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

CMS-4068-P-1103

Submitter : Dr. Merrill Matthews **Date & Time:** 10/04/2004 07:10:58

Organization : Council for Affordable Health Insurance

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached are our comments on the proposed revisions to Section 403.205.
Thank you for this opportunity

CMS-4068-P-1103-Attach-1.doc

The Council for Affordable Health Insurance

October 5, 2004

Mark McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014
Electonic submission via: http://www.cms.hhs.gov/regulations/ecomments

Dear Dr. McClellan:

We are writing you today to offer our expertise on the Medicare Supplemental Insurance market as discussed in CMS-4068-P, "Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule."

Established in 1992, the Council for Affordable Health Insurance (CAHI) is a research and advocacy association of insurance carriers active in the individual, small group, Health Savings Account and senior markets such as Medigap and long-term care products. CAHI's membership includes health insurance companies, small businesses, physicians, actuaries and insurance brokers.

Since our inception, CAHI has been an advocate for market-oriented solutions to the problems in America's health care system. We have an active Medicare Working Group which consists of experts who sell Medigap and/or long-term care insurance products, and actuaries actively involved in studying these markets. CAHI's Medicare Working Group has reviewed the proposed rule and would like to submit comments on the proposed revision to Section 403.205, the definition of a Medicare Supplemental Insurance (Medigap) policy.

In the opinion of our Medicare Working Group, the definition of Medigap could, through regulatory discretion, extend far beyond the current definition of Medigap. Members have advised us that there are several types of non-Medigap policies that, under the proposed regulation, would be redefined as Medigap plans. Examples include cancer, long-term care, stand alone prescription drug plans, property and casualty plans, major medical plans (those not HIPAA-related) as well as typical hospital indemnity plans. Our Medicare Working Group experts believe that the spirit of the law did not intend to redefine these types of policies, however, such a redefinition presents signficant operational challenges to companies due to what Medigap regulation entails.

Several of our Medicare Working Group members are also members of the American Academy of Actuaries (AAA) Working Group that submitted comments on this very issue. CAHI's concerns with

112 S. West Street, Suite 400, Alexandria, VA 22314 ◆ Phone: (703) 836-6200 ◆ Fax: (703) 836-6550
E-mail: mail@cahi.org ◆ Web Site: www.cahi.org

the redefinition of Medigap plans mirror those outlined in the AAA letter, and they are reiterated below –

- Plans annual filing and state-by-state review of rates—some of the non-Medigap policies mentioned above are not filed in every state in which they are sold;
- Many of these plans have underwriting limitations and guaranteed issue requirements imposed on them whereas the proposed Medigap rules will likely not be consistent with these products;
- Many of these plans have annual loss ratio calculations to be filed with the state departments of insurance to show that their company is in compliance with minimum loss ratio standards for existing and new blocks of business. The Medigap loss ratio standards and refund requirements could not be considered in the pricing of the such other products as listed above; and
- Medigap policies have standardized benefit designs—the aforementioned policies do not comply.

As a solution to these concerns, the CAHI Medicare Working Group suggests that CMS delete Section 403.205(c)(4). We believe this would resolve the issue of inadvertantly expanding the definition of Medigap and eliminate the resulting complications.

Thank you for the opportunity to work with you on this important issue.

Sincerely,

Merrill Matthews	Victoria Craig Bunce	Kelly O. Cates
Director	Research and Policy Director	Operations Director

CMS-4068-P-1104

Submitter : Mrs. Anne Erickson **Date & Time:** 10/04/2004 07:10:08

Organization : Greater Upstate Law Project, Inc.

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

I have attached our comments. Thank-you.

CMS-4068-P-1104-Attach-1.doc

Greater Upstate Law Project, Inc.

80 St. Paul Street, Suite 660, Rochester, New York 14604-1350; (585) 454-6500 Fax (585) 454-2518
VISIT OUR WEBSITE: WWW.GULPNY.ORG

October 4, 2004

Centers for Medicare & Medicaid Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Maryland 21244-1850

VIA EMAIL TO http://www.cms.hhs.gov/regulations/ecomments

Re: File Code # CMS-4068-P.

Comments Regarding CMS Proposed Regulation for the Medicare Prescription Drug Benefit under the Medicare Prescription Drug, Improvement , and Modernization Act (MMA)

Dear Madam or Sir:

The Greater Upstate Law Project, Inc. submits these comments regarding the proposed regulation for the Medicare's new, Part D, Prescription Drug Benefit.

The Greater Upstate Law Project has operated as a resource center for legal services across upstate New York and Long Island since 1974. Access to health care is a critical component of our mission to protect the legal rights of the poor and disenfranchised. As such, we are well-versed in the issues confronting low-income individuals in need of prescription drug services.

While we welcome the introduction of a new drug benefit to be financed with federal funds, we are gravely concerned about how implementation of this benefit will impact those low-income New Yorkers dually eligible for both Medicare and Medicaid. We are grateful for the opportunity to comment on the plan put forward in the Proposed Rule. Before moving to our specific comments related to individual sections of the Proposed Regulation, we have some general comments that relate to the entirety of the Regulation.

Many Pro-Consumer Comments in the Preamble Do Not Appear in the Proposed Rule. We are concerned that many statements in the Preamble that we support 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 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.

Community-based groups with historical expertise working with the unique needs 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) 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. It is to these organizations, that beneficiaries with disabilities know and trust, 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 that incorporates 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-DPs 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 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.[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

[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.

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]

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 exceptions process as a means of securing coverage of off-formulary medications (Section M, Appeals and Grievances; our concerns with specific language in that Section 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

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[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.

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 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 (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 for a year, by no less than six months but preferably a year. 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 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 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 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 MAPD 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(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, 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 you and may in fact be an indication that one is 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 cognative 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, 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 program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. We see from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them.

We disagree with CMS' observation that healthy beneficiaries will not apply; we believe that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness and cognitive disabilities. The Medicare Part D program is new and confusing. We know from the experience with the Medicare endorsed discount card that people delay enrollment in a drug card because they do not understand the program and find the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

Alternatively, implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy. Again, individuals may not understand that they have to apply separately for the subsidy and a drug plan, and may think application for the subsidy is sufficient.

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complications.

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**. CMS should incorporate an enrollment "grace period" for individuals with disabilities. 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 disabilities, 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 this population.

- **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 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. 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.

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.

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 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.

- 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 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).

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 add to the following critical points for information to the requirement that plans make available—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 that 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 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.

All of the information outlined above information 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.

[4] See Lori Racki, *Medicare Scams Prey on Seniors*, Chicago Sun-Times, News Special Edition at 8 (May 24,2004).

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. 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 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

[5] H.R. CONF. REP. NO. 108-391, at 432 (2003).

would actually be useful in determining which plan to select. We recommend the following in the disclosure of identifiable information:

- 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 (option 3 of the options provided in the preamble to the proposed rule). 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.

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.

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 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 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.

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 rebats, 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.

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 will 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.

1860D-11(e)(2)(D) authority to review plan designs to ensure that they do not substantially discourage enrollment by certain Part D eligible individuals.

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(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), 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.

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 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 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 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.

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) are in every instance clinically inappropriate and irresponsible, given the serious public health implications of shifting prescriber behavior in this context 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.

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 statyus.

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 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.

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 provisions in the proposed rule 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 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.) Morever, 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, however, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual. Based upon experience with the Medicare+Choice market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

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 b e met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

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 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.

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 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 error rates.
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 market shape these programs. We disagree with this reliance on the market to set required parameters for the required MTMPs. We do not believe that stand alone prescription drug plans have sufficient incentives 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 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 statutes 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.

