at all. Missed doses of antibiotics may lead to recurrent infection and also may contribute to the emergence of antibiotic-resistant microorganisms.[3] Failing to take medication as prescribed can lead to lengthy and costly hospital stays, greater disability, and even death. Recognizing that drugs really can be life saving when patients take them properly, CMS is appropriately looking to compliance/adherence programs, such as those Adheris has been helping pharmacies disseminate for 9 years, as one means of combating the problem.

Proposed Requirements For An MTMP

Improving patient compliance and adherence to prescribed medicines is precisely one of the goals the MMA and the proposed rule seek to promote. 42 U.S.C. § 1860D(4)(c)(2)(B) and 69 Fed. Reg. at 46668. In the final rule, CMS should explicitly provide for and recognize written communications from the pharmacy to the patient discussing compliance with, adherence to, and refills of prescribed medications as one part of an adequate, effective, and compliant MTMP. Adheris suggests that the language CMS uses in the preamble to the proposed rule (69 Fed. Reg. at 46668) be incorporated into the final rule. A new subsection (6) could be added to proposed 42 C.F.R. § 423.153(d):

> (6) MTMPs must include elements designed to promote:
>
> (i) Enhanced enrollee understanding--through beneficiary education counseling, and other means--that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications;

[1] *See also* "The Real Drug Problem: Forgetting to Take Them," *Wall Street Journal*, October 21, 2003, Section D, p. 1; http://www.medicines-partnership.org/research-evidence/major-reviews; Berg, et al., *The Annals of Pharmacotherapy*, 27 (9): S3-S22 (1993) (patients who do not comply with their prescriptions cost the U.S. healthcare system an additional $100 billion each year); Food and Drug Administration, Prescription Drug Product Labeling; Medication Guide Requirements; Proposed Rule, 60 Fed. Reg. 44182, 44186 (August 24, 1995) (FDA Med Guide Proposed Rule) ("The literature on patient compliance since 1982 continues to demonstrate a significant lack of medication adherence. … [O]ne-third of patients fail to take their prescribed medications…. parental noncompliance with drug therapy prescribed for their children exceeds 50 percent and noncompliance in the elderly ranges from 26 percent to 59 percent") (references omitted); Survey by AUS/ICR for AARP, National Pharmaceutical Council, and Pharmaceutical Executive Magazine, May 1996 (available at http://research.aarp.org/health/summary.html) (some kind of non-compliance with their doctor's prescription orders occurs for about four in ten Americans age 50 and older and at a higher rate for women).

[2] *See* FDA Med Guide Proposed Rule, 60 Fed. Reg. at 44186.

[3] *See* FDA Med Guide Proposed Rule, 60 Fed. Reg. at 44186.

> (ii) Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, and other compliance programs and other appropriate means); and
>
> (iii) Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.[4]

Identifying Targeted Beneficiaries

As provided under proposed § 423.153(d)(2), "targeted beneficiaries" would be defined as plan enrollees who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that CMS determines. 69 Fed. Reg. at 46668. Adheris urges CMS to consider the role that health care providers, particularly pharmacies, can play in identifying patients taking multiple Part D covered drugs for management of chronic conditions. Pharmacies store and maintain data on their patients' prescriptions -- such information is vital to the pharmacists' professional counseling obligations and to assuring that their patients are not receiving contraindicated medications. Pharmacy data will be an excellent resource for identifying those patients with chronic diseases and multiple medications who are most in need of MTMP services.

CMS further seeks guidance in defining who should fall within the definition of "targeted beneficiary," and defining "multiple chronic diseases" and "multiple Part D covered drugs." In looking to the common dictionary definitions, "multiple" is understood to mean more than one.[5] The term "chronic" is that which is marked by long duration, frequent recurrence over a long time, and often by slowly progressing seriousness. A chronic condition is that which is not acute.[6]

For purposes of MTMP eligibility, Adheris suggests looking to the above definitions. A patient whose doctor prescribes more than one medication for more than one disease or health condition would meet the definition of "multiple." The disease or health condition would be chronic if it is requiring therapy over a long period of time: for instance, more than one course of drug therapy and/or one or more refills.

The Role of the Pharmacist in MTMPs

As CMS discusses in the preamble, the MMA specifically provides that a pharmacist may furnish MTMP services. CMS believes that pharmacists will be the primary providers of MTMPs. 69 Fed. Reg. at 46669. Adheris agrees.

A plan sponsor may be in the best position to identify the targeted beneficiaries -- although again, Adheris notes that pharmacies maintain data on patients and the extent to which they are on multiple

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[4] *See* 69 Fed. Reg. at 46668.

[5] *See* Merriam-Webster Medical Dictionary (2002 Merriam-Webster, Inc.).

[6] *See* Merriam-Webster Medical Dictionary (2002 Merriam-Webster, Inc.).

drugs for chronic diseases. Once a targeted beneficiary is identified by whatever criteria CMS adopts, Adheris believes that a health care professional should implement the MTMP and deliver those services to the patient. As a matter of professional responsibility, and as a function of state and federal laws, the pharmacist is already charged with and experienced in management of a patient's medication therapy. Pharmacists are easily accessible to their patients and best suited to deliver MTMP services. Management of a patient's medication therapy, and especially where there are complex issues of multiple drugs, with different risk profiles, is best left to licensed health care professionals.

Best Practices in Current MTMPs

CMS solicits comments on current MTMP best practices and which quality assurance measures might be incorporated into MTMPs. 69 Fed. Reg. at 46668. Dissemination of drug information to patients has been an integral part of pharmacy services for many years, even as privacy concerns have arisen regarding the practice. Adheris has been proud to be part of a broad coalition that recently looked at performance-based best practice principles for pharmacy-based health care communications. On August 18, 2004, the National Consumers League (NCL) issued a report, Health Care Communications Provided By Pharmacies: Best Practice Principles For Safeguarding Patient Privacy ("Best Practices For Pharmacy Communications" or "Principles").[7] These Principles, developed by representatives from public interest organizations, health care professionals, pharmacy and industry trade groups and retailers, pharmacy vendors, and pharmaceutical manufacturers build upon and supplement the requirements of the HIPAA Privacy Rule.

The Best Practices For Pharmacy Communications are intended to provide guidance to pharmacies that disseminate tailored messages about prescription drugs, disease states, and treatment options to their patients. The Principles acknowledge that these communications can be viewed as encouraging the purchase of drug products. "However, these types of messaging programs serve to educate and empower patients and, thus, have real value not only to individual patients but also to society."[8] While the communications are very valuable, there must be safeguards in place to protect patient privacy as well. The Best Practices For Pharmacy Communications "educate regulators and policymakers about the importance of pharmacy messaging and the kinds of measures that can be adopted to alleviate concern about the misuse of health information, while preserving the ability of pharmacists to communicate, and patients to receive, important health information."[9]

The Principles set out in the NCL report include:

- Ensuring that a pharmacy's Notice of Privacy Practices can be readily understood
- Providing patients with a description of pharmacy messaging programs
- Providing patients with an opportunity to opt out of pharmacy messaging programs

[7] Available at http://www.nclnet.org/pressroom/pharm_practices_09.04.htm

[8] Best Practices For Pharmacy Communications at 7-8.

[9] Best Practices For Pharmacy Communications at 5.

- Ensuring that opt-out mechanisms function properly
- Identifying sponsorship of messaging programs
- Disclosing limitations of materials as a source of healthcare information
- Providing information that is clear and reliable
- Endeavoring to use discretion and sound judgment in communicating about sensitive subjects
- Ensuring that persistence and compliance messages are written in a manner consistent with available data about the characteristics of effective messaging
- Engaging in messaging about alternative and/or adjunctive therapies only where there is a clear potential benefit to patients.

Adheris recommends that CMS review these best practices recommendations -- a product of long discussion among privacy advocates, consumer representatives, and the health care industry. As the Principles make clear, pharmacies have long experience in administering the types of programs now contemplated in MTMP services and have already addressed many of the issues CMS will now have to address. Many of the best practices set forth in the Principles could be incorporated into the requirements for MTMPs.

Reimbursing Providers for MTMPs

Currently, most compliance/adherence programs and refill reminders are supported by payments from the drug manufacturer or distributor to the pharmacy. In this way, the pharmacy does not have to bear the additional communication costs; nor does the pharmacy have to pass the costs on to its patients. As the Best Practices For Pharmacy Communications report recognizes, "the business reality for pharmacists is that crafting printed informational materials that are accurate, informative and easy to understand, and providing these materials to large numbers of patients is a costly undertaking. For that reason, most pharmacists have welcomed the assistance of third parties (including pharmaceutical manufacturers, medical organizations and others) in developing and funding these materials."[10]

In its programs, Adheris is careful to assure that patient well-being is enhanced. First, the programs do not compromise the patient's privacy – Adheris's programs comply with HIPAA's privacy requirements and the Best Practices for Pharmacy Communications. The pharmacy keeps the patient's protected health information (PHI) confidential and never communicates PHI to the drug manufacturers. Patients receiving these communications are also given the opportunity to "opt-out" of receiving future communications simply by talking to their pharmacist, calling a toll-free number, or visiting a website. The manufacturer's sponsorship of the communication is also fully disclosed to assure that consumers are not misled.

[10] Best Practices For Pharmacy Communications at 11.

Second, a physician has already prescribed a particular drug for a patient, and the pharmacy has already dispensed the drug. Thus, there is no reward paid to the physician or the pharmacy if the patient refills the prescription. The communication is intended to encourage patients to follow their doctor's instructions, and take and refill their prescribed medication as the doctor has already prescribed. The manufacturer pays for the communication, not the drug, and payment is not contingent upon whether the patient refills the prescription.

Given the benefits of manufacturer-sponsored compliance/adherence communications, it would be useful if CMS specifically acknowledged these arrangements in the final MTMP rule. Such a specific endorsement would clarify any uncertainty that may arise under other HHS requirements. For instance, under HHS Office of Inspector General pronouncements, a manufacturer-sponsored pharmacy letter could theoretically be objectionable if the pharmacy urges a recipient of a Part D drug to simply refill his or her prescription drug, in accordance with the prescribing physician's instructions.[11] While there is no current evidence OIG would actually deem the manufacturer's payment to be an unlawful "inducement" under the anti-kickback statute, a clear statement from CMS that manufacturer sponsorship of MTMPs is an acceptable funding source would aid tremendously in encouraging these programs.[12]

Adheris suggests the following be added to final rule, 42 C.F.R. § 423.153(d):

> (7) Sources of funding for MTMPs. A PDP sponsor, an MA organization, or other MTMP provider may receive direct or indirect remuneration from a manufacturer or distributor of a Part D drug to support the MTMP for that manufacturer's drug, provided that the payments are made for the purpose of preparing and sending communications to targeted beneficiaries to educate the target beneficiary regarding: a prescription medication a health care professional has prescribed; the underlying disease or condition being treated; or to improve compliance and adherence with the course of treatment the physician has prescribed.

* * *

[11] *See* 67 Fed. Reg. 62057, 62061-62 (Oct. 3, 2002) and 68 Fed. Reg. 23731, 23734 (May 5, 2003).

[12] Adheris notes that some manufacturers have also expressed concerns that payments to fund MTMP services may be incorporated into Best Price calculations. As CMS moves closer to finalizing this rule, Adheris urges the agency to be mindful of how existing HHS requirements could be interpreted to impede the implementation of effective MTMP services.

Adheris thanks the CMS for this opportunity to comment. The MMA and the prescription drug benefit are a historic opportunity to improve the health of Americans. Adheris is eager to assist in the important task of assuring, through MTMPs, that consumers receive useful, quality information, comply with and adhere to the drug regimens their physicians have prescribed, and achieve the best results that a course of treatment can offer.

Respectfully submitted,

//s//
Daniel E. Rubin
President and CEO

Submitter : Mrs. Phylis Ermann **Date & Time:** 10/04/2004 07:10:34

Organization : American Kidney Fund

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The American Kidney Fund appreciates the opportunity to submit these comments in response to the proposed rule recently published by the Centers for Medicare and Medicaid Services (CMS) on the new Medicare prescription drug benefit established under the Medicare Modernization Act (MMA). The American Kidney Fund is a leading voluntary health organization, serving people with and at risk for kidney disease through direct financial assistance, comprehensive education, clinical research and community service programs.

The American Kidney Fund applauds the administration?s efforts to provide prescription drug coverage to our nation?s elderly and disabled. Among this population of vulnerable individuals, people with chronic kidney disease have very specific and vital medication needs. The American Kidney fund strongly encourages CMS to ensure that the design of all plans and their respective benefits (including any formulary and tiered-formulary structure), including those that conform to the USP Classification Model, do not discourage enrollment of people with chronic diseases and/or disabilities, specifically those with chronic kidney disease.

Given the importance of experienced physician judgment, and recognizing the uncertain, though undeniable variability of patient responses to specific medications, we urge CMS to ensure that Part D regulations provide access to numerous drugs within categories and classes and reflect current medical practice. This is crucial for maximizing positive patient outcomes for kidney patients whose medications are prescribed to:

1. slow the progression of chronic kidney disease

2. prevent complications of end stage renal disease and, thereby, minimize morbidity and hospitalizations, and
3. prevent the rejection of transplanted kidneys.

In addition, since kidney disease disproportionately affects minorities, the American Kidney Fund urges formulary guidelines assure patients have access to all available medications and therapies that have demonstrated efficacy in all populations, including African Americans and other minorities.

The American Kidney Fund considers 30 days notice of a formulary change insufficient for beneficiaries and their health care providers to plan for a change in medication. CMS should require that plan sponsors provide enrollees taking a prescription drug with at least 90 days notice of a change in formulary coverage of the medication unless exceptional circumstances apply, such as the removal of the drug from the U.S. market for safety reasons.

The American Kidney Fund also urges CMS to require that marketing materials, notices relating to formulary changes and all other communications to plan enrollees regarding plan benefits and formularies be written in accordance with the principles of clear health communications so that patients and their families have the ability to obtain, process and understand available health information.

The American Kidney Fund encourages CMS to implement a Part D benefit that protects the needs of individuals at all stages of chronic kidney disease and ensures timely access to appropriate medications.

CMS-4068-P-1086-Attach-1.doc

Submitter : Dr. Sean Gehrke **Date & Time:** 10/04/2004 07:10:12

Organization : University of Wisconsin

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Center for Medicare and Medicaid Services
Dept. Health and Family Services
Att: CMS-4068-P
Baltimore, MD 21244-8014

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As a clinical pharmacist and pharmacy manager, I am deeply concerned with the rules as they are currently proposed and how this will affect not only my practice but also the status of my business.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns being expressed by pharmacists around the nation are being considered. All pharmacists want this program to work.

In order for this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all hospital pharmacy providers that perform MTM services.

? CMS rules must allow for pharmacies to be included not precluded. Plan sponsors should be required to establish CMS specified MTM services.

CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

I perform several clinical services including checking and monitoring blood pressures, performing diabetes and asthma screenings and management, comprehensive medication management, cholesterol screenings, vaccinations, and other services at my particular pharmacy in attempt to improve the health and quality of life at my pharmacy. I truly believe and have received feedback from my patients indicating the benefit of my services. I believe that not only am I saving them money on medications but also by preventing worsening of their health and preventing the need for advanced health care, ER visits and hospitalizations.

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.

Sincerely

Sean D. Gehrke, Pharm.D.
Clinical Pharmacy
University of Wisconsin Hospital and Clinics

CMS-4068-P-1088

Submitter : Mr. Randall Rutta **Date & Time:** 10/04/2004 07:10:09

Organization : Easter Seals

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-4068-P-1088-Attach-1.doc

Creating solutions, changing lives.

Helping people with disabilities gain greater independence.

Easter Seals

Office of Public Affairs
700 13th Street
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Washington, DC 20005
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202.737.7914 fax
www.easter-seals.org

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; Medicare Program; Medicare Prescription Drug Benefit: 69 Fed. Reg. 46632 (August 3, 2004)

Dear Dr. McClellan:

Easter Seals submits the following comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. Easter Seals is a national nonprofit voluntary organization dedicated to promoting independence for children and adults with disabilities. Easter Seals appreciates the careful consideration that CMS has given the implementation of this part of the Medicare Modernization Act that relates to prescription drug coverage and access. Easter Seals is concerned that, as proposed, the 13 million Medicare beneficiaries with disabilities and chronic conditions are at risk of not receiving the medications that they need to achieve function, health, and a desired quality of life.

Specifically, Easter Seals is concerned that the proposed rule does not provide sufficient protections to insure that beneficiaries will have: adequate information and assistance in navigating the enrollment and plan selection process; access to an affordable benefit that provides the drugs they need; and, access to an exceptions and appeals system that permits them to easily resolve unfavorable plan decisions in a timely manner.

Easter Seals is dedicated to promoting health and independence for the nation's 54 million Americans with disabilities and their families. Each year, Easter Seals serves more than one million individuals nationwide through a national affiliate network with more than 500 sites of service. Home and community services offered by Easter Seals range from early intervention and therapy services for school-aged children, inclusive child care, to medical rehabilitation, job training and employment, housing, transportation and recreation, to adult and senior day care. Thousands of Medicare beneficiaries receive services from Easter Seals on a daily basis, and many more turn to Easter Seals for information and advice on Medicare benefits and related issues.

Easter Seals worked closely with dozens of national health, disability, chronic condition, and other organizations to interpret and develop comments on the proposed rule. Consequently, Easter Seals' views are reflected in comments submitted by the Consortium for Citizens with Disabilities, National Health Council, Medicare Consumers Working Group, and Access to Benefits Coalition-Rx. Easter Seals endorses these comments and asks that you give them careful consideration as you and your colleagues at CMS move to prepare and implement final Part D rules.

The following comments highlight areas of particular concern for Easter Seals relative to the proposed rule. We believe that significant revisions in the proposed rules are needed to ensure that people with disabilities have access to a quality prescription drug benefit. We urge stronger protections against any erosion or interruption of essential benefits currently available to dual-eligibles and other pharmacologically vulnerable populations. We recommend that CMS:

- Assure that the full range of existing and emerging prescription drugs used in clinical practice, including for off-label purposes, for treating people with disabilities and chronic diseases are available to all Medicare beneficiaries.