Subpart F -- SUBMISSION OF BIDS AND MONTHL 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.

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 PAPs 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 M—GRIEVANCES, COVERAGE DETERMANTIONS 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. The regulation also fails to satisfy the requirements of the statute. ***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 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.

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.

The processes described in Subpart M of the proposed regulation also fail to comply with the MMA. 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.

Section 423.562 (c)(1).
This subsection precludes an enrollee who has no further liability to pay for prescription drugs from appealing when she has no further liability to pay for the prescriptions. The section should clarify that a low-income institutionalized individual can appeal a determination, even if 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. 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).

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, 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).

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 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).

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.

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.

(See comments above re content of notice.)

Section 423.572 (b).
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 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 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 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 <u>orally</u>, 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 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, 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 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 eligibility 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 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.

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.

Section 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

Section 423.773(b), Full subsidy eligible individual. The indexing of resources should indicate that rounding is always up to the next multiple of $10.

Section 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 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.

Section 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.

Section 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

Section 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.

Section 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.

Section 423.774(c), Redetermination and appeals of low-income subsidy eligibility

[6] Rachel Klein, "Creative Solutions: Presumptive Eligibility" *The Future of Children* 13, no. 1 (Spring 2003): 230-237.

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.

Section 423.774(c), Redetermination Periods. 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.

Section 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 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 under a medically needy program. 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 423.800, Administration of Subsidy

Section 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.

Section 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 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(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.

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.

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 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, 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 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.

Thank you for the opportunity to submit comments.

Sincerely,

Anne Erickson
Executive Director

Submitter : Sister Mary Coleman **Date & Time:** 10/04/2004 07:10:45

Organization : St. Mary's Residential Training Facility

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

October 4, 2004

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

RE: Comments relating to Medicare Part D proposed regulations - 69 Fed. Reg. 46632 (Aug. 3, 2004).

I support the comments submitted by Voice of the Retarded (VOR). We feel strongly that:

The definition of !?long term care facility!? must include Intermediate Care Facilities for Person with Mental Retardation (ICFs/MR).

* 'Institutionalized' should include all individuals eligible for ICF/MR placement, including current residents, home and community-based services (HCBS) waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

The regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives.

Thank you for your consideration.

Sincerely,

Sr. Mary Coleman, OLS
Administrator
St. Mary's Residential Training Facility
P. O. Drawer 7768
Alexandria, Louisiana 71306
(318) 445-6443
(318) 449-8520
srmarysmtf@hotmail.com

CMS-4068-P-1106

Submitter : Ms. Janet Astle **Date & Time:** 10/04/2004 07:10:06

Organization : Ms. Janet Astle

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. Please see comments as follows:

Subpart C Benefits and Beneficiary Protections
Requiring plans to provide patients fair access to their pharmacy was part of Congress' original intent. Therefore, the pharmacy access standard should be revised to meet the TRICARE requirements on a local level (not the plan's overall service level). All beneficiaries should have convenient access to a local pharmacy. Allowing plans to designate "preferred" and "nonpreferred" providers could give plans the ability to drive beneficiaries to one particular pharmacy. Therefore, it is important to count only "preferred" pharmacies when evaluating whether a plan's network meets the pharmacy access standard. This more closely meets the "any willing provider" language of the proposed regulations and provides beneficiaries with more realistic access AND choice.

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

I appreciate CMS' recognition that pharmacists will be the primary providers of MTM services. To that end, plans should be required to notify pharmacists regarding who among their patients are eligible for MTMS. Also, plans should be required to notify beneficiaries when they are eligible for MTMS in addition to providing a list of those pharmacies which offer such a benefit. Finally, patients with two or more chronic diseases should qualify for MTMS. Pharmacists and physicians are in a prime position to identify eligible beneficiaries.

Thank you for considering my comments.

Submitter : Dr. STEPHEN PIERCE **Date & Time:** 10/04/2004 07:10:49

Organization : NORTHSIDE HOSPITAL

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

DEAR SIR OR MADAM:

THANK YOU FOR THE OPPORTUNITY TO COMMENT ON THE PROPOSED REGULATION TO IMPLEMENT THE MEDICARE PRESCRIPTION DRUG BENEFIT. ALTHOUGH MY PRIMARY WORK PLACE IS A HOSPITAL PHARMACY, I WOULD LIKE TO OFFER THE FOLLOWING COMMENTS FOR YOUR CONSIDERATION AS CMS DEVELOPS THE FINAL REGULATION.

I AM CONCERNED ABOUT BENEFICIARY ACCESS TO COMMUNITY RETAIL PHARMACIES. I FEEL THAT EVERY BENEFICIARY SHOULD HAVE ACCESS TO ANY PHARMACY THEY CHOOSE AND THAT ANY PHARMACY SHOULD HAVE EQUAL OPPORTUNITY TO PARTICIPATE. THIS INCLUDES MAIL ORDER PHARMACIES. BENEFICIARIES SHOULD BE ABLE TO CHOOSE WHERE THE OBTAIN THEIR MEDICATIONS AND COMMUNITY RETAIL PHARMACIES SHOULD BE ALLOWED THE SAME ADVANTAGES AS MAIL ORDER PHARMACIES.

THERE SHOULD ALSO BE MULTIPLE DISPENSING FEES BASED ON THE AMOUNT OF TIME NEEDED TO PREPARE/COMPOUND THE MEDICATIONS.

AS FOR MEDICATION THERAPY MANAGEMENT PROGRAMS, THERE SHOULD BE STANDARDS THAT MUST BE MET TO PARTICIPATE AND THESE SHOULD BE REIMBURSED AS APPROPRIATE DEPENDING ON THE LEVEL OF MANAGEMENT PROVIDED.

THANK YOU FOR CONSIDERING MY COMMENTS

SINCERELY,

STEPHEN S. PIERCE, DPh.
224 MAY FIELD DR.
ELIZABETHTON, TENNESSEE 37643
PIERCESS@MSHA.COM

CMS-4068-P-1108

Submitter : Mr. John Arlotta **Date & Time:** 10/04/2004 07:10:30

Organization : NeighborCare, Inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

NeighborCare is submitting specific, detailed comments on the rulemaking which are contained in the attached letter and memo.

CMS-4068-P-1108-Attach-1.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

601 East Pratt Street, 3rd Floor Baltimore, Maryland, 21202-6000
Tel 410.528.7300 **Fax** 410.528.7377

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.

[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.

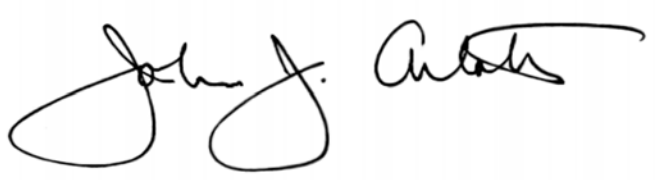
14. Prompt Payment – There is no provision in the rule requiring plans to pay providers promptly.

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.

CMS-4068-P-1109

Submitter : Mr. David Czekanski **Date & Time:** 10/04/2004 07:10:09

Organization : Massachusetts Group Insurance Commission

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attached

Issues 1-10

BACKGROUND

See attached

CMS-4068-P-1109-Attach-2.doc

CMS-4068-P-1109-Attach-1.doc

CMS-4068-P-1109-Attach-1.doc

CMS-4068-P-1109-Attach-2.doc

October 4, 2004

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

By email to: www.cms.hhs.gov/regulations/ecomments

Comments on file code CMS-4068-P

Dear Sirs:

The Commonwealth of Massachusetts Group Insurance Commission appreciates this opportunity to comment on the proposed rules for the new Medicare Prescription Drug benefit.