- Delay the implementation of the Part D program for dual-eligibles to permit extra care and clarity in designing and implementing guidelines that support appropriate and effective education, enrollment, transition, and participation in the new program

- Recognize beneficiaries with three or more disabilities or chronic diseases as a vulnerable population under Part D, potentially including dual-eligibles, persons with life-threatening illnesses, persons who are institutionalized, and persons with conditions that are pharmacologically complex conditions to manage. Additional protections and restrictions on plan sponsors should be incorporated to protect this vulnerable population, including a requirement for access to non-formulary prescriptions

- Delete provisions that allow for disenrollment for "disruptive and threatening" behaviors

- Expand screening of and outreach to Medicare beneficiaries with disabilities and chronic diseases, including through independent livening centers and other resources that are known, trusted, and accessible to individuals with disabilities and their families

- Maintain strong non-discrimination requirements for formulary design, implementation and revision, and for all Medicare Part D benefits interactions

- Increase beneficiary, family member, and advocate participation in the implementation of the prescription drug benefit

- Encourage clear and effective communication with beneficiaries, their families, and their physicians and other practitioners about the new and ongoing prescription drug benefit

- Require that communications, services, and processes be fully accessible to persons with disabilities and chronic diseases, taking into account mobility, sensory, cognitive, and other impairments

- Assure comparable access to Medicare Part D information and processes that are web-based for persons with disabilities who, as a group, have less access to the Internet than the general population

- Impose reasonable limits on cost containment tools and invest cost-savings achieved by prescription drug plans and accrued to CMS in improving beneficiary access to prescription drugs and quality of overall care

- Strengthen and improve the exceptions and appeals processes

- Require plans to dispense a temporary supply of drugs in emergencies

- Encourage accountability and oversight of plan sponsors as well as CMS

- Encourage plan flexibility to incorporate new prescriptions drugs and biologics

- Ensure independence, expertise, and transparency for pharmacy and therapeutic (P&T) committee members and associated processes, and assure that the patient perspective is represented in P&T deliberations and decisions either directly or through other means of input

Easter Seals strongly encourages CMS to implement a Part D benefit that truly serves and protects the needs of individual with disabilities and/or chronic diseases and assures timely access to appropriate medications. Easter Seals is available to collaborate with CMS in implementing the recommendations expressed in these comments and those submitted on our behalf by the Consortium for Citizens with Disabilities, National Health Council, Medicare Consumers Working Group, and the Access to Benefits Coalition-Rx. We are available to further refine these rules and to develop additional rules to ensure beneficiary access to a meaningful and effective prescription drug benefit. Thank you for your efforts in this regard.

Sincerely,

Randall L. Rutta
Senior Vice president, Government Relations

CMS-4068-P-1089

Submitter : Dr. Don Hawley **Date & Time:** 10/04/2004 07:10:14

Organization : Utah Dept. of Health, DHCF

Category : State Government

Issue Areas/Comments

Issues 11-20

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

1. It is not clear how the flexibility in establishing copayments effects dual eligibles. The PDPs should be locked into a set copayment schedule and not allowed any copayment flexibility for dual eligibles. Federal Register pg 46634 and 423.82

SPECIAL RULES FOR STATES

1. The state, by statute, must make the asset determination for those who apply to Medicaid and who qualify for Part D and Part D subsidy. More definition is needed as to how this process will occur. Without significant details, states will have problems gearing up with staff to facilitate the asset determination process and reporting it to SSA. Reference 423.780

2. Since the states are taking on activities to support the Medicare program and the responsibility is given to the Secretary in the statute, administrative FFP should be 100%. FR 46639\

3. The State would like CMS to work with the State Issues Work Group to develop additional information to more accurately factor in the value of rebates, supplemental rebates and other cost
containment efforts by states in the 2003 base year.

Submitter : Dr. Seth Tucker **Date & Time:** 10/04/2004 07:10:23

Organization : Anderson and Haile Drug Company/ Blount Memorial H

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thanks for the opportunity to comment on this legislation. Having the opportunity to work in a small rural community, I see the need for the local pharmacy on a daily basis. The elderly patients I care for would be placed at a tremendous disadvantage if they were unable to visit their local pharmacist. At the pharmacy they are able to get their medications and more specifically their drug information/education from a person they know and trust. The pharmacist is almost always the first level of care that a patient seeks. Countless referrals to the next level of care have been contributed by a knowledgeable pharmacist. Our patients appreciate the service that is provided to them by the local pharmacist, and it is imperative that this be allowed to continue. The patient care that is provided by their local pharmacist cannot be overlooked. The face to face counselling that the patient gets from the pharmacist is necessary for our patients. It is with these patients in mind that I ask you to revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirement on a LOCAL level, not on the plans overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that ALL benificiaries have convenient access to local pharmacies and pharmacists. Also I feel that it is necessary to comment on the proposed ability to establish preferred and non preferred pharmacies. This sets up the ability to coerce patients to use a specific 'preferred' pharmacy over a 'non-preferred' pharmacy through the enticement of lower copays which goes totally against what the Congress wanted when establishing this program. Therefore, I implore you to only count preferred pharmacies when evaluating whether a plan has met the pharmacy access standard. Allowing the plans to count 'non-preferred' pharmacies conflicts with the Congress'
intent to provide patients fair access to local pharmacies. I feel that CMS should requre plans to offer a standard contract to all pharmacies. Thank You again for your consideration.
Sincerely,
Seth Tucker,Pharm.D.
739 Majestic Mountain Blvd.
Walland, Tannessee 37886
865-977-8169
865-603-3479

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

Thank you for the opportunity to comment on this proposed legislation. As a practicing pharmacist who works in the hospital and community pharmacy setting I feel the need to spreak strongly on the value of a pharmacist and medication therapy management(MTM) as a system. With the sheer volume of patient care that has been placed on the health care system, I see daily where there is a huge vaccum in patient care. Our physicians, nurses, and physican assistants are overwhelmed with the volume of patient visits both in the community and in our hospitals. On a daily basis I get the opportunity to fill the hole in our system. As pharmacists, we have been trained to be the drug therapy expert. A pharmacists' training on drug therapy far surpasses all other healthcare professionals. I have been very fortunate to work with cutting edge physicians, nurses, and physician assistants where collaborative care is the standard and I getto see the benificiary.
OUR PATIENTS. This is where CMS has the opporunity to help our patients with the medication therapy management(MTM) services. I appreciate that CMS recognizes that different patients will need different levels of care through the MTM services. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Again, I would like to emphasize that pharmacists are the ideal health care professionals to provide MTM services and determine which services each benificiary needs. Everyday I have the opportunity to provide medication therapy management services at the hospital and community pharmacy level. The true benefit is to the patient. It has been proven time and again that safety is enhanced, money is saved, and patient oucomes are improved when a pharmacist is involved in the patients care.
When our patients know:
1. what their medications are for.
2. how to use them.
3. what side-effects to look for.
4. what follow-up monitoring is needed for each medicine.
5. how their medicines can modify their disease states.

6. that their medications are monitored for drug-drug interactions.
When pharmacists provide these type of benefits, this is truly when the healthcare system will see an improvement in our nations health. When our system provides these services to our patients, they will be the winners.
These are only a few examples of what pharmacists can and do provide on a daily basis. I am confident that all of these services can be best provided using a pharmacist, because I see the patients and their outcomes everyday. Plans should be encouraged to use my services- because I truly feel that I help my patients get the most benefits from their medications. In conclusion, I urge CMS to revise the regulations to help implement the above suggestions. Thanks again for considering my views.
Sincerely,
Seth Tucker
739 Majestic Mountain Blvd.
Walland, Tannessee 37886
865-977-8169
865-603-3479

CMS-4068-P-1091

Submitter : Mary Beilby **Date & Time:** 10/04/2004 07:10:45

Organization : Access to Independence of Cortland County

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment from disability community

CMS-4068-P-1091-Attach-1.doc

CMS-4068-P-1091-Attach-2.doc

Access to Independence of Cortland Co. Inc.
37 Church St. Cortland, NY 13045
Oct. 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:

Access to Independence welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. Access to Independence 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:

DELAY 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. 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 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 sheer implausibility 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 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.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES ARE CRITICAL TO AN

EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

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.

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 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:

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

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. 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 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.

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 a truly independent review by an administrative law judge (ALJ) and 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; 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:

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.

Mary Beilby
Systems Advocate
Access to Independence of Cortland County

Access to Independence of Cortland Co. Inc.
37 Church St. Cortland, NY 13045
Oct. 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:

Access to Independence welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. Access to Independence 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:

DELAY 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. 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 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 sheer implausibility 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 recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We
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Thank you for your consideration of our views.

Mary Beilby
Systems Advocate
Access to Independence of Cortland County

CMS-4068-P-1092

Submitter : Ms. Grace Sierchio **Date & Time:** 10/04/2004 07:10:39

Organization : Vital Care Inc.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

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.

We represent the voice of approximately 135 community based home infusion therapy pharmacies located in non-urban and rural areas throughout the United States.

Our attachment supports the comments being submitted by the National Home Infusion Association.

CMS-4068-P-1092-Attach-1.doc

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 Inc. is a system of individually owned community pharmacies providing home infusion services to patients in predominantly non-urban areas. We have approximately 135 pharmacies in our system, predominantly in the Southern U.S. and southern Mid-West. We have been serving this remote and medically complex patient population since 1985.

Vital 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,

Grace P. Sierchio
Director of Quality Management and Regulatory Compliance
Vital Care Inc.

CMS-4068-P-1093

Submitter : Ms. Mary Ewing **Date & Time:** 10/04/2004 07:10:39

Organization : Ms. Mary Ewing

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability cmmunity.

CMS-4068-P-1093-Attach-2.doc

CMS-4068-P-1093-Attach-1.doc

Re: Part D Program for “Dual Eligibles”

There are numerous concerns regarding the proposed regulations. Some recommendations from the disability community include:

- It is urgent that you delay the implementation of the Part D program for dual eligibles
- Outreach to Medicare beneficiaries with disabilities should be expanded
- Special populations should be designated to receive affordable access to an alternative drug formulary
- Limits should be instated for cost containment tools
- Appeals processes are inadequate and need to be strengthened
- A temporary supply of drugs should be made available in emergencies

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CMS-4068-P-1094

Submitter : Ms. N. Lois Adams **Date & Time:** 10/04/2004 07:10:45

Organization : Freedom Pharmacy and Cystic Fibrosis Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Dear Sir or Madam: I am a licensed consultant pharmacist and have received the 2003 Business Woman of the Year Award from the Republican Congressional Committee. I have likewise received the 2004 Award and the Ronald Reagan 2004 Medal for Entrepreneurship for 2004. I have been inducted into the University of Central Florida Business Hall of Fame, received the 2004 RQ Richards Public Relations Award for Florida and the EON Labs award for Innovative Pharmacy Practice. I am also President/CEO/Chairman and Licensed Consultant Pharmacist for the HHCS Health Group and its related corporations- all
pharmacy related. I have started the Center for Memory Disorders- a 501 (c)(3) organization- to assist the elderly in the Central Florida area.in Orlando. I have reviewed the proposed regulations and wish to make very pointed comments- stemming from a background in pharmacy and business for the past 42 years. Thank you N. Lois Adams, C. RPH MBA Licensed Consultant Pharmacist.

BENEFITS AND BENEFICIARY PROTECTIONS

All beneficiaries must have access to their local pharmacists- if those professionals are qualified by education, training, certification, and professionalism. 'Preferred' and 'non-preferred' status should be determined by pharmacy profesional organizations and not by PBM's who chose providers based upon those activities which only benefit the PBM bottom line. Further, 'preferred' pharmacies must not be selected upon the basis of the ownership by the PBM such as Medco Health, Curascript/Advance PCS and others who would direct beneficiaries to their own pharmacies for mail order. Co-pays should be the same for both mail order and the community pharmacist. The 90-day supply promotes waste, overstocking by the patients, overmedication, and lack of control. The PBM's have received rebates, excessive fees, and the benefits of double billing for medications which have been returned- not credited- and then re-dispensed. There is presently a case St. of Florida vs.Caremark for just those reasons. The abuses in the PBM industry are well known.Attorney Generals and members of the Dept. of Justice have been busy investigating these organization. They have been investigated, prosecuted,fined, indicted for fraud and failure to pass rebates on and collect from insurers, manufacturers, and providers. They should be placed upon probation just as violators of the Medicare Act, securities brokers, and others. The concept of 'any willing provider' must prevail instead of the U.S. government allowing a monopoly to form and control.

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

Pharmacists are the ideal health care professionals to provide medication management for the chronically ill, the elder population and conditions which are disabling in nature. CMS recognizes that different beneficiaries will require different MTM Services such as a medication treatment plan, monitoring, and evaluating therapies- to name a few. I do not believe that it should be within the purview of the plans to design the MTM services but that these should be set forth by the pharmacy professinal organizations and groups. The pharmacist is the expert in the field of medication management. Criteria such as experience, academic credentials, certifications, and experience in the area of disease management. Pharmacists should be allowed to bill for these services. Plans must be required to use quality providers- not just their 'preferred company owned providers' for which they believe will increase their profits and improve their bottom line. They should not be allowed to outsource claims processing, provider help-lines, etc. to India and other countries. Medications should be restricted to a 31-34's day's supply to halt waste, abuse of the system, double billing, and inappropriate substitution without the consent of the prescribing physician. Compounded medications should also be eligible for reimbursement at a rate which is consistent with the cost factors involved in their preparation.Our organizations have provided consulting services, medication management for the past 20 years through our Cystic Fibrosis Pharmacy and our Circle of Care Disease Management programs in ther area of cystic fibrosis, asthma, COPD, Alpha 1 anti-trypsin, Alzheimer's Disease, Parkinsons Disease and other neurological disorders, osteoporosis, HIV, Congestive heart failure, womens and mens health, wellness programs, mental health, fibromyalgia, chronic fatigue syndrome and other immune and auto-immune disorders through our various entities-Freedom Pharmacy and Wellness Centers, Cystic Fibrosis Pharmacy, Diabetes Center, Freedom Specialty Pharmacy, and our new Center for Memory Disorders. Pharmacies must demonstrate quality and excellent outcomes.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

Access should be provided to all beneficiaries, " any wiling provider" should be able to participate if they meet criteria for quality and excellent

outcomes, possess credentials, have a record for excellence in healthcare, and follow the criteria for medication management created by the pharmacy organizations. The Plan must define "preferred" and "non-preferred" providers and justify their selection exclusive of profit motive for the plan. Plans must be prohibited from outsourcing processing of claims, etc. to other countries as this has only served to increase the salaries of the CEO and upper management. It should be determined if this practice is a violation of HIPAA. PBM's who have been prosecuted, indicted, fined, etc. must be placed upon probation and should not be the PBM of choice for insurers.

CMS-4068-P-1094-Attach-1.txt

CMS-4068-P-1094-Attach-1.txt

CMS-4068-P-1094-Attach-1.txt

CMS-4068-P-1094-Attach-1.txt

Oct 1, 2004

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

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I have made my comments on your Comment Page with the hopes that you will consider these comments for consideration as CMS develops the final regulation I am enumerated the Medication Management Services that I currently provide through our various organizations We are a quality provider often lowering prices from $350.00 to $54.00 and decreasing the number of prescriptions for a single patient form 25 to 4. This is not only in the best interest of the patient but has included the physician in the entire circle. Thank you for considering my comments and views on this most important piece of legislation. I would be most happy to assist or answer any questions that you may have.

Very truly yours,

HHCS HEALTH GROUP
N. Lois Adams, C. R Ph. MBA
President/CEO
Licensed Consultant Pharmacist.
(407) 898-4427
HHCS Health Group
Corporate Office
633 E. Colonial Drive
Orlando, FL 32803
(407) 898-4427 (800) 741-4427
Fax (407) 897-2108

CMS-4068-P-1095

Submitter : Mr. John Arlotta **Date & Time:** 10/04/2004 07:10:49

Organization : NeighborCare, Inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

NeighborCare is filing extensive and specific comments related to the rulemaking, which are included in the attached letter.

CMS-4068-P-1095-Attach-1.doc

CMS-4068-P-1095-Attach-2.doc

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-g
200 Independence Avenue, S.W.
Washington, D.C. 20201

File Code: CMS-4068-P

Re: Medicare Program: Medicare Prescription Drug Benefit, Notice of Proposed Rulemaking, 69 Fed. Reg. 46632 (August 3, 2004).

To Whom It May Concern:

NeighborCare is pleased to submit comments to the Centers for Medicare and Medicaid Services regarding the proposed rules implementing the Medicare prescription drug benefit under Part D. Based in Baltimore, Maryland, NeighborCare is now the nation's third largest provider of institutional pharmacy services to long term care facilities, assisted living communities and assorted group settings. NeighborCare's history goes back almost half a century and has grown out of a series of strategic and highly successful acquisitions and mergers.

NeighborCare presently services over 265,000 beds through its 65 pharmacies in 34 states. Additionally, NeighborCare At Home provides and delivers home medical and respiratory equipment, home infusion, customized seating/wheelchair mobility and more to more than 1,000,000 covered lives in home settings in fourteen states.

I. Introduction

Prescription drug therapy today is a critical tool in the treatment and management of patients with both acute and chronic illnesses. For frail elderly seniors confined to nursing facilities, and for many others with chronic illness, pharmaceutical treatment is the mainstay of therapy.

Typically, nursing home residents are older, poorer and sicker than community-dwelling seniors. On average, nursing facility residents take an average of over eight drugs, with over 40 percent receiving nine or more medications daily. Attaining optimal pharmaceutical therapy for this population is complicated by several factors. First, the

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prevalence of multiple chronic diseases and co-morbidities is much higher in the elderly. Second, the elderly react differently to drugs due to physiological changes associated with aging: metabolism rates change, organ function declines and sensitivity to certain drugs can be altered. Finally, there is a wider variation in pharmacological action among the elderly when compared with younger adults.[1] In sum, nursing home residents require the highest quality and highest intensity pharmaceutical care due to their health status, frailty and increased risk of adverse drug interactions.