The Group Insurance Commission (GIC) is the state agency that provides health and other employee benefits to Massachusetts state employees, retirees and their dependents. Of the 267,000 individuals for whom we provide health insurance coverage, 50,000 are retirees with Medicare to whom we currently offer prescription drug coverage. The new Medicare Part D prescription drug benefit will therefore have a significant impact on our Medicare retirees and on the GIC, and the final rules and regulations governing this benefit will influence how these Medicare retirees obtain their prescription drugs when Part D comes into effect on January 1, 2006.

Some background information on our Medicare retiree benefits may be helpful to you as you review our comments. These retirees currently may choose from six health plans that offer benefits, including prescription drugs, extending beyond their Medicare Parts A and B coverage. 92% of our Medicare retirees have enrolled in our self-insured indemnity plan. Benefits in this plan are carved-out to a PBM contracted with the GIC. The remaining retirees are enrolled in two insured HMO Medicare Advantage plans and two insured HMO Medicare supplement plans.

Depending upon the date of their retirement, these retirees pay only 10% or 15% of the monthly premiums for these plans; the Commonwealth pays the 90% or 85% balance. All of the plans have an unrestricted drug benefit: there is no cap of any sort on the amount of prescription drugs that a retiree may receive. All of the plans use a three-tier member copayment structure for generic, preferred brand and non-preferred brand medications.

The GIC's philosophy regarding prescription drug coverage for retirees has been that benefits should be the same as that of employees. We are also aware that the monthly premium cost of Medicare Part B poses a burden on many retirees, and we therefore do not want to add to this burden by requiring retirees to pay an additional monthly premium for Medicare Part D. For these reasons, our intention had been to maintain our current benefits, not to require Part D enrollment, and to apply for and receive the employer subsidy allowed under the Part D statute. We have concerns, however, that some of these proposed rules may impede our ability to obtain the employer subsidy and may require us to consider alternatives that may be far less attractive to us and to our retirees. Our comments and concerns regarding the proposed rules follow:

Section J Coordination Under Part D Plans with Other Prescription Drug Coverage

Since our members currently may choose from three Medicare Advantage (MA) plans, we are pleased to see that rules contemplate and allow an MA plan to offer a plan without the Part D benefit to employer groups. It is unclear, however, whether or not the current ability of MA plans to customize their benefits for GIC retirees remains. At present the GIC benefits in MA plans can have different office visit copayments, prescription drug coverage and copayments, and additional benefits (e.g., hearing aids) than those in the standard MA plans. We customize these benefits so they may be comparable to the benefits offered to retirees in our other benefit plans. The loss of this customization of benefits could make the MA plans subject to adverse selection, and the current latitude needs to be maintained so that we can continue to offer these plans to our members.

Section R Payments to Sponsors of Retiree Prescription Drug Plans

1. We are very concerned about CMS' policy position regarding so-called "windfalls" and the passing on of the employer subsidy to beneficiaries. Our understanding of the statute is that its intention was to encourage employers to continue providing prescription drug coverage to their retirees, and the total or gross value of the benefit was the determining factor. The addition of the net value tests proposed by CMS seems unsupported by the statute, is administratively burdensome and onerous, and may result in employers no longer providing benefits.

   In addition, CMS needs to consider that for many governmental agencies, such as the GIC, reimbursements such as the employer subsidy are often required to be directed into the government's General Fund and do not directly offset the cost of health insurance provided by the government's employee benefits agency.

   For these reasons, the "single prong" test is the approach that should be used to determine actuarial equivalence.

2. Another issue that needs to be addressed is that of rebate information. The rules propose that rebates be reported and deducted from the value of the benefit. However, pharmaceutical manufacturers and PBMs treat the specific rebate amounts given on particular drugs as proprietary information. We receive rebate information, and we are in fact guaranteed 100% of the rebates, but the rebate information we receive is in the aggregate only by manufacturer, and is lagged at least six months. Considering these facts, we do not see how we could report the detailed rebate information contemplated by the rules. If the rules were to specify that rebate information was indeed proprietary, and would not be subject to disclosure under any federal or state laws and regulation, rebate information might become available to the degree required by the rules.

3. Regarding the requirement that an actuary must attest to the value of the plan, the use of an outside actuary must be allowed. Most organizations, including the GIC, do not have staff actuaries, and must hire consulting actuaries. This is very expensive, and we suggest that these costs be added to the value of the drug benefit when the subsidy is determined.

4. We would know, by September 30 of each year, what health plans our retirees have joined, since our annual enrollment occurs in the spring for enrollments effective July 1. However, the information on our retirees supplied to you in September would not be fixed, in that by the following January 1, new members would have become Medicare retirees and some members would have died. We should be able to provide you with the information requested, with the exception of the HIC number. We obtain the HIC number at the time of the member's retirement, but claims are adjudicated based on the member's Social Security Number. Changes made to the HIC after retirement are not maintained and we could not report them to CMS.

5. Notices of creditable coverage are indeed administratively burdensome. Rather than requiring notice mailings to all retirees, we suggest that we be allowed to post notices on our website, or include them in either the quarterly newsletters or the annual enrollment materials we already mail to all retirees. Few retirees change health plans, but we could provide those who do with a mailed notice.

6. On the Plan Year Versus Coverage (Calendar) Year Issue, our preference would be the plan year option, since our fiscal year begins on July 1, and our health plan contracts and reporting data revolve around that date. Of the options you propose, we could comply with either the second or third.

7. We believe that your assumption that the plan sponsor could certify by the 15th of a month the drug spend for the prior month is too optimistic, considering unexpected system and operational snafus. A 30-day lag would be a more realistic target.

8. Of the three payment options proposed on page 46747, the first alternative, that of making a single payment after the close of the year, seems the least administratively burdensome and most feasible.

9. Of the three options proposed on page 46748 regarding data collection, option 1 is preferable to us. We do not understand the stated concern that this would be the most problematic in terms of accuracy, since the data would be simply a total of all individual claims data.

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It is not clear to us if the HMO Medicare supplemental plans offered to our members are considered to be Medigap plans. If they are, the proposed requirement that Medigap plans no longer offer prescription drug benefits other than Part D would mean that we could no longer offer these plans to our retirees, who will not have Part D coverage. Our other comments on Section J earlier in this letter apply to Medigap plans as well.

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Thank you for your careful consideration of our comments. If you have any questions, please feel free to contact me at 617.727.2310 extension 3035.

Very truly yours,

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Assistant Director and Program Manager
Policy and Program Management

October 4, 2004

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

By email to: www.cms.hhs.gov/regulations/ecomments

Comments on file code CMS-4068-P

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Thank you for your careful consideration of our comments. If you have any questions, please feel free to contact me at 617.727.2310 extension 3035.

Very truly yours,

David A. Czekanski
Assistant Director and Program Manager
Policy and Program Management

CMS-4068-P-1111

Submitter : Dr. Ted Walton **Date & Time:** 10/04/2004 07:10:33

Organization : Grady Health System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to offer my comments regarding the Medicare Part D rules. I am a clinical pharmacist working in a urban public hospital in Atlanta GA.

My first comment is that I believe all pharmacists should be able to be a provider under the Medicare plan instead of contracting with specific groups. I fear that contracting with private, for-profit companies will deliver a low-bid and use non-pharmacists to screen patients and provide care (for example, using a pharmacy technician who has no training in the therapeutic use of medications).

As a pharmacist, I work in collaboration with medical staff to improve the treatment of anemia in our ESRD population. This collaboration has resulted in a significant increase in patients with therapeutic blood counts while reducing expenditures for epoetin therapy (average dose of 10,000 units/week versus USRDS average of around 17,000 units/week). I believe that a program such as this should be exclusive of dispensing product. In fact, I believe that linking product and disease management reimbursement would increase costs to the system. Several studies have documented that private, for-profit dialysis facilities have markedly increase epoetin expenditures with no improvement in anemia management. This is believed to be because administration of the drug is a major profit center for the facilities. Again, I think this demonstrates that drug product and disease management should be separated.

Finally, to ensure that pharmacists are qualified to provide service, I would like to suggest that certain certifications be used to determine eligibility of the pharmacist. These certifications would include board certification from the Board of Pharmaceutical Specialties or pharmacists with certifications in diabetes education. Alternatively, approved courses could be used to ensure qualifications are met.

Thank you for allowing me to comment and please contact me if there any questions.

Ted Walton, Pharm.D., BCPS

Submitter : **Date & Time:** 10/04/2004 07:10:36

Organization :

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Community pharmacies should be allowed to compete on a level playing field with mail order pharmacies. Beneficiaries should be able to obtain a 90-day supply of medication from either a community pharmacy or mail order pharmacy with the same level of cost sharing. Allowing plans to give beneficiaries a "discount" (lower level of cost sharing) when utilizing mail order will decrease the quality of health care beneficiaries receive.

I support the use of a standard ID card for Medicare beneficiaries.

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

Targeted beneficiaries should be defined only by disease states and chronic medications used. Likelihood to incur high annual costs is an inappropriate mechanism for qualifying individuals for MTMS. Physician visits, emergency room visits, and hospital admissions cost the same whether the causative factor was an inappropriately used, (relatively) cheap generic medication or an inappropriately used, expensive brand name medication.

MTMS must be rendered by health care professionals who have an established relationship with the beneficiary. Impersonal phone calls from a third-party administrator will not provide the enhanced level of care this provision was meant to create.

MTMS fees should be separate and distinct from those fees associated with product dispensing.

Targeted beneficiaries could be defined by having one of the following 12 chronic disease states: heart failure, gastroesophageal reflux disease, peptic ulcer disease, asthma, depression, ischemic heart disease, diabetes mellitus, hypertension, hyperlipidemia, atrial fibrillation, osteoarthritis, and COPD.

Targeted beneficiaries could be defined by the use of four or more chronic, non-topical, non-PRN medications.

Health care providers should not be reimbursed for the provision of MTMS based on time required to provide the service. Instead, health care providers should be reimbursed based on the poor health care outcomes reasonably and foreseeably avoided as a result of the services provided.

Submitter : Mr. William Hanes **Date & Time:** 10/04/2004 07:10:27

Organization : Kentucky Retirement Systems

Category : State Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

These comments are filed by the Kentucky Retirement Systems in response to the request for public comments by the Centers for Medicare and Medicaid Services (CMS) concerning proposed regulations implementing the Medicare Part D program enacted pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The proposed rule was published in the Federal Register on August 3, 2004 (69 Fed. Reg. 46632). We specifically address our comments to subparts J and R concerning Coordination Under Part D Plans with Other Prescription Drug Coverage; and Payments to Sponsors of Retiree Prescription Drug Plans.
Introduction
Kentucky Retirement Systems (KRS) is responsible for the investment of funds and administration of benefits for over 267,000 state and local government employees in the Commonwealth of Kentucky. These employees include state employees, state police officers, and city and county employees, as well as nonteaching staff of local school boards and regional universities. The Kentucky Retirement Systems administers the Kentucky Employees Retirement System (KERS), County Employees Retirement System (CERS) and State Police Retirement System (SPRS). A nine-member Board of Trustees administers the systems, and the Board appoints an Executive Director to oversee administration.

KRS provides retiree health benefits to over 28,000 Medicare-eligible retirees and their families. Total benefit expenditures for these benefits are over $65 million annually.

Several insured health plan options are offered to retirees, all of which offer prescription drug benefits. These plans use a prescription drug formulary, a tiered-benefit reimbursement level (e.g. generic, preferred brand, and non-preferred brand), and a mail-order program. In addition, all insurance carriers that contract with the Commonwealth of Kentucky are required to provide disease management programs. The amount, if any, that KRS contributes toward a retiree?s health insurance premium depends upon the years of service credit he or she has with KRS and when that service credit was earned or purchased.
If you have any questions or need additional information, please do not hesitate to contact the Executive Director of KRS, Mr. William P. Hanes, Esquire.

BENEFITS AND BENEFICIARY PROTECTIONS

As noted above, KRS provides retiree health benefits to over 28,000 Medicare-eligible individuals. Given the magnitude of retirees and their families covered by state and local governmental group health plans, CMS must ensure these programs are treated equitably under the Medicare Part D program. The preamble to the proposed MMA regulation specifically recognizes that it is important to maintain current retiree coverage under governmental plans.
The final regulations should assure the rights of state group health plans to receive the subsidy and other benefits set forth in the MMA. In addition, we request that the final regulations ?do no harm? to state group health plans. No additional rules or constraints should be placed on the ability of governmental group health plans to either provide qualified retiree prescription drug coverage and receive the subsidy or, in the alternative, provide wrap-around coverage that is secondary to the benefit offered under Medicare Part D

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

ELIGIBILITY, ELECTION, AND ENROLLMENT

Public Sector Retiree Plans are an Integral Component of our National Health Care System
Benefits, including retiree health care, continue to be an important factor in the attraction and retention of employees in the public sector. This is the case in Kentucky and around the country. State employees, in many cases, choose the better and more secure benefits typically associated with public sector employment in lieu of the higher compensation that traditionally characterizes the private sector.

A recent report issued by AARP found that State governments continue to offer their retirees health coverage at a higher rate than any other industry. State purchase health care for more than four million employees and retirees, and millions more dependents, according to the JSI Research and Training Institute. These public retiree health care programs are an integral component of our nation?s system of health care insurance for non-working seniors and should receive strong consideration by CMS when finalizing the regulations implementing the new Medicare Part D Program. Additionally, many state systems are required to provide retiree health coverage at certain specific levels for different groups of retirees. For example, certain Kentucky government employees whose service began prior to July 1, 2003 have an inviolable contractual right, obligating the state to a prescribed level of health care coverage through KRS that is protected under the State Constitution. Those who begin service after that date will be treated in a different fashion and no longer have that right. Consequently, unlike many private employers, state government systems face limitations on the extent to which they can modify retiree prescription drug benefits.

GENERAL PROVISIONS

Given the significant level of cost increases and the expected growth of the retired population?particularly relative to the number of active employees?the new Medicare Part D Program could provide much needed assistance to many public sector employers aiming to preserve their health care program for the long term. CMS is encouraged to establish final procedures and subsidy calculations that maximize the number of plan sponsors continuing to provide benefits to their retirees. However, great care should be taken to ensure the highest level of simplicity and flexibility as to the administration of the program.

Strong Consideration Should be Given to State Group Health Plan Comments

We greatly appreciate the opportunity to comment on the proposed regulations implementing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The millions of retirees and dependents in our country covered by a state and local government retiree health care plan necessitates that strong consideration be given to the implementation issues and that these plans, in fact, comply with the new Part D Program. These comments address only general issues faced by the public sector. We strongly encourage CMS to give great attention to the individual comments submitted by state and local government employers and their retiree health care plans.

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

The MMA provides that the plan sponsor shall receive the retiree drug subsidy. CMS should not define ?plan sponsor? for purposes of the entity that receives the subsidy, but should allow a state governmental group health plan such as KRS to define the sponsor in accordance with applicable state or local law.