Unlike retail pharmacies, long term care pharmacies (LTCPS), such as NeighborCare, have developed expertise in addressing the highly specialized needs of this extremely vulnerable population. We are not only experts in the pharmacological care of the frail elderly, as an industry, we are organized to provide nursing and other long term care facilities with the services they need to attain and maintain compliance with federal requirements for participation in Medicare and Medicaid and state requirements for licensure.

Critical to compliance with federal quality standards is adherence to the principal of "one nursing home, one long term care pharmacy." Like hospitals, nursing facilities establish a relationship and contract with a single pharmacy in order to control quality, ensure delivery and promote consistency and the highest standards of practice. As the contracted pharmacy, we provide specialized geriatric formularies and alternative dosage forms that ensure that frail elders have access to a wide range of drugs in the dosage forms that are most suited to their needs and tolerances. We conduct both prospective and retrospective reviews of the resident's pharmaceutical profile to ensure that the right medications have been prescribed and to identify and eliminate adverse drug interactions. We operate 24 hours a day, seven days a week, to ensure that prescriptions are filled and delivered as needed, and we provide the nursing home with specialized packaging such as unit dose and blister packs. We also stock and organize medication carts and emergency drug kits to ensure availability and reduce medication administration error rates. Without these services, very simply, we risk endangering the health and safety of tens of thousands of frail elderly seniors. We also risk spending more on health care because nursing facilities will be forced to send frail and chronically ill residents to hospitals obtain the drug therapy that they need.

Accordingly, while CMS is to be commended for its yeoman's efforts to develop the rules to implement Part D, NeighborCare is concerned that the proposed rules do not go far enough to ensure that frail elderly seniors have access to long term care pharmacy when they are admitted to a long term care facility. We are also deeply concerned that nursing facilities and other long term care facilities will not be able to preserve the one long term care facility, one long term care pharmacy relationship that has served as the industry's keystone of quality control and quality assurance.

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[1] Nash, DB, Koenig, J., Chatterton, M., "Why the Elderly Need Individualized Pharmaceutical Care," Thomas Jefferson University, April 2000.

Given these concerns, we felt compelled to provide you comments that elaborate and expand upon the comments submitted by the Long Term Care Pharmacy Alliance (LTCPA) – an organization in which NeighborCare participates. We have concluded that, given the structure of the Part D benefit, the only way to ensure that all Medicare beneficiaries have access to appropriate, high quality prescription drug therapy in long term care facilities and to preserve the one pharmacy, one facility relationship is for CMS to amend the rule to incorporate the following 10 essential elements. Specifically, CMS must:

(1) Establish network access standards that require plans to contract with long term care pharmacies to ensure that plans have the capacity to meet the specialized needs of all Medicare enrollees in long term care facilities and to ensure that long term care facilities meet federal and state quality, licensure and certification standards.

(2) Provide for standardize long term care pharmacy contracts that recognize long term care pharmacy's essential role in the delivery of needed services to long term care facility residents.

(3) Require PDP sponsors and MA-PD organizations to contract with any willing long term care pharmacy that meets the plans' standardized terms and conditions.

(4) Ensure that Medicare enrollees are guaranteed a special enrollment period upon admission to a long term care facility to enable them to receive services from the facility's contracted long term care pharmacy and to minimize out-of-network utilization.

(5) Safeguard Medicare enrollees who are enrolling in or changing drug plans from being subjected to inappropriate drug changes and substitutions by prohibiting plans from initiating drug changes or substitutions without clinical review and certification and by requiring plans to monitor and report all adverse drug events associated with such changes.

(6) Ensure that Medicare enrollees in long term are facilities have access to needed drugs by requiring plans to cover all medically necessary drugs and utilize specialized geriatric formularies; strengthening Pharmacy and Therapeutics Committee requirements; ensuring coverage of "excluded" Part D drugs, and ensuring that the appeal and exceptions processes are meaningful.

(7) Strengthen requirements for plan quality assurance and medication therapy management programs so that plans are held accountable for health outcomes, as well as costs.

(8) Close the coverage gap for dual eligibles by ensuring that all dual eligibles are enrolled in prescription drug plans by January 1, 2006, when Medicaid coverage ends, or by seeking Congressional approval of an extension of time for dual eligible enrollment.

(9) Expand the definition of long term care facility to include assisted living and other facilities where frail, elderly Medicare beneficiaries rely upon cost-effective, long term care pharmacy services to obtain pharmaceutical care that keeps them out of more costly care settings.

(10). Ensure that long term care pharmacies are paid for their specialized services by clarifying the definition of dispensing fee, ensuring prompt payment of claims and making sure that when dual eligible beneficiaries must go out-of-network to obtain services, that CMS pays the difference between the plan allowance and the usual and customary charge.

Our detailed comments below elaborate on these 10 key provisions in the rulemaking. We also provide specific recommendations and draft language, where appropriate.

II. **Specific comments**

A. Subpart B – Eligibility and Enrollment

1. Special enrollment periods (Section 423.36(c)) – The proposed rule provides for special enrollment periods under identified circumstances for specific populations (e.g., full benefit dual eligibles). Enrollees are also entitled to a special enrollment period if "[t]he individual demonstrates to CMS, in accordance with guidelines issues by CMS that . . . (ii) The individual meets other exceptional circumstances as CMS may provide."

Recommendation: CMS must explicitly recognize that admission to a long term care facility, or a change in placement from one long term care facility to another, constitutes an exceptional circumstance that should *automatically* trigger eligibility for a special enrollment period. Specifically, we recommend that CMS renumber subsection (8) as subsection (9) and add new subsection (8) as follows:

(8) the individual has been admitted to a long term care facility.

Rationale: To ensure that Medicare enrollees receive appropriate pharmaceutical services and that long term care facilities are able to maintain quality in compliance with federal and state standards, a Medicare enrollee who is admitted to a long term care facility must be assured access to the specialized services of the long term care pharmacy that is the contracted pharmacy for that long term care facility. Accordingly, enrollees must be given the *choice* of enrolling in a PDP plan that includes the LTCP that is under contract to provide services to residents of that facility. Further, under the Medicare Discount Drug Card Program, we note that CMS provided for a Special Election Period whenever the beneficiary changed his or her residence to or from a long-term care facility. See 42 C.F.R. § 408.811(b) (2). In absence of a special enrollment period:

- If the enrollee's plan does not include the facility's LTCP, and the enrollee desires to receive pharmacy services from the facility's

LTCP, the enrollee will be forced to receive those services as out-of-network services.

- Enrollees who obtain drugs from an out-of-network LTCP will bear significant out-of- pocket costs, including the differential between the plan's allowance and the usual and customary charges of the out-of-network pharmacy, while continuing to pay premiums for plan coverage.
- Dual eligibles and other low-income beneficiaries simply cannot afford to pay the differential between in and out-of-network drugs without government subsidy.
- For private pay enrollees, paying out-of-pocket for out-of-network prescription drug coverage will accelerate the rate at which nursing home residents spend down their income and become eligible for Medicaid, as well as catastrophic coverage under Part D.
- If enrollees cannot afford to pay out-of-pocket to obtain drugs out-of-network, the nursing facility could face a proliferation of pharmacies operating within a single facility – a situation that will compromise patient safety and quality of care and will drive up costs.

2. Enrollment of Dual Eligibles (Section 423.34(d)) – The proposed rule provides that full benefit dual eligible individuals who fail to enroll in a PDP or MA-PD plan during the initial enrollment period will be automatically enrolled into a PDP offering basic prescription drug coverage in the PDP region in which the individual resides, or in the case of an individual enrolled in a MA plan, a MA-PD plan offered by the same MA organization. In both situations, by statute, the plan must have a monthly premium that does not exceed the premium subsidy. Under the proposed rule, automatic enrollment of dual eligibles will not occur until after May 15, 2006, the end of the initial enrollment period. However, pursuant to 42 U.C.S. § 1935(d) (1), Medicaid prescription drug coverage for dual eligibles ends on January 1, 2006. Thus, dual eligibles face up to 4.5 months with no coverage for prescription drugs.

Recommendation 1: CMS must ensure that dual eligibles experience no break in prescription drug coverage between the time that Medicaid prescription drug coverage ends and pending auto enrollment in a Part D plan. Specifically, we urge CMS to seek Congressional approval to extend Medicaid coverage and delay enrollment of dual eligibles until January 1, 2007. If Medicaid coverage can not be extended and enrollment of dual eligibles cannot be delayed, CMS must make sure that all dual eligibles are enrolled in appropriate prescription drug plans prior to January 1, 2006.

Rationale: Compared to the average Medicare beneficiary, dual eligibles are sicker and have higher drug costs. According to CMS, more than half of dual eligibles are in poor or fair health, while nearly one-quarter live in nursing homes. Twenty-four percent have diabetes, 20 percent have pulmonary disease, 15 percent have had a stroke and 12 percent have Alzheimer's disease. Over a third are under age 65 and many in this cohort have serious physical and mental disabilities. Sixty-eight percent of the 20 percent

of Medicare beneficiaries with HIV/AIDS are dual eligibles. Without prescription drug coverage, dual eligibles will get sicker and ultimately, will drive up total health care spending. While recognizing that the "gap" in coverage is the result of the statute, it is nevertheless imperative that CMS identify a way to ensure that dual eligibles do not experience any break in prescription drug coverage.

3. Transition of Dual Eligible to New Drug Plans – Dual eligibles, who currently receive prescription drugs through state Medicaid programs, generally have access to all medically necessary drugs. The new Part D benefit gives plans broad discretion to use formularies and other cost and utilization control mechanisms that are more restrictive than the Medicaid program. In addition, pursuant to Section 1935(d) (2), many drugs, including barbiturates and benzodiazepines, which have been covered under Medicaid, are not covered by the new Part D benefit. As a result, dual eligibles who are transitioned to Part D are likely to find that the drugs that they take are not covered by the new Part D plan.

Recommendation: To ensure continuity and reduce adverse medication events and drug errors, CMS must ensure that if and when a dual eligible beneficiary is automatically enrolled in a PDP or MA-PD plan, the plan is required to notify the beneficiary and provide him or her with information about coverage and how to access benefits. For long term care facility residents, plans should be required to notify the facility in which the resident resides. Specifically, CMS should:

> Amend Section 423.128(a)(1) as follows: *"to each enrollee, including each full benefit dual eligible enrollee enrolled in the plan under Section 423.34(d), of a prescription drug plan offered by the PDP sponsor or the MA-PD plan offered by the MA organization under this part."*
>
> Amend Section 423.34(d) by adding new subsection (2), (and renumbering the remaining subsections), as follows: *"Upon auto-enrollment in a plan, the plan immediately shall notify the full-benefit dual eligible individual, or in the case of a full benefit dual eligible individual residing in a long term care facility, the long term care facility in which the individual resides, of the following:*
>
> > *(i) the name of the plan in which the individual has been enrolled,*
> > *(ii) the effective date of enrollment, and*
> > *(iii) the information in section 423.128(b)."*

Rationale- At whatever point a dual eligible is auto enrolled into a plan, CMS must require plans to notify enrollees of their auto assignment and how to access benefits. Otherwise, we know from the early experience with auto assignment in Medicaid manage care plans, plans may profit by accepting payments without providing any benefits because the beneficiary is simply unaware of his assignment to a prescription drug plan and has never been informed about how to access benefits.

4. Assuring Appropriate Clinical and Administrative Transitions – Neither the statute nor the regulations address a plan's obligations to ensure that beneficiaries enrolling in new plans or changing plans are appropriately transitioned. Experts in drug benefits management and pharmacy issues recommend that transition planning and implementation, including data transfers, should start at least six months before the transition date, though eight to nine months is preferable.[2]

Recommendation: To ensure continuity of care and to minimize adverse drug events that occur during transitions, CMS must require plans, as part of their medication therapy management programs, or otherwise, to:

> (1) maintain the beneficiary's prior drug regimen, and not initiate drug changes or substitutions prior to a clinical review and certification of the clinical appropriateness of those changes,
> (2) monitor any changes in the drug regimen of a dual eligible and report all adverse drug events to CMS, and
> (3) provide notice of the proposed change to the beneficiary and the prescriber to inform the beneficiary and the subscriber of the opportunity to file a grievance, appeal or request for exception.

Specifically, to incorporate the above changes into the rule, we recommend the following:

> Amend Section 423.153(d) as follows: *"The Medication Therapy Management Program:*
>
> *(_) shall establish processes for ensuring that PDP and MA-PD plans cover all drugs, including non- formulary drugs, of full benefit dual eligibles who have been auto assigned to the plan and may not discontinue, substitute or change drugs unless the plan has*
>
> > *(i) conducted a clinical review and has certified the clinical appropriateness of the changes, and*
> >
> > *(ii) notified the beneficiary and prescriber of the proposed changes and the opportunity to file a grievance, appeal or request an exception.*
>
> *(_) shall monitor the responses of enrollees to all drug changes and track and report to CMS data concerning all adverse drug events associated with such changes."*

Rationale: Under Section 1860D-4(c), plans have an affirmative obligation to establish quality assurance and medication therapy management programs that are designed, in part, to reduce the risk of adverse events, including adverse drug

[2] Medpac, Report to Congress (2004, June). *New approaches in Medicare.*

interactions. The obligation to operate a plan under principles that reduce the risk of adverse events dictates that Part D enrollees should not be subjected to arbitrary medication changes without clinical review. In the absence of such a requirement, Medicare beneficiaries, and especially nursing facility residents, and other duals who have been auto assigned into plans that offer only basic coverage, could face myriad medication changes dictated by limitations in a plan's coverage or formulary design. Given the clinical profile of dual eligibles and particularly the drug sensitivities of the frail elderly in long term care facilities, such changes require a high level of monitoring and clinical oversight. Depending on the drugs and the enrollee, gradual dose reductions may be needed to wean the beneficiary off the old drug, while new drugs may need to be titrated and added slowly. Simply stated, changing drugs is potentially dangerous to enrollees and creates a high level of opportunity for drug misadventures and adverse drug events that could jeopardize a dual eligible's health.

Recommendation 2: CMS must clarify that when an individual is enrolled in a new plan or changes plans, the old plan remains financially responsible for payment of claims until the effective date of enrollment in the new plan.

Rationale: When an individual changes plans (for example, during a special enrollment period), often it may take several days for enrollment forms to be inputted into computer systems. If claims are filed in this time period, the new plan may appear to be the payor, when in fact it is not. To minimize claims disputes, CMS should make clear that the old plan remains financially responsible for payment of claims until the beneficiary's effective date of enrollment in the new plan.

5. Information to enrollees (Section 423.128) – The proposed rule provides that upon request, plans must provide information to Part D eligible individuals regarding coverage, benefits, rights and other issues.

Recommendation 1: CMS should specify that plans must include information about access to long term care pharmacy services. Specifically, we recommend the following:

Amend Section 423.128(c) (1) (iv) to add new subsection (G) as follows:

The extent to which an enrollee may obtain benefits and services from a specialty pharmacy including a long term care pharmacy.

Recommendation 2: Under Section 423.48, plans are required to provide CMS with information to enable CMS to provide current and potential eligible Part D beneficiaries with information to help them make informed choices. We strongly recommend that CMS require every plan to provide information that explains the availability and accessibility of Part D coverage should the enrollee be admitted to a long term care facility.

Rationale: Informed consumer choice is key to ensuring that PDPs offer benefits that are responsive to consumer demand. Seniors will want to know how drug costs will be covered (or will not be covered) should they require long term care services and should be informed, up front, about which plans offer access to the specialized consulting services, packaging and delivery options that are a necessity of LTCP.

B. Subpart C - Benefits and Beneficiary Protections

1. Long-term care facility definition (Section 423.100) – As proposed, CMS has defined a long-term care facility only as a skilled nursing facility (as defined under § 1819(a) of the Act), or a nursing facility (as defined in § 1919(a) of the Act). However, CMS is interested in whether other types of facilities contract exclusively with long term care pharmacies and would consider modifying the definition.

Recommendation: We strongly recommend that CMS expand the definition of long term care facility to include assisted living facilities and other facilities and programs that are certified either by the federal government or a state to provide services to individuals who require long term care. Specifically, we recommend:

Amend the definition of "long term care facility" as follows:

A long term care facility is any facility or program that has been certified by either a state or federal agency to provide long term care services to individuals in need of such services. A long term care facility includes, but is not limited to: skilled nursing facilities (as defined under 1819(a) of the Act), nursing facilities (as defined in 1919(a) of the Act), programs that provide services under Section 1915(c) or 1115 waivers, PACE programs, assisted living or managed long term care programs certified and eligible for funding under Title 19, and other assisted living, adult care or adult day health programs certified under state law to provide long term care services.

Rationale: Nursing homes are no longer the only environment in which frail elders and others with long term care needs receive services. Indeed, in recent years, there has been an overall decline in nursing home utilization and an expansion of community-based, alternatives. The growth of community-based alternatives to nursing facility care has been fueled, in part, by consumer demand, demographic changes and the need to identify more cost-effective approaches to providing long term care to an expanding population of seniors. Additionally, the Supreme Courts landmark decision in *Olmstead v. L.C.* and President Bush's New Freedom Initiative have spawned increases in both public and private sector, community-based long term care programs.

Today, NeighborCare, and other long term care pharmacies, provide long term care pharmacy services to a growing market of assisted living facilities, adult day care programs and other service sites where the frail elderly receive care. In fact, of the 265,000 people who are served by NeighborCare's institutional pharmacy services, one-third reside in assisted living and other non-nursing home settings. In many cases, we are

the contracted pharmacy because state regulation makes facility and program operators responsible for quality care and appropriate management and control of drug dispensing, etc. Increasingly, however, there is growing recognition that long term care pharmacy provides important quality controls and packaging that can help the frail elderly remain compliant with medications, avoid adverse drug reactions and reduce medication misadventures, thus ultimately saving money by supporting the frail elderly and providing them with optimal drug therapy in less costly care settings. Additionally, as CMS is certainly aware, as the population has aged, the level of care needs among residents in assisted living facilities has increased. Today's assisted living residents resemble the SNF or ICF residents of ten years ago. Many have chronic diseases, including Alzheimer's disease, and take multiple medications. Many assisted living providers have, in fact, developed a medical model of care for their residents, and specialized pharmaceutical care is a keystone in their goal to provide quality care.