The proposed rule references the ERISA definition of ?plan sponsor? at ERISA Section 3(16). State and local governmental group health plans are excepted from ERISA. Consequently, the ERISA definition of plan sponsor, while a reference point, is not necessarily applicable for state and local governmental health plans.

KRS is administered by a Board of Trustees, which is responsible for determining application of state and federal law to the retiree health plan and will make decisions regarding application for and use of the retiree prescription drug subsidy. Consequently, we request that CMS refrain from defining the ?plan sponsor? for purposes of state and governmental plans or, in the alternative if a definition is necessary, simply refer to the ?plan sponsor? as defined under applicable state or local law and regulation.

PAYMENTS TO PDP AND MA-PD PLANS

The regulations should assure that public retiree plans have the same opportunity as private plans to contract with and/or become a Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD). The law and regulations provide that a plan sponsor may either provide a Part D plan under a contract with a Medicare Advantage Prescription Drug plan (MA-PD) or a Prescription Drug Plan (PDP), or directly sponsor (e.g. ?become?) a Part D or MA-PD plan.

With respect to contracting with a PDP or MA-PD, we encourage CMS to use its waiver authority to grant waivers favorable to public sector retiree drug plans, such as those that recognize that public retirees may be served by a nationwide PDP. We encourage that any waivers be publicly available on-line and easily accessible.

With respect to direclty sponsoring an MA-PD or PDP plan, we recommend that, either through final regulations or the waiver process, CMS assure that state group health government plans have the same opportunity to directly sponsor one of these programs as private employer-sponsored plans. State government group health plans have significant numbers of retirees and may be in a unique position to directly sponsor a PDP. For example, a governmental plan could either take on the administrative functions of a PDP or contract with an administrator to run the PDP for them but allow the governmental entity to absorb the risk of the PDP agreement. The proposed regulations state that a PDP sponsor is limited to a

non-governmental entity that is certified as meeting the Part D requirements for a PDP sponsor. We recommend that this limitation be removed to allow state governmental plans to explore the option of directly sponsoring a PDP so as to assure continuity of retiree drug coverage for their retired population and beneficiaries.

CMS-4068-P-1113-Attach-1.doc

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CMS-4068-P-1113-Attach-1.doc

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non-working seniors and should receive strong consideration by CMS when finalizing the regulations implementing the new Medicare Part D Program.

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Parity for Public Retiree Health Plans is Imperative

As noted above, KRS provides retiree health benefits to over 28,000 Medicare-eligible individuals. Given the magnitude of retirees and their families covered by state and local governmental group health plans, CMS must ensure these programs are treated equitably under the Medicare Part D program. The preamble to the proposed MMA regulation specifically recognizes that it is important to maintain current retiree coverage under governmental plans.

The final regulations should assure the rights of state group health plans to receive the subsidy and other benefits set forth in the MMA. In addition, we request that the final regulations "do no harm" to state group health plans. No additional rules or constraints should be placed on the ability of governmental group health plans to either provide qualified retiree prescription drug coverage and receive the subsidy or, in the alternative, provide wrap-around coverage that is secondary to the benefit offered under Medicare Part D.

Public Group Health Plans Entitled to MMA Benefits

The proposed regulations recognize two essential facts about governmental plans, which should also be reflected in the final rule. First, governmental group health plans are entitled to the subsidy. As a group health plan, KRS is clearly entitled to the retiree drug subsidy available to employer sponsored qualified retiree prescription drug plans as recognized in the MMA Section 1860D-22(c)(3)(A) and the implementing regulations at 45 CFR § 423.882.

Second, one of the purposes of the subsidy is to allow governmental plans to achieve savings from the Part D program. CMS recognizes that state and local governmental group health plans will achieve savings from the Part D program either as a result of receiving the Part D subsidy or because their retirees enroll in a Medicare Part D plan. (69 Fed. Reg. 46772)

Plan Sponsor Definition Should Defer to State and Local Law

The MMA provides that the plan sponsor shall receive the retiree drug subsidy. CMS should not define "plan sponsor" for purposes of the entity that receives the subsidy, but should allow a state governmental group health plan such as KRS to define the sponsor in accordance with applicable state or local law.

The proposed rule references the ERISA definition of "plan sponsor" at ERISA Section 3(16). State and local governmental group health plans are excepted from ERISA. Consequently, the ERISA definition of plan sponsor, while a reference point, is not necessarily applicable for state and local governmental health plans.

KRS is administered by a Board of Trustees, which is responsible for determining application of state and federal law to the retiree health plan and will make decisions regarding application for and use of the retiree prescription drug subsidy. Consequently, we request that CMS refrain from defining the "plan sponsor" for purposes of state and governmental plans or, in the alternative if a definition is necessary, simply refer to the "plan sponsor" as defined under applicable state or local law and regulation.

Public Plans Should Be Permitted to Contract with or Become PDPs and MA-PDs

The regulations should assure that public retiree plans have the same opportunity as private plans to contract with and/or become a Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD). The law and regulations provide that a plan sponsor may either provide a Part D plan under a contract with a Medicare Advantage Prescription Drug plan (MA-PD) or a Prescription Drug Plan (PDP), or directly sponsor (e.g. "become") a Part D or MA-PD plan.

With respect to contracting with a PDP or MA-PD, we encourage CMS to use its waiver authority to grant waivers favorable to public sector retiree drug plans, such as those that recognize that public retirees may be served by a nationwide PDP. We encourage that any waivers be publicly available on-line and easily accessible.

With respect to direclty sponsoring an MA-PD or PDP plan, we recommend that, either through final regulations or the waiver process, CMS assure that state group health government plans have the same opportunity to directly sponsor one of these programs as private employer-sponsored plans. State government group health plans have significant numbers of retirees and may be in a unique position to directly sponsor a PDP. For example, a governmental plan could either take on the administrative functions of a PDP or contract with an administrator to run the PDP for them but allow the governmental entity to absorb the risk of the PDP agreement. The proposed regulations state that a PDP sponsor is limited to a non-governmental entity that is certified as meeting the Part D requirements for a PDP sponsor. We recommend that this limitation be removed to allow state governmental plans to explore the option of directly sponsoring a PDP so as to assure continuity of retiree drug coverage for their retired population and beneficiaries.

Administrative Flexibility and Simplicity Critical to Retaining Coverage

Given the significant level of cost increases and the expected growth of the retired population—particularly relative to the number of active employees—the new Medicare

Part D Program could provide much needed assistance to many public sector employers aiming to preserve their health care program for the long term. CMS is encouraged to establish final procedures and subsidy calculations that maximize the number of plan sponsors continuing to provide benefits to their retirees. However, great care should be taken to ensure the highest level of simplicity and flexibility as to the administration of the program.

Strong Consideration Should be Given to State Group Health Plan Comments

We greatly appreciate the opportunity to comment on the proposed regulations implementing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The millions of retirees and dependents in our country covered by a state and local government retiree health care plan necessitates that strong consideration be given to the implementation issues and that these plans, in fact, comply with the new Part D Program. These comments address only general issues faced by the public sector. We strongly encourage CMS to give great attention to the individual comments submitted by state and local government employers and their retiree health care plans.

If you have any questions or need additional information, please do not hesitate to contact the Executive Director of KRS, Mr. William P. Hanes, Esquire.

CMS-4068-P-1114

Submitter : Emily Stewart **Date & Time:** 10/04/2004 07:10:49

Organization : Health Privacy Project

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Comments Attached.

CMS-4068-P-1114-Attach-1.doc

HEALTH PRIVACY PROJECT

October 4, 2004

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

Re — File Code CMS-4068-P

Dear Administrator McClellan,

The Health Privacy Project and the undersigned organizations are submitting these comments on the proposed rule (42 CFR Parts 403, 411, 417, and 423) for the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which was issued in the Federal Register on Tuesday, August 3, 2004. The Health Privacy Project (HPP) is a 501(c)(3) nonprofit organization dedicated to raising awareness about the importance of ensuring health privacy in order to improve health care access and quality, both on an individual and community level. The Health Privacy Project conducts research and analysis on a wide range of health privacy issues, including objective analysis of the HIPAA Privacy Rule and state health privacy laws, genetics and workplace privacy, e-health activities, and bioterrorism and public health surveillance initiatives. HPP also coordinates the Consumer Coalition for Health Privacy (CCHP), which is comprised of over 100 major organizations representing a broad range of both consumers and health care providers. A complete list of Coalition participants, as well as all of the Project's resources related to health privacy, can be found at our web site, www.healthprivacy.org.

The Health Privacy Project's mission is to foster greater public trust and confidence in the health care system, thereby enabling people to more fully participate in their own care and in research without putting themselves at risk for unwanted—and unwarranted—intrusions. It is wrong to force people to choose between seeking health care and safeguarding their privacy. And, unfortunately, when people do have to choose, they very often choose to forgo quality health care. As captured by a 1999 California HealthCare Foundation survey, one out of every six Americans withdraws from full participation in their own health care out of fear that their medical information will be used without their knowledge or permission. These privacy-protective behaviors include patients providing inaccurate or incomplete information to doctors, patients paying out of pocket to avoid a claim being submitted, and people avoiding care altogether.

These comments are intended to provide an examination of the proposed rules for the implementation of the MMA within the scope of patient privacy. Medicare beneficiaries are a

uniquely vulnerable population. As a group, they have both more need for medical attention and oftentimes less control over decisions about their own health care. It is essential that Medicare beneficiaries are guaranteed the same privacy protections all Americans are afforded. Anything less compromises both the quality of health care that Medicare beneficiaries receive and the efficacy of the Medicare program.

Health Privacy Project Concerns with Medicare Prescription Drug Benefit, Proposed Rule: 42 CFR Part 423

The proposed rule for the Medicare Prescription Drug Benefit raises significant privacy concerns. In many ways, the proposed rule glides over privacy protections for Medicare beneficiaries. For instance, the proposed rule simply references other laws protecting privacy as applicable, but doesn't actually detail the corresponding provisions in the rule. The absence of comprehensive, detailed provisions that reflect both the importance of protecting the information of Medicare beneficiaries and the nature of the new prescription drug program is troubling. We are concerned that this will result in a loose patchwork of protections that will leave Medicare beneficiaries vulnerable to privacy violations. The lack of a truly deliberative process that considers how patients' personal health information should be *uniquely* protected under this new program is obvious. As a result, the impact of existing health privacy law could actually be weakened under this new program. ***HPP opposes any weakening of existing health privacy law as it applies to the prescription drug program.*** In the Final Rule, CMS must carefully address privacy as it relates to how information will be collected, used, and disclosed under the prescription drug program.

HPP Urges Strong Privacy Protections to Be Included in the Final Rule

Congress provided a broad outline in order to protect the privacy of Medicare beneficiaries' personal health information. The MMA adds Section 1860D-4(i) to Title XVIII of the Social Security Act, applying the provisions of section 1852(h) to prescription drug plan (PDP) sponsors and prescription drug plans just as it applies to Medicare Advantage (MA) organizations and Medicare Advantage plans.[1] Under Section 1852(h), MA organizations that maintain medical records or other health information regarding enrollees must establish procedures "to safeguard the privacy of any individually identifiable enrollee information; to maintain such records and information in a manner that is accurate and timely; and to assure timely access of enrollees to such records and information."[2]

In the proposed rule, CMS applies this provision of the MMA by applying existing law to prescription drug plan (PDP) sponsors. Proposed § 423.136 requires PDP sponsors to meet the same requirements regarding confidentiality and accuracy of enrollee records that MA organizations offering MA plans must currently meet under 42 CFR 422.118. Section 422.118 stipulates that for any medical records or other health and enrollment information it maintains with respect to enrollees, MA organizations must establish procedures that:

[1] Title II of the MMA replaces the Medicare+Choice (M+C) program with the Medicare Advantage (MA) program.
[2] Section 1852(h) [42.U.S.C. 139w-22]

1) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. MA organizations must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify for what purposes the information will be used within the organization and to whom and for what purposes it will disclose the information outside the organization;

2) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas;

3) Maintain the records and information in an accurate and timely manner; and

4) Ensure timely access by enrollees to the records and information that pertain to them.[3]

While the proposed rule cross-references § 422.118, it does not actually detail the corresponding provisions in the rule itself. It is important that the Final Rule specifically outlines privacy provisions as they relate to prescription drug plan sponsors. This is not only necessary so that patients' are aware of their rights, but necessary for sponsors so that they are aware of their specific responsibilities.

In addition to detailing privacy safeguards in the Final Rule, CMS should go further to protect the health information of Medicare beneficiaries. Although it is important that PDP sponsors and plans must "abide by all federal and state laws regarding confidentiality and disclosure of medical records," CMS should comprehensively consider the scope of these laws and how they would apply to prescription drug plans. Many federal and state laws have significant gaps that could be grossly exploited under the new prescription drug plan. Accordingly, CMS should incorporate added protections for Medicare beneficiaries. Medicare beneficiaries are in a particularly vulnerable position in regard to control over their health information. They *must* share highly sensitive information in order to participate in the program, so decisions about how this information is collected and shared should be made with caution. This is a significant opportunity to match Medicare beneficiaries' heightened vulnerability with stronger privacy protections.

Recommendations

- **Privacy safeguards must be detailed in the Final Rule**. At a minimum, the confidentiality and disclosure requirements set forth in § 423.136 should be detailed explicitly in the Final Rule, instead of simply referencing § 422.118. Because privacy protections are such an important component of earning patients' trust and confidence, it is vital that required protections are re-iterated in the Final Rule itself. It is also critically important that PDP sponsors adequately understand their responsibility to safeguard the health information of Medicare beneficiaries. Most importantly, without privacy safeguards built directly into the regulation, they could be vulnerable to another amendment.

- **Privacy safeguards should be strengthened for Medicare beneficiaries**. In addition to detailing the requirements set forth in § 422.118, CMS should make privacy provisions stronger for prescription drug plans. Gaps in existing health privacy law could be especially problematic in the implementation of the new prescription drug benefit. The Final Rule

[3] See 42 CFR 422.118

should not only re-iterate the provisions of § 422.118, but should outline specific rules as to uses and disclosures of beneficiary information, that both incorporate provisions of important laws (such as the notice and authorization provisions of the HIPAA Privacy Rule) and strengthen the provisions of those laws to better protect the health information of Medicare beneficiaries.

HPP strongly urges CMS to apply *specific* privacy safeguards to prescription drug plans.

CMS provides that prescription drug plans will fall under the scope of the HIPAA Privacy Rule. In the Preamble referencing proposed § 423.136, CMS states that "prescription drug plans would be considered covered entities under the HIPAA Privacy Rule because they meet the definition of "health plan" as described in 45 CFR 160.163."[4]

While we appreciate the intention to bring prescription drug plans under the scope of the law, classifying them as "health plans" under the Privacy Rule is problematic.[5] The result of this provision is to essentially re-write the Privacy Rule without a full and separate consideration of how to most effectively apply privacy standards to prescription plans under the new Medicare program. Identifying Medicare prescription drug plans as "health plans" under the proposed rule is concerning for the following reasons:

1. A wide variety of companies could qualify as prescription drug plan sponsors. Under the proposed rule, CMS could allow a variety of industries to fulfill the role of PDP sponsors. Proposed § 423.401[6] provides the following general provisions for PDP sponsors:

1) Except in cases where there is a waiver as specified at § 423.410, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan;
2) The entity assumes financial risk for on a prospective basis for benefits that it offers;
a) The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage;
b) And in the case of a PDP sponsor for a waiver is approved, the sponsor must meet the solvency standards detailed in § 423.420.