At NeighborCare, we believe that the structure of the Medicare Part D benefit creates a tremendous opportunity to allow the market to drive innovation and cost savings. As the demand for cost effective, community-based long term care increases, plans should be free to negotiate with long term care pharmacies to provide the long term care pharmacy services in alternative care settings. Otherwise, if we limit long term care pharmacy only to skilled nursing facility and nursing facility settings, we create perverse incentives that may ultimately increase nursing home utilization and drive up health care costs by forcing people into institutional settings in order to obtain clinically appropriate medication management services. Accordingly, in order to recognize both the current and future role of long term care pharmacy in meeting the needs of the frail elderly across care settings, CMS must expand its definition of long term care facility.

2. Dispensing fee definition (Section 423.100) – Pursuant to Section 423.104(h), PDP and MA –PDPs are required to provide enrollees with access to negotiated prices for covered Part D drugs included in its plan's formulary prices. In the preamble, CMS states that negotiated prices must take into account price concessions such as discounts, direct or indirect subsidies, rebates and direct or indirect remunerations, and would include any applicable dispensing fees. CMS is considering three different definitions of dispensing fee." Option 1 would differentiate between dispensing a covered part D drug and administering one in order to restrict the dispensing fee to include only those charges for pharmacy services related to the preparation and delivery of a covered Part D drug. Under this option, the dispensing fee could not include any charges associated with administering the drug once the drug has already been transferred to the beneficiary. Option 2 includes the activities 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. Option 3 would include the activities in Option 2 but in addition, would include activities associated with ensuring the proper and ongoing administration of the drugs, such as professional services or skilled nursing visits and ongoing monitoring by a clinical pharmacist. Option 2 and 3 are framed to be limited to cases where (a) a typical patient with the condition at issue could not receive the benefit of the medication in the absence of the associated supplies, and (b) the patient is receiving home infusion therapy. None of these definitions, however, clearly encompass

the additional costs associated with dispensing prescriptions in a long term care setting. These costs include the cost of delivery, specialized packaging and around the clock access.[3]

Recommendation: CMS should make clear that dispensing fees must include the costs associated with dispensing for both retail and long term care pharmacy, including the costs of specialized packaging, around-the clock service and delivery to the site of care.

Rationale: While we concur with CMS that Option 1 represents the best reading of the statute, since it would limit dispensing fees to a transfer of possession of the drug and would not include any fees associated with administering the drug, the preamble does not identify the components of a dispensing fee that are associated with the specialized services provided by long term care pharmacies.

3. Access to covered Part D drugs (Section 423.120) – Sec. 1860D-4(b)(1)(C)(i) mandates that the PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary). Pursuant to Sec. 1860D-4(b) (1) (C) (iii), the Secretary is also required to include adequate emergency access for enrollees.

Pursuant to Sec. 1860D-4(b)(1)(C)(iv), the Secretary may, but is not required to, include standards with respect to access for enrollees who are residing in long term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U pharmacies).

In the proposed rule, CMS has proposed access standards for retail pharmacy. Instead of requiring plans to provide emergency access, however, CMS would require that plans assure their enrollees have adequate access to drugs dispensed at out-of-network pharmacies. Similarly, while CMS recognizes that LTCPs have a special mission and that access to such pharmacies should be preserved because it would "greatly enhance Part D benefits for enrollees in long term care facilities . . . ," CMS has not promulgated standards for access to long term care pharmacy, but seeks to preserve access as an "out-of-network" benefit. CMS' reluctance to propose LTCP access standards is based upon a concern that if plans are required to include LTCP in their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer other retail pharmacies willing to a participate in their network) with a number of long term care pharmacies in order to meet the requirement.

CMS also recognizes I/T/U pharmacies have a special mission and that access should be preserved. But unlike LTCP, CMS proposes using its authority to require plans to approach I/T/U pharmacies in their plan service areas.

[3] "Institutional Pharmacy Dispensing Cost Study," BDO Seidman, LLP, April 5, 2002.

Under the proposed rule (sec. 423.124(a)), out-of-network access is assured only if the plan has determined that the enrollee could not reasonably be expected to obtain covered Part D drugs at a network pharmacy. CMS *expects*, but has not mandated, that plans provide "out-of-network" access to long term care pharmacy "when a Part D enrollee resides in a long term care facility and the contracted LTCP does not participate in his or her plan's pharmacy network," and "the enrollee cannot reasonably be expected to obtain such drugs from a network pharmacy." CMS seeks comments regarding how to balance convenient access to LTCPs with appropriate payment to long term care pharmacies under MMA. Specifically, CMS seeks comments on two approaches: (1) requiring plans to contract with LTCPs, or (2) strongly encouraging plans to negotiate and include long term care pharmacies in their plans.

Recommendation 1: NeighborCare strongly endorses requiring plans to include long term care pharmacies in their network. CMS should use its authority to establish minimum access standards for long term care pharmacy. Specifically, CMS should:

Amend Section 423.120(a) (1) as follows: *"Convenient access to network pharmacies – Except as provided in paragraph (a) (3) of this section, a prescription drug plan or MA-PD, including any fallback, plan must have a contracted <u>retail</u> pharmacy network, consisting of pharmacies other than mail order pharmacies, sufficient to ensure that for beneficiaries residing in the prescription drug plan's service area, as described in . . . ."*

Add new Section 423.120(a)(2) as follows: *"A prescription drug plan, or MA-PD plan, including any fallback plan, must have a contracted long term care pharmacy network, consisting of pharmacies other than mail order pharmacies, sufficient to ensure that beneficiaries residing in or receiving services in a long term care facility have access to pharmacy services that:*

> *(i) comply with the facility's legal obligations under federal and state law with respect to pharmaceutical services, quality control and quality assurance,*
> *(ii) ensure 24 hour, seven day a week access to covered Part D drugs,*
> *(iii) provide for emergency access to covered drugs, and*
> *(iv) meet the specialized needs of Medicare enrollees receiving long term care services."*

<u>Rationale:</u> Under the proposed rule, PDP sponsors would have to contract with retail pharmacies to ensure convenient access, but would have no obligation to contract with long term care pharmacies to ensure that the most vulnerable Medicare beneficiaries, the frail elderly, have access to the specialized pharmaceutical services that are critical to their health and safety. Instead, CMS suggests that a liberalized out-of-network standard is sufficient to ensure that residents of long term care facilities obtain the services they need. Yet, as we have noted above, long term care facility residents who must go out-of-network to obtain needed prescription drugs incur substantial out-of-pocket costs because of the differential between the plan allowance (which is based on retail pharmacy costs) and the usual and customary charges of the out-of-network, long

term care pharmacy. Under the proposed rule, Section 423.124(b) (2), CMS makes clear that it is the Part D enrollee who is responsible for this differential. However, the vast majority of long term care facility residents do not have the resources to pay this differential. Consequently, they either will be forced to go without the drugs or they will try to obtain them in-network, through retail pharmacies. Either way, access and quality control will be irreparably compromised. We believe that CMS has an obligation to ensure that the Part D drug benefit works to support and not undermine the one nursing home, one pharmacy relationship that is key to ensuring that nursing facilities are able to meet federal requirements for participation.

In addition, we question whether the Secretary has the authority to approve a plan that fails to include long term care pharmacy as an in-network benefit. Under Section 1860D-11(e)(2)(D), the Secretary may only approve a prescription drug plan 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." For the frail elderly, it is hard to imagine more of a deterrent to enrollment than a Part D plan that forces beneficiaries to pay out-of-pocket for covered Part D drugs because the enrollee receives care in a long term care facility.

Finally, while CMS has raised concerns that long term care access standards might force plans to negotiate preferential contracting terms and conditions with LTCP (relative to other pharmacies), we note that the market dynamics for long term care pharmacy are similar to the market dynamics created by the retail pharmacy access standards. Moreover, long term care pharmacies can provide plans with much needed expertise that ultimately will help save lives and dollars. In other words, CMS must require plans to serve the frail elderly across care settings. Once plans understand they must serve this population, CMS should allow the market (and competition among plans) to drive negotiations between plans and LTCPs.

In sum, long term care pharmacy must become a required part of every PDP, MA-PD and fallback plan with appropriate recognition of the critical role that LTCP plays in assuring that long term care facility quality is maintained.

Recommendation 2: CMS must develop emergency access standards to ensure appropriate in-network access to prescription drugs on an emergency basis. In particular, CMS should make clear that plans must provide for emergency dispensing of covered Part D drugs, whether or not on the plan's formulary, for residents of long term care facilities.

Rationale: Although CMS is required, by statute, to establish adequate emergency access standards for enrollees, CMS has declined to do so because of the "inherent difficulties in establishing emergency access standards." Instead, CMS suggests that establishing a broader out-of- network access standard will suffice. While out-of-network access will address certain types of emergency situations, there are, as noted above, costs to the beneficiary. Furthermore, we do not believe that beneficiaries should have to go out-of -network to address all emergency situations. Specifically,

CMS must make clear that Plans must provide for emergency dispensing of drugs to long term care facility residents, where due to the frailty of the population, a 24 hour, emergency dispensing is needed to address emergent situations such as seizures, pain, diabetic emergencies, wounds, infections etc. If plans are not required to provide for emergency medication needs, long term care facilities will be forced to send their residents to the hospital. The result will be poorer health outcomes and substantially increased costs.

Recommendation 3: CMS should use its authority under Section 1860D-4(b) (1) (C) (iv) of the Act to require PDP sponsors and MA-PD plans to contract with I/T/U pharmacies in their plan service areas.

Rationale: Plans are required to serve all enrollees within their service area. In addition, the Secretary may not approve a plan if it substantially discourages certain beneficiaries from enrolling. Accordingly, plans must be required to include I/T/U pharmacies in their networks to ensure that all beneficiaries within a service area are served.

4. Pharmacy Network Contracting Standards (Section 423.120(a)(4)) – As currently drafted, the proposed rule merely provides that a PDP or MA-PD plan must contract with any willing provider who meets the plans terms and conditions and may not require that a pharmacy accept risk as a condition of participation in the plan's network. CMS seeks comments as to whether CMS should require that plans make available to all pharmacies a standard contract for participation in the plan network. However, CMS recognizes that this requirement would not preclude plans from negotiating terms and conditions different from those in standard contracts with a subset of pharmacies including LTCPS. CMS also states that with the exception of I/T/U and rural pharmacies, CMS expects that standard contracts would require network pharmacies to adjudicate drug claims at point of sale.

Recommendation 1: CMS should require that plans make available to long term care pharmacies a standard long term care pharmacy contract.

Rationale: We agree that CMS should develop standard contracts for participation in plan networks. However, we have concerns that a standard *retail* contract will not adequately recognize or compensate long term care pharmacies for the specialized services that we provide, that are essential to the needs of long term care facility residents and assure compliance with state and federal standards. .

Recommendation 2: CMS should amend Section 423120(a) (4) by renumber subsection (ii) as subsection (iii) and adding new section (ii) as follows:

(ii) must contract with any long term care pharmacy that meets the prescription drug plan's or MA-PD plan's standard terms and condition for long term care pharmacy, and

Rationale: Plans should be required to contract with any long term care pharmacy that is willing to accept the terms of the plans' standard long term care pharmacy contract.

5. Formulary requirements (Section 423.120(b)) – The LTCPA has provided CMS with extensive comments regarding formulary issues and NeighborCare fully endorses these comments. We note that the failure to provide a specialized geriatric formulary for long term care facility residents is itself, a plan design element likely to discourage a substantial number of frail elderly beneficiaries from enrolling in a Part D plan.

Recommendation: CMS should use its authority under 1860D-11(e)(2)(D)(i) to disapprove of any plan that does not provide adequate access to drugs needed to treat the specialized pharmaceutical needs of long term care facility residents.

6. Formulary changes – (Section 423.120(b) (5)) – With respect to formulary changes, the proposed rule provides only that a 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 it's plans formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug. Additionally, plans are prohibited from removing a drug from the formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug during the annual coordinated enrollment period or three days after the beginning of the contract year.

Recommendation: CMS must add additional protections for targeted enrollees who are taking drugs that are being removed from a plan's formulary. Specifically, CMS should:

Amend section 423.120(b) by adding new subsection (7) (and renumbering the remaining subsections) as follows:

A PDP sponsor or MA-PD plan:

(i) must continue in-network coverage of a covered Part D drug that has been removed from its formulary for all targeted enrollees who were receiving that drug prior to the date of removal unless the plan has received a certification from the prescribing physician that the enrollee can be safely transitioned to the new formulary drug without adverse effect, and

(ii) provide for continued in–network coverage of the removed drug during any such transition.

Rationale: Drug transitions and changes are especially dangerous for targeted beneficiaries who fit the profile of medically fragile and complex patients. Plans are responsible for having medication therapy management programs for targeted beneficiaries. Such programs require active management and monitoring of transitions to avoid adverse outcomes.

7. Pharmacy and Therapeutics Committee – The proposed rule only requires that, minimally, one practicing physician and one practicing pharmacist be independent and free of conflict of interest and be expert in the care of the elderly or people with disabilities.

Recommendation: CMS should require that all physicians and pharmacists serving on a P&T committee have expertise in providing care and prescription drug therapy to people who are elderly or who have disabilities and all voting members should be free of conflicts of interests.

Rationale: While the Medicare population is by no means homogeneous, there are certain shared characteristics including age and disability that distinguish Medicare beneficiaries from the general population. In order for plans to successfully manage the treatment needs of this population, they will need P&T committees composed of physicians and pharmacists with knowledge and expertise in the appropriate fields. Additionally, while we acknowledge that there is no single industry standard governing the composition of P&T committees, at NeighborCare, our P&T Committee is composed of four pharmacy school professors who have no ties to NeighborCare and are experts in geriatric care, a Medical Director representing one of our customers, NeighborCare's Medical Director and a medical ethicist. Only P&T Committee members with no conflict of interest are able to vote. We believe that the composition of our P&T Committee and our safeguards against conflicts of interest, ensures that decisions are based on resident care and outcomes, rather than on financial considerations.

8. Out-of-network Access - In the preamble, CMS states that it expects plans to guarantee out-of-network access under at least four scenarios including in cases where a Part D enrollee resides in a long term care facility and the contracted long-term care pharmacy does not participate in his or her plan's pharmacy network. However, the proposed rule only states that a plan must assure out-of-network access "when enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy."

Recommendation 1: CMS must state its expectations (including access to out-of-network long term care pharmacy) as requirements in the actual regulation text.

Rationale: The current text does not adequately protect residents who need to go out-of-network to obtain covered Part D drugs.

Recommendation 2: CMS needs to clarify the process for appeal of any adverse decision with respect to out-of-network access.

Rationale: Under the proposed rule, plans have broad discretion to decide when to provide out-of-network access. If a plan denies out-of-network access and refuses to pay even the plan allowance, it is not clear how the dispute is adjudicated.

Recommendation 3: CMS needs to clarify that the out-of-network access standards also apply to fallback plans.

Rationale: Section 423.855 provides that fallback plans must meet all the requirements of a PDP sponsor except that it does not have to be a risk-bearing entity. Fallback plans must also meet other requirements as specified by CMS. For clarity, CMS must state that fallback plans also must meet the out-of-network standards established under Section 423.124.

9. Treatment of Out-of-network Cost Differential – Currently, the proposed rule provides that beneficiaries are responsible for the differential between the plan's allowance and the out-of-network pharmacy's usual and customary charges. Plans are financially "held harmless" for out-of-network use by enrollees. CMS believes this is necessary to curb unnecessary use of out-of-network pharmacies and to ensure that plans can achieve cost savings.

Recommendation: As noted above, NeighborCare believes that access to long term care pharmacy should be required as an in-plan benefit. However, to the extent that dual eligible plan enrollees must obtain drugs out-of-network because in-network access is not reasonable, CMS must: (1) clarify that CMS will pay the cost differential; (2) amend Subpart G to clarify that CMS is responsible for paying the cost differential subsidy for dual eligibles directly to the out-of-network pharmacy (3) ensure that plans are monitoring out-of-network use closely and are reporting data to CMS.

Rationale: While CMS has made clear that plan enrollees are responsible for the cost differential when they must go out-of-network for covered Part D drugs, dual eligibles are, by definition, impoverished, and will not be able to pay these costs without government subsidy. Unless CMS identifies how these costs will be covered and how out-of-network pharmacies will be paid, dual eligible enrollees effectively will be denied access to out-of-network coverage. We also believe that out-of-network utilization must be closely monitored because high utilization of out-of-network pharmacies may indicate that plan formularies are too restrictive or that plans are not making needed drugs available.

10. Waiver of public disclosure requirements (Section 423.132): Plans must disclose the differential between the price of dispensed drug and the price of the lowest price generic version available at the pharmacy. This requirement is waived for certain types of pharmacies such as I/T/U pharmacies. However, only the timing of the notice is changed for LTCP.

Recommendation: We recommend that this notice be waived for LTCP

Rationale: Disclosure of this information will have little or no impact on the prescribing behavior of treating physicians in a long term care setting, but will increase administrative burden, thereby increasing costs.

11. Subpart D – Cost Control and Quality Improvement Requirements: Under the Act and proposed Section 423.153(d), each PDP sponsor and every Medicare Advantage organization offering a Medicare Advantage Prescription Drug Plan (MA-PD) must have: (1) a cost-effective drug utilization management program, (2) a quality assurance program, and (3) a Medication Therapy Management Program (MTMP).

(1) Cost-effective Drug Utilization Management Program (CDU) – The proposed rule identifies only two elements of a CDU program: incentives to reduce costs when medically appropriate; and policies and systems to assist in preventing over/underutilization of prescribed medication. These two elements focus only on the cost of medications themselves and not on the total medical costs of treating a particular beneficiary. By focusing on the cost of medications only, CMS promotes a system that is very likely to create greater incentives to under-treat or ineffectively treat Medicare beneficiaries in order to demonstrate cost savings. In order to avoid this result (which can endanger the frail elderly and other Medicare beneficiaries with chronic illness), any CDU system must also be linked to clinical outcomes that are tracked and reported.

(2) Quality Assurance – The proposed rule requires each plan to have a quality assurance program that includes measures to reduce medication errors and adverse drug reactions and includes processes for drug utilization review, patient counseling, and patient information record-keeping. These requirements, however, do not go far enough to identify the elements of a quality assurance program or to require plans to collect data and to respond to identified issues. We note that under current Medicare regulations, Medicare Advantage plans must have QA systems that: (1) measure performance using CMS defined standard measures that relate to both clinical and non-clinical areas and; (2) achieve minimum performance levels that CMS establishes locally, regionally or nationally with respect to the standard measures. We believe that at-risk PDP plans and MA-PD plans should be held to similar standards. A defined set of measures and defined minimum performance levels can lead to the development of quality report cards and other reports that help consumers make informed choices about Part D plans based upon quality.

(3) Medication Therapy Management Programs (MTMP) – Under the proposed rule, plans must have MTMPs for all targeted beneficiaries and must meet two requirements: 1) improved medication use that optimizes therapeutic outcomes, and 2) reduced risk of adverse events. LTCPs, such as NeighborCare, use MTMP to proactively manage the pharmacotherapy of frail elders in long term care settings. We therefore have a number of specific comments and recommendations with respect to the MTMP provisions of the proposed rule.

Recommendation 1. While CMS would like to give plans some flexibility to decide whom to target for the medication therapy management program, we strongly believe that all long term care residents should be deemed targeted beneficiaries. Therefore, CMS should amend Section 423.153(d) (2) to add to the end of subsection (iii)

", or" and add new subsection (iv) as follows: "Are residents of a long term care facilities."

Rationale: Long term care facility residents are among the heaviest users of health care services, including prescription drugs and fit the profile of targeted beneficiaries which, by statute, are defined as Part D eligible enrollees who have multiple chronic diseases, are taking multiple covered Part D drugs and have high drug costs. In fact, medication therapy management is an integral component of what long term care pharmacy provides to these residents. Yet, because PDP plans have a financial incentive to cut their costs, including costs for medication therapy management programs, and are not accountable for total health care costs, plans are unlikely to target long term care facility residents for medication therapy management unless CMS requires them to do so. If CMS does not require plans to target long term care facility residents for medication therapy management programs, CMS is likely to spend much more on the cost of avoidable hospitalizations.

Recommendation 2: CMS must require PDP and MA-PD plans to provide a MTMP to targeted beneficiaries that meets specific requirements. Specifically, CMS should:

Amend Section 423.153(d) to add new section (2) as follows:

(2) A mediation therapy management program, at minimum, should include:

(i) an assessment of the targeted beneficiary's drug therapy,
(ii) a system to ensure that medications are dispensed to the right targeted beneficiary in the right form and correct amount and can meet emergency needs,
(iii) a system for data tracking, monitoring, evaluating patient outcomes include adverse events and drug errors, and
(iv) a staff of licensed pharmacists with specialized expertise in the management of drug therapy for targeted beneficiaries.

Rationale: While the proposed rule addressing the MTMP identifies important goals, CMS must go further to identify what plans must do to achieve these goals. Specifically, CMS must identify the basic elements of an MTMP plan and must hold plans accountable for MTMP activities and associated health and quality outcomes. This is especially critical given the structure of the new Part D benefit, which gives PDPs financial incentives to control costs through restrictive formularies and coverage denials, but does not hold them accountable for adverse health outcomes that are likely to result when authorization for needed drug therapy is withheld or delayed.

NeighborCare's MTMP program consists of the following elements:

1. Prospective Admissions Screening – a review of hospital discharge orders for appropriate recommendations with respect to possible allergies, drug interactions, generic

or branded lower cost alternative drug products, long acting products and preferred products.

2. Point of Service Interchange Program – Operations Pharmacists' intervention to review the resident's drug regimen for utilization of high cost medications, doses, dosage form and packaging issues and clinical assessment based on evidence-based treatment protocols.

3. A Retrospective Drug Regimen Review – a patient specific, clinical initiative driven by consultant pharmacists in the long term care facility that employs automated consultant software supported by clinical guidelines.

4. A Retrospective Utilization Review – an opportunity for further drug conversion that identifies trends in physician acceptance/resistance, calculates projected savings and permits nursing facility staff to establish cost management programs with prescribers on staff.

Through each of these steps, data tracking is integral to our operations. By tracking various data elements, we are able to optimize clinical care and cost savings, while reducing adverse events. CMS should require no less of PDP and MA-Plans that will become responsible for the administration of the new Part D drug benefit.

12. Subpart M – Grievances Coverage Determinations and Appeals – The proposed rule sets forth requirements for the exception determination process. While only the enrollee, the enrollee's representative or the enrollee's prescribing physician can request an exception, the rule does not identify who, within the plan, is qualified to make decisions about exception requests. The rule also fails to adequately identify the standard of review. (See comment 13 below).

Recommendation: Only a physician or pharmacist with specialized experience relevant to the patient population, who has no conflict of interest, should be qualified to make a decision about an exception determination.

Rationale: The decision maker should be impartial and knowledgeable.

13. Clarification of Coverage Standard – Under Section 423.752, plans may be sanctioned with civil fines and penalties for substantially failing to provide medically necessary services that the organization is required to provide (under law or under contract) to a PDP enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee. We note, however, that neither the statute nor the contract provisions in Section 423.505(b) state that plans are required to provide medically necessary prescription drug coverage.

Recommendation 1: CMS must amend the rule to make clear that the standard for coverage is "medically necessary" prescriptions. Specifically, CMS should:

Amend Section 423.505(b) to include new subsection (4), (and renumber the remaining subsections), as follows: *"To ensure coverage of medically necessary prescription drugs up to the limits of the plan."*

Rationale: Clarification of the standard for coverage in the contract between CMS and the plan is essential to ensure that beneficiaries receive the drugs they need and that plans base decisions, including exception determination decisions, on objective criteria.

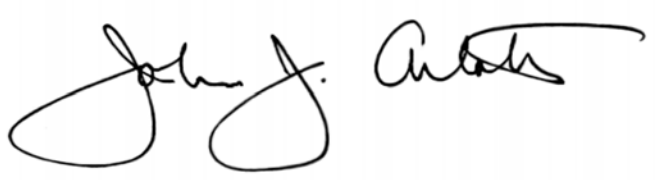
14. Prompt Payment – There is no provision in the rule requiring plans to pay providers promptly.

Recommendation: Amend Section 423.120(a) to require that plans pay network, and when appropriate, out-of-network, pharmacies, including long term care pharmacies, within 30 days of a claim.

Rationale: CMS needs to ensure that plans do not profit by withholding payments from vendors.

Again, we thank you for the opportunity to comment on this important rulemaking. Please do not hesitate to contact me if you have any questions.

Sincerely,



John J. Arlotta
Chairman, President and Chief Executive Officer
NeighborCare, Inc.

Submitter : Dr. Octavia McCalla **Date & Time:** 10/04/2004 07:10:13

Organization : VA Memphis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 04 __, 2004

Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

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 rule 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 average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) 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.

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.

I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.

A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.

A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.

Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical? pharmacists, as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?

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 should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should 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 populat

CMS-4068-P-1097

Submitter : Dr. James C. Martin **Date & Time:** 10/04/2004 07:10:48

Organization : American Academy of Family Physicians

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the comments from the American Academy of Family Physicians.
Susan Hildebrandt
Assistant Director
Division of Government Relations

CMS-4068-P-1097-Attach-1.doc

October 4, 2004

The Honorable Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Via Email

Dear Dr. McClellan:

On behalf of the 93,700 members of the American Academy of Family Physicians, I am pleased to offer our comments on the *Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule, CMS-4068-P*. The regulation details the requirements outlined in the Medicare Modernization Act, which establishes a new Part D within Medicare, the Voluntary Prescription Drug Program, and is effective January 1, 2006.

The AAFP also commented on the model drug formulary guidelines created by the United States Pharmacopeia (USP) as required by section 1860D-4(b)(3)(C)(ii) of the law. USP was charged with creating guidelines consisting of drug categories and classes that could be used by private prescription drug plan sponsors and Medicare Advantage organizations. The Academy was pleased that a family physician was able to serve as our representative on the USP Providers Advisory Panel.

Our primary goal in those comments to USP – and our ambition in this statement - is to ensure that the regulations provide sufficient flexibility for physicians to prescribe effective, safe and affordable medications to their Medicare patients. While we supported adding a prescription drug plan to Medicare, the enormity of the change to the program, the complexity of the law and the comprehensiveness of the proposed regulation require that we do our best to establish a valuable framework that truly benefits our senior patients and controls costs.

As family physicians, we know also that our specialty will be impacted particularly by the regulation's requirements. In fact, due to the breadth of our patient population, family physicians prescribe medications at a higher rate than other physicians. According to the National Center for Health Statistics, of all visits to physicians in 2002 in which drugs were prescribed or provided, family physicians were responsible for 29 percent of the total. All other specialties made up the remaining 71 percent.

Our comments will focus on the sections regarding drug formularies; cost control and quality improvement; medication therapy management programs; fraud and abuse; electronic prescribing and the exceptions procedures.

S 423.120 Access to covered Part D drugs, (b) formulary requirements

The structure of the health plan drug formulary is one of the most critical elements within the regulation since coverage is essentially meaningless if a patient is unable to access his or her necessary medication, Absent access to the medication, a patient would be forced to go without the drug; switch to another, potentially ineffective product, or ask his or her physician to go through a burdensome process to win approval for health plan coverage. We seek to avoid those scenarios and our comments on this section will reflect that perspective.

P&T Committees

Under this section, if a plan uses a formulary, it must use a pharmaceutical and therapeutic (P&T) committee to develop and review the framework. CMS requests comments on its interpretation of the law that a P&T committee's decision regarding the plan's formulary be binding on the plan.

In addition, the proposed rule states that the majority of the P&T committee should include both practicing physicians and/or practicing pharmacists. Furthermore, at least one of each would need to be expert in care of elderly and disabled individuals. Finally, CMS encourages plans to select P&T members representing various specialists. While we support the inclusion of different specialists on the P&T committees, we believe family physicians should be included on the majority of the panels since they prescribe more medications than any other specialty.

CMS also requests comments on its decision to strengthen the regulation by requiring that more than just one pharmacist and one physician be independent and free of conflict to serve on the P&T committee. This mandate is defined in the preamble as "P&T committee members must have no stake, financial or otherwise, in formulary determinations. In other words, these individuals would be required to be independent and free of conflict with respect not only to a PDP sponsor and its prescription drug plan or an MA organization and its MA-PD plan, but also with respect to pharmaceutical manufacturers." As stated above, the formulary is a crucial element of the new drug plan. Individuals on P & T panels who are making decisions about the inclusion of various medications must be as objective and unbiased as possible. We support this provision. As a result, we also believe that the P&T decision should be binding.

Evidence-Based Decision Making

The draft regulation states that P&T committees must base clinical decisions on strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies and outcomes research data. The preamble further clarifies this issue by stating that pharmaeconomic studies may be considered by the P & T committee; however, CMS expects that cost will be balanced by clinical considerations in formulary development. It also indicates that the panel must take into account whether including a drug in the formulary has any therapeutic advantages in terms of safety and efficacy.

The above issue, requiring P&T panels to base decisions on research and studies, cannot be emphasized too strongly: the Academy is firmly in support of evidence-based clinical decision-making. However, we believe there is a paucity of evidence-based research (particularly regarding generic drugs or drugs that are not being currently promoted because they are available in generic form).

As a result, we support Section 1013 of the Medicare Modernization Act, which calls for the Agency for Healthcare Research and Quality (AHRQ) to conduct research on comparative clinical effectiveness. As family physicians, we believe that more objective, reliable data is needed so that we can determine the best treatment decisions for our patients. In fact, we suggest adding language to the regulation mandating that P&T seek out available comparative clinical effectiveness research to emphasize the importance of this issue. While this field is still developing, we think it is appropriate that the brand new Medicare regulations begin to focus attention on this subject.

USP Model Guidelines

The preamble discusses the law's intent that the USP create model guidelines for formularies. This section is important as the Medicare act states that health plan drug formularies that are consistent with USP's model guidelines will be deemed to be in compliance with the law. And, USP has stated that the "mission of the Model Guidelines Expert Committee is to fulfill the intent of Congress by creating a list of categories and classes that protects Medicare beneficiaries' access to the drug they need…" Consequently, it is crucial that the model guidelines be drafted to provide sufficient options for physicians to prescribe the appropriate drug to their patients. In our view, the guidelines do not meet this goal.

Since the USP model guidelines will not be finalized until December, and the proposed regulation will build on that framework, we will reiterate a portion of our comments to the USP. Specifically, as proposed, the model guidelines establish three subdivisions: therapeutic category; pharmacologic class; and recommended subdivisions. Under the proposed regulation, health plan formularies must include at least two drugs within each therapeutic category and class (unless only one drug is in a category or class).

Our primary concern is that the classes are too general to include all appropriate drugs that physicians may wish to prescribe to their patients. Specifically, the recommended subdivisions include several generations of drugs that have different mechanisms for action, indications and are suitable for various individuals. In general, our recommendation to the USP is that the "recommended subdivisions" become separate classes.

Simply stated, while the recommended subdivisions may include a list of four drugs, the health plan will be required to offer only two. And, if a physician wishes to prescribe one of the remaining drugs that are not on the formulary, even though it is included in the subdivision, he or she will be required to go through a burdensome exceptions process. Otherwise, the patient will be unable to receive the medication except by paying the full price.

Finally, the USP model guidelines include both old and new drugs and drugs that are appropriate for different patients under the assumption that they are interchangeable for treating various diseases. The result of this classification is that plans will be permitted to exclude many types of medications that are a necessary part of physicians' treatment regimens for acute and chronic illnesses. As a result, we recommend that the USP expand the list of 146 therapeutic categories and classes. We offer the following example on well-known antidepressants as evidence that the current classification model is not workable.

Under the antidepressants, pharmacologic class 16, "reuptake Inhibitors," recommended subdivisions include SNRIs, SSRIs and tricyclics. Under the model guideline and under the proposed regulation, health plans would be required to offer only two drugs from the above three subdivisions. And, since tricylics are older and less expensive, health plans could potentially cover only two of these early generation antidepressants. As a result, our elderly patients would be unable to obtain the newer and generally safer medications. We ask USP to make each of these three subdivisions separate classes.

Finally, the preamble states that USP will revise its classification periodically using public meetings and comments, and also will research the best practices in formulary development. CMS invites comment on how to ensure that formularies do not discourage certain beneficiaries from enrolling. The agency also states it expects plans to provide a comprehensive number and variety of drugs to treat all disease states. We believe that our comments above, which argue for a greater number of classes, would meet these goals.

Off-Label Use

In the preamble, CMS states that model categories and classes developed by USP will include at least one drug that is approved by the FDA for the indication in the category or class. No category or class would be created for which there is no FDA approved drug, which would mean the drug would have to include an "off label" indication. However, while the regulation does not preclude physicians from prescribing drugs for off-label indications, CMS "strongly encourages" prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records.

We oppose this requirement. According to longstanding AAFP policy, we believe that physicians have the right under their medical license to diagnose, prescribe for, and dispense pharmacologic agents or other therapeutic products whenever appropriate. Documentation and justification of off-label use interfere with the physician's ability to practice medicine. In addition, an off-label drug use would not even be included in the subcategory and therefore would not be available for prescription if the diagnosis were required.

Cost Saving Measures
The preamble to the proposed rule states that CMS expects health plans to employ various measures to save money on medications. For example, it expects plans to provide a formulary that includes a number of strategies, e.g., incentives to encourage use of generics; tiered cost-sharing; prior authorization procedures; therapeutic substitution; step therapy; and use of mail order pharmacies. CMS supports these strategies but seeks comment on how to ensure vulnerable populations (e.g., those who are chronically ill or mentally ill) will not be negatively impacted financially.

The Academy's policy, *Principles for the Development and Management of Patient-Centered Formularies*, incorporates our understanding that health plans will use various cost management tools. Specifically, the policy states, "The AAFP recognizes the role of appropriately designed restrictive formularies used by providers of pharmacy benefits and third party insurers which have the goal of optimizing clinical outcomes while minimizing overall health care costs."

Nevertheless, the statement does not change the Academy's position that mandatory substitution requirements interfere with a physician's ability to practice medicine. We believe strongly that the family physician is best positioned to determine the optimal pharmaceutical regimen for his or her patient. In addition, we believe these requirements are detrimental to the patient-physician relationship.

In addition, we are opposed to cost saving measures such as prior authorization procedures and step therapy. In our view, it does not make sense from a clinical perspective to require a physician to receive approval to prescribe a drug he or she believes is appropriate for a patient. Moreover, it is not only illogical, but could be even harmful to force a patient to try out -- step through -- various medications before he or she can be prescribed and be covered for the one that is the most effective. In addition, to use a specific example, there is new evidence that ACE inhibitors prevent kidney damage in hypertensives whereas diuretics do not although both drugs can control blood pressure. Finally, step therapy ignores the new evidence that patients can be genetically tested for efficacy of some drugs, a scenario that is likely to increase in the future.

Viewed over the long-term, requiring patients to take a series of drugs that may not work, or even worsen his or her condition, is more costly to the health care system. While the reason for step therapy is ostensibly to save money, costs will increase in the form of uncontrolled illness. However, of utmost importance is the personal harm that could be inflicted on the patient in terms of poor quality health care. As advocates for our patients, we oppose step therapy requirements.

We realize that large increases in the cost of prescription drugs have made generic drugs an affordable option for our patients. And, because of the nature of family medicine, we want to respond to the needs of our patients with limited resources. Nevertheless, the Academy continues to oppose mandatory generic substitution as an unwarranted intrusion into the practice of medicine.