As referenced in § 423.401, CMS is able to grant a waiver for the licensure requirement as long as certain standards are met as provided in § 423.410.[7] With the waiver for licensure, CMS is

[4] Medicare Prescription Drug Benefit, Proposed Rule, Federal Register, Vol. 69, No. 148, 46666.
[5] In 2002 comments to HHS regarding a proposed rule creating a prescription drug card assistance program for Medicare beneficiaries, HPP called for stronger privacy protections for the program. While highlighting that the proposed rule did not even refer to the applicability of the HIPAA Privacy Rule, HPP assumed that drug card sponsors would not be "covered entities" or "business associates" and instead detailed specific privacy protections that should have applied to sponsors. However, the discount drug card plan was halted in 2003 when US District Judge Paul Friedman permanently enjoined HHS from going forward with the initiative. The judge ruled that the government lacked the statutory authority to implement the program.
[6] See Proposed § 423.401.

clearly establishing an avenue whereby PDP sponsors would neither have to be a health plan nor even a health-related organization. In this respect, CMS' interpretation classifying prescription drug plans as "health plans" under the Privacy Rule may have negative consequences. PDP sponsors could represent a wide variety of industries, many of which may not currently have any investment in health care services.

2. Prescription drug plan sponsors function very differently from traditional health plans. Classifying PDP sponsors as "health plans" under the Privacy Rule overlooks important distinctions between traditional health plans and other PDP sponsors, such as PBMs, pharmaceutical companies, and other institutions. When the Privacy Rule was issued, an explicit decision was made not to cover pharmacy benefit managers (PBMs) and other similar health care entities. Therefore, in their current role in the health care system, many potential PDP sponsors actually function as "business associates" under the Privacy Rule. "Business Associates" essentially step into the shoes of covered entities, and their collection, uses and disclosures of health information must be consistent with the covered entity's policies and procedures. Changing that classification to "health plan" is a significant alteration. Still, other potential PDP sponsors are currently not even a part of the health care industry at all. Specific rules should be implemented to reflect this issue and the impact it could have on privacy safeguards.

3. Prescription drug plan sponsors will have increased access to personal health information: There are many sponsors who currently may not have access to personal health information at all. As health plans, prescription drug plan sponsors such as pharmacy benefit managers, pharmaceutical companies, and others will have increased access to personal health information. Although there are some limits on their use and disclosure of information, these limits may not be sufficient, as traditional health plans function very differently from other PDP sponsors. Sponsors will not need beneficiaries' consent to use or disclose protected health information (PHI) for treatment, payment, or health care operations. It seems possible that they could also receive PHI from other covered entities for their own treatment, payment, and health care operations.

4. Patient access to personal health information will be limited. As health plans, sponsors only have to provide patients access to their records if the records are "enrollment, payment, claims adjudication, and case or medical management records systems" or "used, in whole or in part, by or for the covered entity to make decisions about individuals" (45 C.F.R. § 164.501). This may leave some records unavailable to patients. Whereas patients are currently accustomed to receiving significant disclosure from related entities such as pharmacies, designating PDP sponsors as "health plans" could cut patients off from important treatment information.

While we understand that the regulatory process is a substitute for the more deliberative congressional review, it is appropriate here for CMS to carefully consider the implications of classifying prescription drug plans as "health plans" under the Privacy Rule.

Recommendation

- **HPP strongly urges CMS to apply specific privacy safeguards to prescription drug**

[7] See Proposed § 423.410.

plans. These safeguards should reflect both the operating nature of PDP sponsors and their relationships with consumers.

HPP Opposes the Use of Personal Health Information for Marketing Purposes

Unfortunately, Congress authorized the use of personal health information for marketing. We have grave concerns that Congress authorized the Secretary to disclose sensitive health information for the purposes of marketing. Section 1860D-1(b)(4)(A) of the Act authorizes the Secretary to provide to each PDP sponsor and MA organization identifying information about part D eligible individuals as the Secretary determines to be necessary in order to facilitate efficient marketing of prescription drug plans and MA-PD plans to such individuals. Section 1860-1(b)(4)(B) of the Act imposes limitations on this provision, citing that the Secretary may only provide the information for the intended purpose and that such information can only be used by PDP sponsors or MA organizations to facilitate the marketing and enrollment of Part D eligible individuals.[8]

The proposed rule reinforces the use of health information for marketing. In the proposed rule § 423.50, CMS provides guidance on marketing materials, the definition of marketing materials, guidelines for CMS review, and standards directed at Prescription Drug Plan (PDP) sponsor marketing. Proposed § 423.50 replicates the marketing provisions established under § 422.80 for MA plans, as appropriate for PDP sponsors.[9]

Although Section 1860D-1(b)(4) issues limitations on CMS' authority to share information with PDP sponsors and MA organizations, proposed § 423.50 does not contain any provision that regulates how the Secretary may provide information about Part D eligible individuals to PDP sponsors. In the preamble to the proposed rule, CMS seeks comments related to the impact of sharing information on beneficiaries with PDP sponsors. In particular, CMS raises questions regarding whether or not patients should be able to choose not to have their information shared and regarding limitations on how PDP sponsors should be able to contact beneficiaries.[10]

Sharing information on beneficiaries with PDP sponsors for the purposes of marketing violates an important tenant of privacy. Allowing the Secretary broad authority to share the identifiable information of beneficiaries raises serious privacy concerns. One of the most important principles of privacy is having control over one's personal health information. Using personal health information for the purposes of marketing is a controversial practice that has garnered much media attention and public discord in recent years. For instance, in July 2002, the *New York Times* reported that a number of Florida residents received samples of the anti-depressant Prozac in the mail from a large chain drug store. A lawsuit filed by a woman who received the drug names her doctor, the drugstore, and the drug's maker as illegally violating her privacy. And in 1998, a series of stories in the *Washington Post* detailed the use of patients' prescription drug records for marketing by chain drug stores accepting fees from direct mail and

[8] Section 1860D-1(b)(4)(A); Section 1860D-1(b)(4)(B)
[9] Preamble, Proposed Rule, Federal Register, Vol. 69, No. 148, 46643.
[10] Preamble, Proposed Rule, Federal Register, Vol. 69, No. 148, 46644.

drug companies. The sharply negative response from the public and policymakers prompted the companies to take out full-page ads in the Post promising to discontinue the practice.[11]

Recommendations

- **Congress erred in giving the Secretary the authority to disclose highly sensitive information for the purposes of marketing, and CMS has an opportunity to correct this oversight and ensure that Medicare beneficiaries' are afforded a strong standard of privacy.** The MMA authorizes *but does not require* the Secretary to disclose this sensitive information. **Therefore, in the Final Rule, the Secretary should not have the authority to disclose this information to entities interested in marketing to patients.** Rather, CMS should market the program on behalf of PDP sponsors. Direct communication about plan options should come from the government, allowing Medicare beneficiaries both privacy and important information about plan benefits. We recognize that there are issues surrounding the efficiency of the program, but there are also significant issues revolving around the importance of safeguarding patients' privacy. Furthermore, in recent years, CMS has greatly improved on its ability to educate beneficiaries about benefits, making www.medicare.gov "one of the most comprehensive and consumer-oriented sites available to the public."[12]

However, if CMS chooses to disclose personal health information for marketing services, the most stringent restrictions should be in place, and the Final Rule should reflect a great deal of caution on this matter.