Changing Drug Formularies
The proposed rule includes a number of provisions regarding when health plans may make changes to their formulary. The draft states that plans must provide at least 30 days' notice to enrollees before removing a covered drug from a formulary, or before making any changes in the preferred or tiered cost-sharing status. Moreover, the draft regulation says that plans can only change therapeutic categories and classes in a formulary at the beginning of a plan year; that is, between the beginning of the election period and 30 days after the beginning of the contract year.

However, the proposed rule allows health plans to make changes to take advantage of new therapeutic uses and newly approved covered Part D drugs. And plans would be required periodically to evaluate and analyze treatment protocols and procedures to ensure that their plan members were receiving the best care. In the preamble, CMS seeks comments on the minimum timeframes for periodic evaluation and analysis of protocols and procedures, e.g., quarterly, annually. Finally, the regulation requires notice only to be given to those enrollees taking that drug – not to all plan enrollees.

The AAFP's statement, Principles *for the Development and Management of Patient-Centered Formularies*, indicates specifically that "formularies must be 'stable' since frequent changes create confusion and frustration for patient and physicians leading to non-compliance, adverse reactions, increased costs and erosion of patients' confidence."

While we understand the agency's desire to allow plans to make changes to take advantage of new therapeutic uses and newly approved drugs, on the whole, we believe that drug formulary lists should be changed as little as possible to prevent disruption of a patient's health care. Thirty days' notice does not provide the needed stability for elderly patients who may have decided on a health plan due to its drug formulary. As a result, we recommend that changes be done no more than annually. We also suggest that periodic evaluation and analysis be done no more frequently than once every 12 months.

Similarly, we do not believe that the provision in the proposed regulation preventing health plans from changing their formularies at the beginning of the plan year is in the patient's best interest. For example, a beneficiary may have selected the plan for coverage of a specific drug, only to learn that its status on the formulary has changed. The patient, unlike the health plan, does not have the ability to provide 30 days notice and change to another plan. Instead, he or she must appeal to the physician for coverage of a drug that until only recently was covered by the plan.

Finally, while the proposed rule requires health plans to notify individuals taking a medication that it is no longer on the formulary, we believe plans should notify all beneficiaries. This requirement would be useful to another covered individual who may be planning to begin that drug in consultation with his or her physician and learn only belatedly that it is no longer on the covered drug list.

Subpart D Cost Control and QA Requirements for Drug Plans
Under this subpart, the draft regulation specifies requirements relating to cost and utilization management programs, quality assurance programs, medication therapy management programs (MTMP) fraud, abuse and waste.

S 423.153 Cost Effective Utilization Management
In this section, the proposed rule requires each plan to provide a program to include incentives to reduce costs when this is medically appropriate. The preamble clarifies the draft regulation by specifying that these activities are not "switching," in which one branded drug product is switched with another similar branded drug product, commonly referred to as therapeutic substitution. In fact, the preamble indicates that therapeutic substitution would always require explicit prescriber notification and approval. However, the preamble also notes that these programs could include prior authorization; step therapy; tiered cost-sharing and other utilization tools. Our comments on those elements appear earlier in this document.

The preamble also asks specifically for recommendations on whether cost reduction tools should be under the direction of the P&T committee. In our view, this is entirely appropriate. Since health plans will be eager to employ a variety of cost utilization methods, we believe that placing them under the oversight of a P&T committee would ensure that they are clinically sound.

Quality Assurance
The proposed regulation states also that health plans must have quality assurance programs that include measures to reduce medication errors and adverse drug interactions and to improve medication use. Furthermore, the programs must include drug utilization review; patient counseling; and patient information record keeping.

In the preamble, CMS states that it also expects plans to move quickly on elements of quality assurance such as electronic prescribing and clinical decision support, although the agency does not expect that all health plans will adopt each of these elements. Finally, CMS invites comments on appropriate quality assurance elements.

The well-known Institute of Medicine (IOM) report, *Crossing the Quality Chasm*, has documented the performance gap between high quality health care and what is actually delivered in our current fragmented and costly system. The report is clear: "The current care systems cannot do the job. Trying harder will not work. Changing systems of care will." Consequently, while we clearly support efforts to improve quality in medication management, we believe a more appropriate goal is "quality improvement."

We believe efforts in this area have evolved: health plans have been moving away from an old-style punitive approach toward one that is focused on identifying the gaps within the system and determining the appropriate intervention. Quality assurance has implied setting artificial goals for individuals – in contrast to quality improvement which means examining the system as a whole and putting structures in place to reduce errors.

More specifically, we believe that any quality improvement program for medications must include three elements: a check for possible allergic reactions; drug interactions and a system to ensure the appropriate dosage for the medication.

Medication therapy management
The law requires plans to establish medication therapy management programs (MTMP) and lists specific elements, including beneficiary education and methods to improve enrollee compliance to drug regimens. The purposes of these MTMPs are to assure that drugs are used appropriately and to reduce the risk of adverse events for targeted beneficiaries. Targeted beneficiaries for these programs include those individuals with multiple chronic diseases; those taking multiple Part D drugs; and people who are likely to incur high annual costs. The rule indicates that these programs should be developed with pharmacists and physicians and coordinated with any care management plan established under Section 1807 of the law to discourage duplication of services. Finally, CMS indicates that the agency has no experience reimbursing for this type of program and seeks comments on best way to do so.

We believe that many of the elements in the law and in the proposed regulation flow from the Chronic Care Model and that the MTMP programs could be patterned on that construct. In addition, the AAFP supports a "care management fee" for physicians in addition to current fee-for-service payments. The fee should be paid to the personal physician chosen by the patient to coordinate the patient's health care. The recommendation springs from the need to transform the overall health care system into one that is more integrated and efficient (i.e., less wasteful and duplicative).

The incidence and prevalence of chronic disease among Medicare beneficiaries, as well as the multiple challenges of treating and managing these diseases and the cost associated with doing so, are well documented. Medicare funds are increasingly directed toward beneficiaries with chronic illness. The Robert Wood Johnson Foundation's initiative entitled, *Partnership for Solutions,* estimates that about two-thirds of Medicare dollars go to participants with 5 or more longstanding conditions.

Right now, 82 percent of the Medicare population has at least one chronic condition and two-thirds have more than one. Significantly, however, the 20 percent of beneficiaries with five or more chronic conditions account for two-thirds of all Medicare spending.

Recent efforts to stem these growing costs, such as the chronic care pilot in the Medicare law, have focused mainly on supporting disease management programs and not on physician coordination models. While evidence suggests this strategy may work for young, healthy people with one disease, it likely does not translate to older patients, such as Medicare beneficiaries, with many conditions.

Evidence suggests that the *Chronic Care Model*, (Ed Wagner, Robert Wood Johnson Foundation) would improve quality and cost-effectiveness; integrate health care; and increase overall patient satisfaction. This model is based on the fact that care for most

people with chronic illness takes place in primary care settings and focuses on the clinical care components that physicians can perform to coordinate patient care. Not only would this model help people with chronic conditions, it also would enhance general care, health promotion, and disease prevention for *all* patients.

The Academy supports a per-beneficiary chronic care management fee that is paid directly to the physician in addition to fee-for-service payments. This fee would be paid to the physician, selected by the patient, who is willing to perform the following activities or functions, as well as provide technology support:

- tracking and monitoring all aspects of the patient's care;
- acting as a referral agent;
- coordinating clinical reports from others involved in the patient's care;
- maintaining an electronic health record;
- providing greater time in the office visit as needed; and
- having appropriate staff and administrative abilities.

Section 423.153 (e) Fraud, Abuse and Waste
The proposed rule requires plans to set up performance standards to programs to control fraud, abuse and waste. However, the preamble notes specifically that plans "need to determine whether or not physicians are illegally prescribing narcotics." While we agree that physicians who illegally prescribe narcotics should be prosecuted, we believe that it is not within the expertise or responsibility of health plans to police this. Rather, plans should be encouraged to report excessive or unexplained prescribing practices.

The preamble also states that CMS is concerned about inappropriate switching of prescriptions by a plan without consulting a physician. This section indicates that switching from a brand drug to a generic may be appropriate but not from one brand to another. As stated above, the Academy believes strongly that the family physician is best positioned to determine the optimal pharmaceutical regimen for his or her patient. Moreover, we oppose any effort to permit therapeutic substitution. Our official policy states, "The AAFP strongly opposes any legislative or regulatory effort at the state or federal level to permit therapeutic substitution, that is the substitution of a therapeutic alternate, a drug product containing a different pharmaceutical moiety but which is of the same therapeutic or pharmacologic class."

<u>Sec. 423.159 Electronic Prescription Program</u>
Under this section, the law states that voluntary initial standards for electronic prescribing may be adopted no later than September 1, 2005. Final standards are to be published no later than April 1, 2008 and become effective not later than 12 months after promulgation of final standards. Furthermore, the Act charges the National Committee on Vital and Health Statistics (NCVHS) to develop recommendation in consultation with constituencies. The law also establishes a pilot project once the Secretary has set up the initial standards. In the preamble, CMS states it will accept any recommendation on this issue in comments on the proposed rule, particularly

regarding e-prescribing standards ahead of the statutory time frame and industry experience.

While the Academy testified at one of the public hearings on this issue, we will reiterate some of the key points of that testimony.

Specifically, the AAFP is very interested in issues of health information technology, particularly in seeing software and hardware that is compatible and interoperable across health care settings. While e-prescribing is important, we are concerned that standards adopted for voluntary e-prescribing as a result of the law not hamper the larger functions of an electronic health record (EHR). Clearly, e-prescribing is complicated because of the several parties that can be involved, including the patient; prescribing physician; the patient's health plan; pharmaceutical reference entities with information on prescribing, dosage, allergic reaction and other drug prescribing information; pharmacy benefit managers (PBMs); and pharmacies.

In order for these parties to communicate, standards will need to allow connectivity between EHRs and a variety of other parties. Family physicians are eager to see a fully functioning EHR that allows communication within the broad community outlined above because there is the great potential for increased safety and productivity from such a system.

In addition, family physicians care about the context in which e-prescribing occurs. The best context for the patient is one in which a comprehensive record of patient health information is available to the prescribing family physician at the time the prescription decision is made. Clearly, refills and renewal are not as complicated, and may not require as much patient information review. However, safety, quality, and cost considerations all favor e-prescribing be done within the comprehensive practice setting, where considerations such as previous drug experience, co-morbidity, drug-drug interactions, and even the patient's economic situation can be assessed prior to ordering the medication.

We prefer that e-prescribing take place within the context of a full-featured EHR, which acts as the central nervous system of a patient's health care system, and not through a single-purpose application that provides an electronic connection to the pharmacy or PBM, but does not assist the clinician by providing access to other information required for quality clinical decision-making. Small- and medium-sized ambulatory primary care offices, where the majority of health care is delivered in the US, must also be able to easily implement any e-prescribing standards developed.

Moreover, we feel strongly that e-prescribing should be based on choice, not coercion. We do not favor governmental mandates that would force physicians or their practices to engage in e-prescribing, but believe this clinical tool should be voluntary and based on its attractiveness to patients and providers. Doctors should not be forced to adopt technological solutions that are not affordable or which lead to unfair incentives for patients or practices to utilize a particular commercial pathway for medication fulfillment.

Such forced adoption, either through governmental or payer mandates, would exacerbate the already precarious financial situation in which many primary care physicians in small and medium-size medical practices find themselves.

Therefore, e-prescribing must be free to physicians and patients. Physicians should not have to pay for e-prescribing through transactions fees or be forced to acquire technologies offered by health plans, pharmacies, PBMs, or their subsidiaries or agents. To allow third parties to determine what technology is acquired in a medical practice would redirect valuable capital that might more appropriately be spent on other technology purchases such as an EHR or other upgrades. Physicians are in the best position to determine their practice management and clinical software needs. Similarly, physicians should not be forced to report practice data to any of these parties, who might later use it for commercial benefit or profit.

In any e-prescribing function, family physicians want to be able to see all of a patient's prescribing history, from as many sources and databases as possible, in real time and prior to prescribing a new medication. This is an important safety issue particularly for Medicare beneficiaries, two-thirds of whom have multiple chronic conditions. Generic and brand product names are often similar and confusing, especially to the patient on multiple prescriptions. Existing EHRs are not able to exchange drug lists from doctor-to-doctor. Such fragmentation of the health care system often leads to errors of duplication in prescribing of medications. The promise that e-prescribing holds out is that it will correct this problem, but only if physicians have access to the full patient prescribing history.

Finally, the regulation allows MA plans to "provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescribing standards, including voluntary standards promulgated by CMS as well as final standards established by CMS once final standards are effective." CMS notes that these must be in compliance with federal/state laws, including physician self-referral prohibition. The Academy supports these additional payments to physicians by MA plans.

Subpart M - Grievances, Coverage Determinations, Reconsiderations and Appeals
Finally, the proposed rule requires plans to establish grievance procedures for making timely coverage determinations; exceptions to a tiered cost-sharing structure; handling exceptions to a formulary and an appeals process. If an individual requests that a drug be covered, the health plan must notify the enrollee of its determination no later than 14 calendar days; this time period can be extended only if the plan can justify how it is in the interest of the beneficiary. Finally, an enrollee or the prescribing physician can request that the coverage determination be expedited.

As physicians who want our patients get the appropriate medication, we hope that neither of us need to utilize these systems. Our belief is that if the drug formularies and overall program are constructed carefully, Medicare beneficiaries will get the drugs they

need in an efficient manner. That said, we believe that these processes are overly burdensome as currently structured.

Section 423.578 Exceptions Process
This section requires health plans using a tiered formulary to establish an exceptions process. Specifically, health plans must establish a procedure for enrollees 1) using a drug and the tiered cost-sharing structure changes mid-year; 2) using a drug and the structure changes at the beginning of a new plan year; 3) for which there is no preexisting use of the drug.

Under the draft regulation, plans may require a written certification from the physician that the preferred drug on the formulary is not as effective as the requested drug, or that it may have adverse effects for the patient, or both. Information may include enrollee name; group or contract number; subscriber number; patient history; primary diagnosis related to drug; why preferred drug is not acceptable; why the drug is needed; any other information reasonably necessary to evaluate the medical necessity of the request.

Secondly, the section requires health plans to establish a formulary exceptions process. Formulary use is defined under the proposed rule as including dose restrictions that cause a drug not to be covered for the number of doses prescribed, or a step therapy requirement that causes a drug not to be covered until the requirements of the sponsor's coverage policy are met.

A sponsor may require that the written certification may include: enrollee's name; contract number; patient history; the primary diagnosis; the reason the formulary drug is not acceptable; why the drug required for step therapy not acceptable; why the available number of doses is not acceptable; why the drug is needed; any other information reasonably necessary.

Our comments are purposely written to include all of the requirements listed in the proposed regulation to emphasize their extremely burdensome nature. As stated above, we hope that the tiered cost-sharing arrangements and drug formularies are developed in a way that we and our patients do not need to use the exceptions processes. However, if that is necessary, we believe that the requirements noted above will require physicians to spend an enormous amount of time advocating for a specific drug they feel is appropriate, rather than spending time with their patients in actual care.

The preamble states specifically that the law provided too much discretion in this area, and, as a result, CMS has established these systems. While we understand health plans' desire to save money, and we are sensitive to the need to strike the appropriate balance between cost and quality, the recommended procedures as written not only second guess the physician, but interfere with the practice of medicine.

Redeterminations
Finally, the regulation specifies that if plans do not issue a timely decision, it must continue to provide coverage until a decision is made on the request. Redeterminations

can be requested, both standard and expedited, and can be made by an enrollee or prescribing physician orally or in writing.

The regulation also establishes an independent review entity (IRE) for enrollees who are dissatisfied with redeterminations. Enrollees must file a written request for reconsideration. However, in order to do so, the physician is required to determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition are not as effective for the individual, has adverse effects for the individual, or both. The reconsideration decision is binding.

Like the above exceptions processes, the redetermination procedure seems similarly onerous. Rather than allowing patients to appeal a determination on their own, physicians will need to determine again that all other drugs are not as effective or will have negative consequences. In our view, both the exceptions processes and the redetermination procedure are significant disincentives for a patient – and his or her physician – to dispute a health plan's determination regarding cost-sharing or drug formularies. As a result, we believe that this section is contrary to the law's goal to provide greater access to medications by our nation's seniors.

Conclusion

We appreciate the opportunity to provide comment on the proposed regulations and realize this is one of many draft rules in a lengthy process to implement the Medicare Modernization Act. This initial framework is crucial, however, as we all work together to provide the best drugs at the least cost to elderly seniors. We urge you to modify the regulations as suggested to fulfill the intent of Congress to create a program guaranteeing beneficiaries access to the drugs they need.

Sincerely,

James C. Martin, MD, FAAFP
Board Chair

Submitter : Dr. Tony Powers **Date & Time:** 10/04/2004 07:10:41

Organization : Medical Alternatives

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I concur with the National Home Infusion's (NHIA) Comments. Medicare patients deserve the same benefits as others have received for the past 25 years. Home Infusion Pharmacies can dramatically reduce healthcare costs and allow patients the safety of receiving their treatments in their homes. Currently such patients receive these treatments in institutional (hospital) and other clinical (out patient treatment centers, physician offices) at a great inconvenience, increased cost, and at an increased risk.

Tony Powers
CEO / Owner
Medical Alternatives
Home Infusion Pharmacy

CMS-4068-P-1099

Submitter : Mr. Joel Ferber **Date & Time:** 10/04/2004 07:10:45

Organization : Legal Services of Eastern Missouri

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See attached comment

CMS-4068-P-1099-Attach-1.doc

Legal Services of Eastern Missouri, Inc.

4232 Forest Park Avenue
St. Louis, Missouri 63108

JOEL D. FERBER
(314) 534-4200, Ext. 1202 **Facsimile (314) 534-1028**

October 26, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068--P
P. O. Box 8014
7500 Security Boulevard
Baltimore, MD 21244-8014

Re: Medicare Modernization Act Proposed Regulations: Comments on Select Provisions, File Code [CMS-4068-P]

Dear CMS:

We are writing to comment on the above-referenced proposed regulations. We are filing these comments based on our experience representing thousands of Missouri Medicaid beneficiaries as well as thousands of other public benefits claimants, in negotiations, administrative advocacy, and litigation. We focus here on the provisions affecting "dual eligibles" and the grievance and appeals provisions which pose the greatest concerns for our Medicaid clients, whose prescription drug coverage will be significantly affected by the new Medicare prescription drug law and implementing regulations. In particular, we are especially concerned with the almost certain *gap in prescription coverage* that would face many dual eligibles under the proposed regulations. We are also deeply troubled by the regulations' failure to adhere to basic constitutional due process principles that apply to the beneficiaries of critical health and welfare programs. We believe that substantial revisions are needed in these areas to protect the health and well-being of the millions of Medicaid beneficiaries who are affected by these provisions and to comply with their due process rights.[1]

I. Enrollment of Dual Eligibles in Medicare Part D

- **Coordinating and Timing Transfer from Medicaid.**

[1]While we have not commented on the entirety of the proposed regulations, we support the comments of the Medicare Consumers Working Group, which include such organizations as the National Health Law Program, Families USA, the Center on Budget and Policy Priorities, and the Center for Medicare Advocacy.

The NPRM fails to adequately address how drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the dual eligibles) will be transferred to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of the enrollment process. The NPRM does not address either in any way that will ensure that these 6.4 million beneficiaries do not lose benefits or suffer a gap in drug coverage, either of which could have disastrous health consequences for these individuals.

Timing. Automatic enrollment of dual eligibles will not begin until the end of the initial enrollment period on May 15, 2006. However, states' Medicaid drug benefit for dual eligibles will end on January 1, 2006. Given the difficulty of reaching this population coupled with inadequate provisions for outreach and education, **a substantial number of dual eligibles will almost certainly face a nearly five-month gap in coverage** between the end of Medicaid's drug benefit and automatic enrollment. This completely foreseeable situation 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 must be delayed.

Automatic enrollment. 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; therefore, we recommend that automatic enrollment be performed by the states. However, this added responsibility *must* include sufficient administrative payments.

- **Continuity of Care for Dual Eligibles.**

We are extremely concerned with ensuring continuity of care for dual eligibles and access to needed prescriptions. A disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications: According to MedPAC, 38% of all duals have cognitive or mental impairments. These issues and concerns, however, apply equally to *all dual eligibles*, and particularly to those with specific health care needs, as well as to other populations with specific needs.

As proposed in the NPRM, duals would be forced to enroll (or be automatically enrolled) in the "benchmark" or average 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 in states that have restricted access to drugs in Medicaid programs with preferred drug lists and prior authorization requirements, mental health medications are generally exempt from these restrictions. **Without access to the**

coverage they need, dual eligibles will be forced to switch medications. In the HIV/AIDS sector, such switches can be deadly.[2]

We believe the same is true for a number of other illnesses and categories. One example of this problem is the danger of changing psychiatric medications. It can take up to 6-12 weeks to determine if a medication works and almost as long to wash a medication out of a consumer's system. Abrupt changes in psychiatric medications bring the risk of serious adverse drug interactions. Moreover, each failed trial results in suffering and possible worsening of a person's condition. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who don't and their treatment typically costs about 50 percent more than it would have if they'd been allowed to continue taking a medication that has already been deemed appropriate.[3]

Not ensuring continuity of care for dual eligibles will greatly increase costs. Dr. Michael Hogan, the former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, states that "[p]atients who are not adequately treated, or treated with the wrong therapeutic agent, tend to utilize more costly crisis intervention, inpatient hospital, and intensive case management services. They also will tend to be less adherent to prescribed medications from that point forward, even when a more clinically appropriate treatment regimen has been prescribed." A study of the overall medical costs and use of services among people who had mental illnesses and were uninsured revealed that continuity of medication therapy resulted in a 65 percent reduction in inpatient costs, a 55 percent reduction in emergency costs, a 23 percent increase in outpatient care and an overall mean cost savings of $166 per patient per month.[4] Fewer prescriptions are needed when access to medications is not limited, but increased restrictions are associated with more physician and emergency room visits, hospitalizations and prescriptions which become increasingly costly each year.[5]

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[2] In a letter to Dr. Mark McClellan, Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, advises that "[a]ppropriate continuity of care provisions for *psychiatric medications for dual eligibles* are critical and needs to be considered in the development of this program. It has been shown that once a patient has evidence of successful response to a particular medication or treatment regimen, switching the treatment without clear clinical indication is deleterious."

[3] Hensely, PL and Nurnberg, H.G. (2001). Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls. *Pharmacoeconomics*, Vol. 19, No. 10, pp. 973-982.

[4] Del Paggio, D., Finley, P., and Cavano, J. (2002). Clinical and economic outcomes associated with Olanzapine for the treatment of psychotic symptoms in a county mental health population. *Clinical Therapeutics*, 24.5, 803-817.

[5] Horn, W. Unintended Costs and outcomes: The Fiscal Case for Open Access. *Drug Benefit Trends*, Vol. 15, Supplement 1.

Moreover, it is clear that **Congress was concerned with ensuring access to psychiatric medications under the new Part D benefit**. The conference report states 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] This type of cost to the system can be cited in disease after disease category. It is clear that CMS needs to find a way to ensure continuity of care for all of those with pharmacologically complex conditions.

The regulations do provide a special enrollment period for dual eligibles to use "at any time" (§ 423.36). However, this provision as written is inadequate to meet the special needs of dual eligibles.

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 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 extremely 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. As Michael Hogan stated in a letter to Dr. McClellan, "*patients with significant psychiatric illness, especially those that are disabled as a result of their illness, have an extremely limited capacity to navigate [grievance and appeals] procedures*." Dr. Hogan also *urges CMS not to rely on the existence of grievance and appeal processes as a substitute for open formulary access to medications.*[6]

In final regulations, CMS must address these issues to ensure continuity of care for dual eligibles as they transition to the new Medicare prescription drug program, and to ensure that they are not made worse off under the new Part D benefit.

- **The Regulations Must Honor Congress and the Administration's Promise to Dual Eligibles**.

Congress and the Administration have 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** just as a number of states have done in implementing preferred drug lists for their

[6] See note 2 supra.

Medicaid programs. For the very vulnerable dual eligible population, for those with life-threatening diseases, such as HIV/AIDS, mental illness, cancers, and other extreme conditions (groups which could be classified as having pharmacologically complex conditions), drug plans must be required to cover their existing medications. At a minimum this protection should be given to the dual eligibles who have so few financial resources. Higher reimbursement for this coverage could be based on "allowable and allocable costs" as CMS has proposed to pay fallback plans. Increased federal payments are warranted as coverage of the full array of mental health medications by these drug plans will prevent increased utilization of more costly inpatient and outpatient services and resulting increases in Medicare Part A and B costs.

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*. Again, increased payments for drug plans based on "allowable and allocable costs" as proposed for fallback plans is warranted to account for the savings to Medicare Parts A and B that will result from ensuring access to needed mental health medications. A more detailed discussion of this alternative flexible formulary proposal can be found in our comments on section 423.120, Access to Covered Part D Drugs.

Section 423.34, Enrollment Process.

423.34 (d), Enrollment of 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. **States opting to conduct auto-assignment should receive full federal financing** for this function given the MMA's explicit directive for the Secretary to accomplish this function. *See* 1860D-1(b)(1)(A) and (C). CMS should not require all states to perform the auto-assignment task, however, because some states may lack the capacity to complete it in an acceptable manner. CMS will therefore have to develop its own systems to automatically enroll dual eligibles in states that do not elect to perform the auto-enrollment.

However, this is an additional and considerable burden on the states and the structure of the program with its "clawback" provision builds in a financial disincentive for states to maximize enrollment in Part D. Under the law, the "clawback payment" will be based on the number of dual eligibles enrolled in the new Part D benefit: the fewer

enrolled, the smaller the giveback to the Federal government. To blunt that disincentive and to maximize enrollment, a*dministrative payments to the states for autoenrollment must be adequate* and must be sufficient to counter the built in financial disincentives inherent in the "clawback" provision. We urge CMS to **reimburse the states for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.**

In addition, regardless of which entity performs the autoenrollment, the regulations should specify that when beneficiaries are automatically enrolled in plans, CMS will inform the beneficiaries clearly about the plans in which they have been enrolled, as well as their right to choose a different plan and where they can get assistance to do so.

423.34(d)(1), Enrollment requirements for full benefit dual eligibles, timing between end of Medicaid's benefit and automatic enrollment.

The NPRM 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^{t}, 2006. However, Medicaid's drug benefit for dual eligibles will end on January 1, 2006.

Given the challenges of both informing and educating dual eligibles about the program, as well as the considerable enrollment challenges, it is likely that a substantial number of dual eligibles will not enroll before January 1, 2006. Because of the gap between the end of Medicaid coverage and the initiation of automatic enrollment, it is highly likely that **there will be a substantial number of dual eligibles confronting a nearly five-month period with no drug coverage at all**. This would be a considerable hardship for this vulnerable population and could have serious health consequences for many dual eligibles.

We strongly recommend that transfer of drug coverage from Medicaid to Medicare for the dual eligibles be delayed for *at least* six months, but preferably a year, 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. Should this require legislative authority, the Secretary should request the appropriate legislative action.[7]

[7] Even if automatic enrollment were completed before January 1, 2006, delaying the transition of drug coverage from Medicaid to Medicare for dual eligibles is necessary. To avoid a disastrous gap in coverage, automatic enrollment of dual eligibles in Part D plans must be complete no later than January 1, 2006. And because beneficiaries who are automatically enrolled will need time to be informed about their new drug plan and to change plans if necessary, automatic enrollment will have to take place several weeks earlier. Therefore, for dual eligibles, the actual period during which they will be able to select a plan will be considerably shorter than the six weeks from November 15 to December 31, 2005. Forcing dual eligibles to choose a drug plan in such a short time is unfair to beneficiaries who are at risk of being made worse off by the change to Medicare Part D.

In the absence of a delayed transition for drug coverage, we believe the least harmful approach would be for dual eligibles to 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 (see our proposed definition of "random" in section 423.34(d)(2), below). 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, even before plan information is released on October 15, 2005, states can begin profiling individuals' drug history to prepare for random auto-assignment among plans that are appropriate for the individual. Additionally, it is critical that *CMS must fund a massive campaign of individualized counseling and assistance both before and after auto-enrollment* to a) explain to individuals their choices and how to enroll in a plan, b) if applicable, explain how to get benefits under the plan to which they have been auto-assigned and c) 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 (see also our suggestions on information and outreach for dual eligibles under section 423.48).

423.34(d)(1)(ii), Enrollment requirement for full benefit dual eligibles in MA plans. It is essential that CMS develop an adequate solution to the issue of automatic enrollment and 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 their medical care. Forcing a dual eligible to choose between continued MA enrollment, paying added premiums, or foregoing drug coverage is inherently disruptive.[8]

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 define "on a random basis" in this section as "among all such plans in the region that meet the beneficiary's particular drug needs."

Section 423.36, Enrollment Periods.

423.36(c)(4), Special Enrollment Periods and Dual Eligibles.

[8] Although absent a statutory change we do not have a comprehensive solution to the problem, we have suggestions to assist some beneficiaries. For institutionalized duals enrolled in an MAPD plan whose premium is higher than the fully-subsidized premium amount, the difference between the premium and the premium subsidy should be considered an incurred medical expense and deducted from their monthly share of cost to the facility. For non-institutionalized duals in such situation, in states where SPAPs will wrap around Part D coverage and will cover duals, SPAPs should be authorized to pay the difference. Or, for medically needy folks, 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 MAPD back into original Medicare.

We support granting dual eligibles special enrollment periods. However, this provision does not adequately address the needs of dual eligibles. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare+Choice plans in the past. In addition, these individuals will not have the resources to pay more in premiums 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.

Section 423.48, Information about Part D.

- **Information plans must provide**.

This section states that "each PDP and MA-PDP plan must provide…information necessary" to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient.

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. **In addition, CMS needs to require plans to make information available in alternative formats for people with disabilities and in languages other than English** to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. CMS should continue to make the information available upon written request and through 1-800-Medicare. We urge CMS to continue to work to improve these information sources, as they sometimes are difficult to use by consumers.

Minimal information plans should be required to provide.

While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on

the benefit itself that potential enrollees will need in order to make a choice among plans. That should be specified in this section. Specifically, beneficiaries will need to understand:

- 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 copay 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.

- Appeals and grievance processes.

- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans. Plans should also be required to provide this information to potential enrollees. Therefore, we urge that CMS specify the minimal information that plans will need to provide. As noted, the guidance provided by CMS is insufficient. Specifically, we urge CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees, who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. We urge CMS to require plans to publish, as part of their marketing materials, price information. This could be provided in a manageable format.

For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish in a standardized format, and post on the Internet, their negotiated price for each of those drugs. Such a list would be easy to prepare and take only about one page in marketing materials.

- **Information and outreach for dual eligibles.**

In the preamble, CMS states that "prior to [this] automatic enrollment process, a widespread education and information campaign (described later in this subpart at Section 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled" (Federal Register, Vol. 69, No. 148, Tuesday, August 3, 2004, Proposed Rules, page 46638). Such an education and information campaign targeted to dual eligible individuals and that does equip them to select among plans and enroll prior to automatic enrollment is critical. However, the proposed regulations fall far short.[9]

The regulations should include specific requirements for plans and states, as well 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. Extensive outreach and assistance has helped limit the need for default enrollment in Medicaid managed care programs. The states or CMS must also involve community-based organizations and providers that serve and work with dual eligibles in this enrollment process. CMS should offer grants and other resources to help these organizations and providers inform dual eligibles of their choices and what they need to do to sign up. These organizations can provide culturally appropriate outreach and assistance to help duals find the best plan available to them and let them know that they can switch plans through the special enrollment provision in § 423.36 if they have been automatically enrolled in a plan that is not the best for them.

In addition, as early as possible, and no later than October15, 2005 (assuming information is available as recommended in 423.34(d), above), CMS or the states **should mail standardized, easy-to-understand notices to dual eligibles** that, among other things: (i) inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA; (ii) list choices of health plans (clearly denoting those that meet the benefit premium assistance limit) and contact information for each plan; (iii) 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; (iv) explain how they may change their drug plans if they wish at any time; and (v) inform them of locations in their community where they can go to get help with enrollment. These notices should be tested for readability by focus groups and

[9] In the preamble, CMS discusses education and information materials that it will provide to beneficiaries. This discussion focuses on support through the Internet sources and the 1-800-Medicare number. Both are necessary but, as noted above, insufficient to meet the needs of the Medicare population and particularly insufficient to meet the education and information needs of dual eligibles. This is a difficult to reach population with limited Internet access and, in many cases, limited telephone access. Further, the NPRM does not outline any requirements for meeting the needs of this population in the proposed Section 423.48.

experts. If the states are required to provide this information, CMS should reimburse 100 percent of the states' costs.

II. Subpart M—Grievances, Coverage Determinations and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution and to satisfy the requirements of the statute. This failure is especially troubling for low-income beneficiaries, including dual eligibles.

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. 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.** CMS should 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. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, 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.

Section 423.560, Definitions.

This section defines "appeal" to exclude grievance and exceptions processes, and defines "authorized representative" as someone authorized by 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 also act on behalf of an enrollee in exceptions and grievances.

Section 423.562, General provisions.

Section 423.562 (c)(1).

This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing. The section should clarify *that a low-income institutionalized individual can appeal a determination, even if he/she has no co-payment responsibilities.*

Section 423.562 (c)(2).

This subsection may preclude an enrollee from challenging a plan's determination that it has no obligation to cover a drug received from a non-network pharmacy and should be deleted. As stated elsewhere in these comments, the actual regulatory language in 423.124 does not establish clear criteria as to when a plan must cover drugs received from non-network pharmacies. Thus, there is no guarantee that plans will interpret the regulation as CMS describes in the preamble. Taken together, proposed 423.124 and 423.562(c)(2) place at risk vulnerable individuals such as those in institutions whose purchases from long-term care pharmacies are all treated as if they are from a non-network pharmacy.

Section 423.566, Coverage determinations.

Section 423.566(b).

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.

Section 423.568, Standard timeframes and notice requirements for coverage determinations.

- **Timeframes.**

Section 423.568(a).

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.

Section 423.568(b).

This section should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

- **Notice.**

Section 423.568(c).

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 Missouri, the pharmacy is usually the entity that 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** (see the discussion below regarding the procedures that were recently adopted in Florida as a result of the settlement of a lawsuit). 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.

- **Content of the notice (Applies also to 423.572(d))**.

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 the following:

- Notice about exceptions and appeal rights should be presented immediately upon denial (including upon determination that drug is not covered on formulary and including by pharmacist) and should explain why coverage was denied and options for obtaining necessary medications as well as appeal procedures.

- Notice should include clinical or scientific basis for denial.

- Notice should be available in multiple languages and the availability of language services noted (see below).

- A recently settled Florida class action lawsuit filed on behalf of Medicaid recipients determined that the state had not provided written notification to people whose prescription coverage was denied of their right to appeal the decision. The settlement's provisions require the state to provide:

    - Written notification that explains why the coverage request was denied
    - Information on how to resolve the issues that triggered the rejection
    - Instructions that explain how consumers can request an appeal
    - Steps 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).[10]

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. We support the August, 2000 HHS OCR guidance on how programs can meet their Title VI obligations to provide written materials in 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.

Section 423.570, Expedited consideration.

423.570(a).

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.

[10] See http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/multi_source.shtml, for an example of information Florida pharmacies must provide when they deny a prescription under the Florida Medicaid program.

423.570(c).

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 time frames 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.

Section 423.572, Times frames and notice requirements for expedited coverage determinations.

Section 423.572 (b).

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 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.'

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 NPRM what notice a beneficiary will receive when sometime during the year a plan changes its formulary and the drug(s) it covers. (This is

also discussed in the next section.) The statute says plans must make the change in information available on the internet, the Preamble discusses a mailed notice, and the NPRM 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.

Section 423.578, Exceptions process.

Overall, the exceptions process does not comply with the statutory requirements or meet the basic elements of due process.

- **Notice**.

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 (pg 46661), the regulatory language just says that notice must be given, and the statute requires posting on the Internet.

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 reasons why a drug is not included on/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 to 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), Plan criteria.

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 regulations propose 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, for example :

- Consideration of the cost of the requested drug compared to the cost of the preferred drug has no bearing on whether a drug would not be as effective or would have adverse effects and should not be a consideration.

- Consideration of whether the formulary includes a drug that is the therapeutic equivalent also is not relevant to the statutory standard. The FDA requires that 80 percent to 125 percent of the medication be the same to be considered "therapeutically equivalent." Treatment for certain conditions, including mental illness, is highly individualized given the non-interchangeability of many medications even within the same class, the high degree of variability in how these diseases present themselves in terms of symptoms, and the many other factors that must be taken into account, including overdose lethality in light of heightened risk of suicide. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the deciding factor.

- Consideration of the number of drugs in the plan's formulary that are in the same class as the requested drug, for the reasons stated above, also is not to the determination of the treating physician that the requested drug is needed.

Inadequate guidance for physicians: The proposed rules fail to provide adequate guidance concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or cause adverse effects has been met.

- The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug <u>would</u> not be as effective or cause adverse effects. The statute does not support allowing 'fail first.' In

fact, for many enrollees, a fail first requirement in and of itself would cause adverse effects. A fail first standard might apply if the statute required the doctor to certify that the drug is not as effective or causes adverse effects.

- The regulation says that the plan sponsor "may require the written certification to include only the following information…" Given that the statute requires a determination by the doctor that the preferred drug would not be as effective, would cause adverse consequences, or both, plans are going to require some kind of written statement. However, the regulation should limit the statement only to the statutory standard. It should read "The sponsor may only require the written certification to include the following information."

- The preamble states that a PDPs exceptions process also would have to describe how a determination on an exception request would affect the enrollee's cost-sharing under the PDP's tiering structure. 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 criteria, which were omitted:

- Rule permitting continued access to a drug at given price when there is a mid-year formulary change.

- 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.

- **Exceptions involving nonformulary drugs**

423.578(b) defining formulary use, **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." (p. 46720). **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"** (p. 46721). 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 criteria and process described in 423.578(b)(2) will make it impossible to get an exception. The process is not transparent, as is stated in the preamble (pg 46720), because it is left totally to the discretion of each plan. We urge CMS, and not each individual plan, to establish the criteria for evaluating the request. 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.

The regulations must also establish standard criteria that plans must use in evaluating a prescribing physician's determination that any on-formulary drug would not be as effective or would cause adverse effects. In addition, independent review entities must be charged with reviewing plan criteria to ensure that they comply with these federal standards and implement the statutory standard requiring that the prescribing physician determine that all on-formulary drugs would not be as effective or have adverse effects.

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.

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.

The regulations need to establish fixed criteria for evaluating the prescribing doctor’s determination that using all formulary drugs would not be as effective or would cause adverse consequences to the enrollee. Requiring this amount of evidence would make it

impossible to meet this standard. Instead the regulation 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 plan 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 older people, people with disabilities, and people with co-morbidities. While some such evidence exists, there may not be this level of evidence for all drugs and conditions. Again, the regulations should require the certificate to meet the statutory standard (not as effective or adverse effects or both) rather than include information why the "preferred drug" is not acceptable for the enrollee. The criteria should recognize a physician's experience in evaluating whether the statutory standard is met.

- For dosing exceptions, the regulation states the standard is a showing that the number of doses that is available under a dose restriction for the prescription drug has been ineffective or based on both sound clinical evidence and medical and scientific evidence the drug regimen is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. The standard should include "or cause an adverse reaction or other harm to the enrollee".

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, et.) and packaging, such as bubble wraps for long-term care facility residents.

423.578(b)(4) again says a PDP sponsor "may" require a written certification. The language should be that the sponsor "may only require the written certification to include the following information. Again, the standards are very high. The list of information is too long and is repetitive; the doctor should only need to explain why the drug that is the subject of the exception request is needed for the enrollee [(b)(5)(iv)(D)], and not all of the previous provisions.

423.578(c)(2) Continuation of drug pending review.

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 (less if they could show the decision needed to be made more quickly because of their condition.) Most people wait to the last minute to refill a prescription, often because of drug plan and pharmacy restrictions.

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 want to stress the importance of drug coverage and ensuring no gaps in the uptake 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.

- **Notice.**

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 concern 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 deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed

provisions raise the 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)).

Section 423.580, Right to a redetermination and Section 423.584(a), Expediting certain re-determinations.

The enrollee's authorized representative should also be able to request a re-determination or an expedited re-determination (See also Section 423.584).

These 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 then disallow an enrollee's representative from pursuing 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".

Section 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: (1) the reason for the denial, including the medical and scientific evidence relied upon; (2) the right to request review or expedited review, to the IRE, including timeframes; and (3) the right to submit evidence in person and orally.

Section 423.586, Evidence for a re-determination.

The regulations should establish clear criteria for informing the enrollee and the doctor that they can submit evidence in person, as well as clear procedures for in-person review.

Section 423.590, Timeframes.

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. We reiterate our 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.

Section 423.600, Reconsideration by the IRE.

Role of the 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 (**pg. 46721**) 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 of 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.

- **Requesting the reconsideration.**

Since the Part D process is supposed 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, we dispute 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 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 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), Requirement to solicit view of treating physician.

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 Medicare Advantage independent contractors are often reluctant and often 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, face-to-face meeting.

423.600(d),Timeframe.

The regulations need to establish a set time frame 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. 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.

Section 423.602, Notice of reconsideration.

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.

Section 423.610, Right to an ALJ Hearing.

Congress recognized the special needs of the low income, and how even small copays 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.

We are 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 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, when the plan denies coverage, in order to satisfy the jurisdictional amount.

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 amount is in August, will you still be timely? Or does it have to be 60 days from the first denial in April?

Section 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 ALJs 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, including any doctor's statements, statements by the enrollee, and other evidence submitted by the enrollee, including information not relied upon in making its decision. It has been our experience that contracting entities often omit evidence submitted by the enrollee when transferring a file to the ALJ or other level of review.

Section 423.634, Reopening and revisions determinations and decisions & Section 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. This is totally unacceptable, since further delays may cause increased health consequences to people who foregone

medication pending appeal. Favorable decisions should be implemented in the same 72 hour time period as reversals at earlier levels of review.

III. 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.**

We have 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.

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." **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.

We also strongly recommend that the final rule 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. 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.

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.[11]

Further, 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 consumers who have been stabilized on a particular psychiatric medication to switch to another medication can be very dangerous for the consumer 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

[11] For example, after the state of Michigan implemented a restrictive preferred drug list for its Medicaid program, a hotline was established for consumers and providers to report their experiences: sixty-six percent reported medication delays or said they had suffered negative consequences after being forced to switch medications (*Report on Prescription Access Hotline, April 22 – June 14, 2002*, Mental Health Association in Michigan and Michigan Association for Children and Families, February 2003).

exception request, and plans should be prohibited from discontinuing access to all drugs in the regimen pending final resolution of the appeals process.

In a very recent report entitled "Psychiatric Medications: Addressing Costs without Restricting Access" (August 20, 2004), CMS encourages State Medicaid Directors to implement innovative approaches to controlling costs without restricting access. CMS must encourage Part D prescription drug plans implementing the Medicare drug benefit to implement these same cost management techniques as alternatives to the more common approaches that restrict beneficiary access to medications. 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). They 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.

IV. Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

Section 423.904, Eligibility determinations for low-income subsidies

Section 423.904(b), Notification to CMS. The rule should direct states to notify CMS of eligibility determinations within 24 hours of making them. As noted in our comments to Subpart P, a similar provision should be included in 423.774 with respect to SSA determinations.

Section 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, proposed § 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 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 Section 1935(a)(3) established in Section 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.

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 should direct states to apply the definitions of resources used in Subpart P, section 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 confusing beyond repair 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, SSA should also screen subsidy applicants for eligibility in MSPs, and develop a system, in conjunction 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.

Screening and enrollment for full Medicaid

We believe that 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 (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program (SCHIP) 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 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.

Screening for other public benefits

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 in 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. In particular:

- Outreach materials that SSA and CMS/State Medicaid programs design should contain information about other major benefits for which applicants may be eligible;

- Applications that are filed and other information that applicants provide should be easily shared between SSA, state agencies, and CMS so that it is available to all agencies and duplication of effort can be avoided;

- The federal agencies involved (USDA, CMS, and SSA) should make it a priority to enroll all eligible applicants in all benefit programs. In addition, these agencies should seek to simplify federal program rules so that Medicare beneficiaries can easily 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 additional questions and are certified automatically for food stamps based on their SSI applications.

Section 423.904(c)(3), Notification.

The section refers to 423.34(d) with reference to notifying individuals deemed subsidy eligible, but 423.34(d) discusses automatic enrollment of full benefit dual eligibles in Part D plans. Notification of deemed subsidy eligible individuals of their entitlement to a subsidy is a different matter from enrollment in a Part D plan. This reference appears inapt. As discussed in our comments to section 423.773, those who are deemed subsidy eligible need immediate notification of that status and of the fact that they need do nothing more with respect to their subsidy, but that they need to enroll in a Part D plan in order to use the subsidy.

Section 423.904(d)(3), The application process and States.

As written, the rule permits states to impose more burdensome documentation requirements on beneficiaries than could SSA. This is counter to the principle of simple enrollment underlying the statue. In addition, states should not be permitted under the cost-effectiveness provisions of section (d)(3)(ii) to transfer the costs of verification to beneficiaries by requiring visits to state Medicaid offices and production of additional documentation. Section (d)(3)(i) should be changed to read: "States may require submission of statements from financial institutions for an application for low-income subsidies to be complete *only if the applicant or personal representative is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information"* (suggested additional language in italics).

Section 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.

V. SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

423.120(b), Requiring P&T committee decisions regarding the plan's formulary to be binding on the plan.

We strongly recommend that the final rule ensures that 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.[12]

423.120 (b)(1), Requiring certain P&T committee members to be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers.

We support the proposal in the proposed rule to ensure that the final rule interprets the requirement that certain P&T members be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers. The essential function of the P&T committee 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.** The final rule must include far stronger provisions than are found in the proposed rule 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

[12] We also believe 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, we will make clear that we have 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 plan financial considerations and it must reinforce the independence and broad-based clinical expertise of P&T committees.

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 expand on the MMA's requirements for independent expertise in the care and treatment of the elderly and people with disabilities. Because of their unique experience at serving institutionalized populations, a significant subset of the Part D eligible population, the final rule should expand the P&T committee requirement to also include members who are independent LTC pharmacists.[13]

- **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 public. The final rule should require P&T committees to hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies. The final rule should specify that meetings of the P&T committee should be open to the public. Further, 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 disabled populations.

- **Timely Review:** The final rule must require P&T committees to meet at least quarterly, and have processes for making formulary revisions between regularly scheduled meetings when new clinical information or FDA approval of medications occurs that could be used for the treatment of life threatening conditions.

[13] At a minimum, 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. Notwithstanding the size of the committee, it will not be possible for any committee to have adequate expertise in all areas. Therefore, 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.

423.120(b), Formulary requirements.

We have many concerns related to formulary requirements:

- **Ensuring that no category or class is approved in the USP model guidelines for which there is no FDA approved drug and which would have to include a drug based on an "off-label" indication.**

We disagree with CMS's 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 prescribers to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

While we understand concerns by CMS that certain pharmaceutical manufacturers may violate federal law by marketing drugs for off-label uses, 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 strongly 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.

- **Recommendations for preventing access barriers to for covered Part D drugs for off-label uses.** We strongly recommend that the final rule include a clear prohibition that prevents plans from denying coverage for a covered part D drug solely because it is prescribed for an off-label indication. We are deeply concerned that while the MMA clearly permits plans to cover covered Part D drugs for off-label indications, financial incentives could lead plans to inappropriately restrict coverage for off-label uses. As stated previously, off-label prescribing has become a common practice across a broad spectrum of clinical conditions. In enacting the MMA, Congress did not carefully consider issues related to off-label prescribing and it would be improper to implement the MMA in a way that removes the ability of treating physicians to prescribe the full pharmacopoeia of FDA-approved medications when medically necessary.

- **Standards and criteria for determining that a PDP sponsor or MA organization's formulary does not discriminate against certain classes of Part D eligible beneficiaries when using a classification system not based on the USP model guidelines.**

CMS has stated that it will not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. We urge CMS to interpret "groups" to extend beyond health status. In particular, there is a growing body of evidence that highlights racial and ethnic differences in responses to specific drugs. We urge CMS to ensure that evaluate plan formularies for their impact on racial and ethnic groups, in addition to other "groups" for whom group status may be unrelated to health status.

CMS has acknowledged that, "prior authorization techniques include clinically appropriate step therapies or diagnosis-related restrictions." **We also strongly recommend that CMS publish in the final rule a list of conditions for which it is *clinically inappropriate* to require step therapies.** For guidance on developing such a list, we recommend that CMS consider the experience of many state Medicaid programs. In most states employing fail-first or step therapy requirements, clinical experience has led many states to exempt certain conditions, including mental illness and HIV/AIDS.

- **Special treatment for specific populations and defining which specific populations to include.**

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 that could create insurmountable access barriers. We recommend that the final must provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs with a valid prescription. 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. According to a Metlife survey, in 2002, the average monthly cost of a private room in a nursing home was $5,110 and the average monthly cost of a semi-private room was $4,350.

- **Persons with Life-Threatening Conditions:** Persons with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening need to have unrestricted and affordable access to the full range of available treatments. Protections in the MMA intended to ensure that beneficiaries will have access to all needed medications are inadequate for persons with life-threatening conditions. For example, the MMA requires P&T committee 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. For example, research shows that different antipsychotic medications affect different portions of the brain. The Report of President Bush's New Freedom Commission on Mental Health states that "any effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services" (New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in American; Final Report*, p. 26).

We recommend 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 and 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 critical dose drugs and 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.

- **Minimum timeframes for periodic evaluation and analysis of protocols and procedures related to plan formularies.**

We recommend that the final rule require plans to evaluate and analyze their protocols and procedures related to plan formularies at least quarterly. For many conditions, every month brings significant advances in the clinical management of

disease making it essential that the final rule require regular ongoing and timely review of their formulary protocols and procedures.

- **Notification requirements for enrollees directly affected by a formulary change.**

The proposed rule provides notification provisions regarding formulary changes that are inadequate 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.

- **Recommendations for limitations on mid-year formulary changes.**

We 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. 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 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, we strongly recommend that plans 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.

Conclusion

It is critical that the new Medicare Part D benefit be implemented in a way that does not limit access to medically necessary medications for dual eligibles and other low-income beneficiaries. In final regulations, CMS should make as many modifications as it can to honor Congress' commitment to ensure that dual eligibles do not fare worse under the new Part D benefit than they do under Medicaid.

Thank you for the opportunity to submit these comments

Very truly yours,

Joel D. Ferber
Managing Attorney
Health and Welfare Unit

James Frost
Staff Attorney

CMS-4068-P-1100

Submitter : Mr. joe mastalski **Date & Time:** 10/04/2004 07:10:16

Organization : joe's lakeland pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

medicare rx services should be available to all patients at the same price no matter which pharmacy the PATIENT CHOOSES. THERE IS NO NEED FOR MAIL ORDER PHARMACIES. INSURANCE COMPANIES SHOULD BID FOR PBM SERVICES. all rx's should be limited to a month. generics should be mandated.IF YOU REALLY DESIRE THE BEST PHARMACY CARE FOR OUR SENIORS THEN THEY SHOULD BE ABLE TO SEE AND TALK WITH THE PHARMACIST OF THEIR CHOICE.
ALL PRICES BY ALL DRUG MANUFACTURERS SHOULD BE NEGOTIATED BY CMS. WHAT HAS BEEN GOING ON WITH MEDICATION COSTS INCREASING AND NOT TO HAVE CONTROL OVER THE COST IS LIKE A ENTITLEMENT WITH OUT COST CONTROLS, how bout offering social security and asking the benefiiciaries what ever they want. ?? the drug companies have had it too good too long. i am an independent pharmacy owner of 35 years.
joe mastalski

CMS-4068-P-1101

Submitter : Ms. Nancy Rhead **Date & Time:** 10/04/2004 07:10:18

Organization : advocate

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am responding as a parent of an adult with developmental disabilities who is supported by The Arc of Howard County.

CMS-4068-P-1102

Submitter : Peg Fikes **Date & Time:** 10/04/2004 07:10:45

Organization : Peg Fikes

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Peg Fikes
27651 Water Street
Chaumont, NY 13622

Dear Ms. Reuther

Are you aware that Medicaid does not charge a copay on psychiatric medications? There is a good reason for this. I am bi-polar, and will only isolate myself when I am not doing well. I do, however, know several people that will be in serious trouble if they go unmedicated. Do the courts and incarceration facilities have funding to take the potential problems that this lack of prescription coverage will cause?
Our family courts will be overflowing with abuse and child custody cases because supportive spouses will be dealing with unmedicated family members. Children with mental illness are already lacking in vital services. The money this legislation could cost is astronomical. .

I do have rights, and there are agencies in place to protect my rights.I have seen nothing on the news, and read nothing in the papers about this change. The timing on this makes it obvious that my rights are being circumvented.I worked 12-18 for several years, and would still be doing so, if I was able. I have spent years learning to accept that the career that I loved was over. The most pathetic aspect to this is that I worked with people with disabilities. I made sure that I protected their rights to the very best of my ability. Then I became disabled myself, and no longer have the strength or energy to defend my own rights.

I am now 51 years old. I take medications to control my cholesterol and my blood sugar. I have allergies. Fortunately, exercise and physical therapy usually make it possible to control my arthritis pain without the use of anti-inflammitory medication .The cost of my prescriptions will take a large portion of my income from SSI and SSD.

Thank you. I now have a choice between keeping my home, or dying here decades before I expected to.

I would like to receive a response to this question, otherwise, I will assume that you are not reading responses to this email.

Peg Fikes