- **Medicare beneficiaries should give authorization for disclosures related to marketing.** Medicare beneficiaries should be given the option to decide whether or not their personal health information is shared with PDP sponsors for the purpose of marketing prescription drug plans. CMS should request the authorization of beneficiaries *before* sharing their personal health information for the purpose of marketing.

- **The Secretary should disclose only the minimum necessary.** In keeping with the HIPAA Privacy Rule's tenant of sharing the minimum necessary of personal health information[13], the Secretary should only disclose the most minimal information about beneficiaries: names, addresses, and phone number. It is not necessary for the Secretary to share health or financial data, because the Part D program is guaranteed, and PDP sponsors are prohibited by § 423.50 from discriminatory activities.[14] Under no circumstances should the Secretary disclose information about a patient's health status or condition to a PDP sponsor or disclose information related to finances or income, except to confirm eligibility for low-income subsidies.

- **Any information shared by the Secretary can only be used to market the prescription drug plan.** As Section 1860-1(b)(4)(B) of the Act outlines, the information shared by the

[11] Janlori Goldman,Health Privacy Project, "Changes to Medical Privacy Regulation Ease Marketing Safeguards, " August 23, 2002, iHealthBeat.
[12] See Preamble, Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule, Federal Register, Vol. 69, No. 148, 46881.
[13] 45 CFR § 164.502 (b)
[14] See Proposed § 423.50.

Secretary can only be used by PDP sponsors or MA organizations to facilitate the marketing and enrollment of Part D eligible individuals. If the Final Rule establishes that the Secretary may disclose identifiable information to PDP sponsors, the limitation that prescription drug plans may only use such information for the intended purpose of marketing and enrollment of the prescription drug plan should be re-enforced.

- **Beneficiaries should *only* be contacted about prescription drug plan-related products**. Regardless of how PDP sponsors collect personal health information about beneficiaries (whether through the Secretary or from another source), a separate limitation should be in place guaranteeing that PDP sponsors can only contact beneficiaries about plan-related products.

- **CMS should stipulate that *any* information PDP sponsors collect, cannot be shared with any other entity for any other reason.**

HPP Supports Strong Limitations on Marketing Activities

It is important that strong limitations are in place regarding what types of communications PDP sponsors can engage in when marketing plan-related products. Proposed § 423.50 provides standards regulating PDP marketing activities. Consistent with § 422.80 for MA organizations, the proposed rule prohibits PDP sponsors from engaging in certain activities, including providing cash or other remuneration for enrollment, door-to-door solicitation, misleading or confusing Medicare beneficiaries, or misrepresenting the PDP sponsor or plan.[15]

Recommendations

- **The current marketing limitations should remain in the Final Rule.** In addition, the Final Rule should also prohibit telemarketing. PDP sponsors should not be authorized to initiate contact with beneficiaries through telephone communication. Rather, a PDP sponsor should be able contact beneficiaries via telephone only if the beneficiary requests contact in this manner and in response to direct advertising or an advertisement. Allowing PDP sponsors to use telemarketing poses the same privacy risks associated with door-to-door solicitation.

HPP Strongly Opposes Marketing Products that Are Not Plan-Related

Allowing PDP sponsors to market to Medicare beneficiaries products that are not related to the prescription drug benefit is unethical. Unfortunately, proposed § 423.50 does not actually limit PDP sponsors to marketing only services and products related to the prescription drug benefit. In the preamble, CMS seeks comment on the advisability of allowing PDP sponsors to offer additional services to Medicare beneficiaries, such as financial services.[16] Under this proposal, PDP sponsors could be permitted to offer potentially any number of products, including credit cards and long term care insurance. PDP sponsors could possibly market such services along with the prescription drug benefit, which would undoubtedly lead to confusion among Medicare beneficiaries. Not only are the privacy considerations significant, but the

[15] See § 422.80(e)(ii)
[16] Preamble, Proposed Rule, Federal Register, Vol. 69, No. 148, 46644.

potentially misleading nature of marketing services not related to the prescription drug benefit is of great concern. Proposed § 423.50 already recognizes the importance of clarity in marketing, as it prohibits marketing activities that could mislead or confuse Medicare beneficiaries or misrepresent the PDP sponsor or its prescription drug plan. Further, Section 1860-1(b)(4)(B) stipulates that information provided by the Secretary can only be used by PDP sponsors or MA organizations to facilitate the marketing and enrollment of Part D eligible individuals in prescription drug and MA-PD plans.[17] Therefore, PDP sponsors would not be permitted to use the information provided by the Secretary under Section 1860D-1(b) for such purposes.

There already exists a foundation of support for prohibiting this type of contact with patients, especially without explicit authorization. In the preamble discussion about marketing other services, CMS acknowledges that in accordance with the HIPAA Privacy Rule, PDP sponsors "*may* have to obtain beneficiary authorization to market certain products."[18] The HIPAA Privacy Rule does require "covered entities" to obtain an authorization for any use or disclosure of protection health information for communications that encourage recipients to purchase or use the product or service (see definition of "marketing" at § 164.501).[19]

The marketing limitations outlined in the Privacy Rule are a reflection of a sentiment among consumers and health care advocates that regulations are needed to protect patients from marketing activities that violate privacy and, as a result, quality health care. Medicare beneficiaries deserve strong privacy protections that aggressively safeguard their personal health information.

Because PDP sponsors could potentially operate outside of the health care industry, it is even more important that sponsors should only be permitted to market services related to the prescription drug plan. Allowing unrelated services to creep into the relationship between patients and providers is alarming. The marketing of financial services simply has no place in the delivery of health care services.

Recommendation

- **The Final Rule should absolutely prohibit the marketing of services that are unrelated to the prescription drug benefit itself.**

HPP Opposes Allowing Medicare Drug Discount Card Sponsors From Using Personal Health Information for Marketing.

Medicare Drug Discount Card sponsors are likely to act as sponsors for the prescription drug plans. Because drug discount card sponsors have information about Medicare beneficiaries' use of prescription drugs, it is important that they are not permitted to use this sensitive information as a basis for selective marketing. While proposed § 423.50 does prohibit PDP sponsors from "discriminatory activity," it is critical that drug discount card sponsors are explicitly prohibited from using Medicare discount card information for marketing purposes related the prescription

[17] Section 1860D-1(b)(4)(A); Section 1860D-1(b)(4)(B)
[18] Preamble, Proposed Rule, Federal Register, Vol. 69, No. 148, 46644.
[19] 45 CFR 164.508

drug plans. The Medicare Drug Discount Card program was intended to serve as an immediate relief for seniors who could not wait for the implementation of Part D in 2006. By no means should Medicare beneficiaries' personal health information that was collected as a part of this benefit be used to market for the prescription drug plans.

Recommendations

- **The Final Rule should explicitly prohibit PDP sponsors from using beneficiary information collected by Discount Card sponsors to market prescription drug plans or any other product not related to the discount card itself.** Proposed § 423.50 should be amended to prohibit prescription drug plan sponsors from collecting or using for marketing purposes personal health information that was collected or maintained by a sponsor of the Medicare Drug Discount Card Program.

- **The Final Rule should prohibit Drug Discount Card sponsors from disclosing or using health information for marketing.** Drug discount card sponsors should be explicitly prohibited from disclosing or using Medicare discount card information for marketing purposes related the prescription drug plans or any other product not related to the discount card itself.

HPP Supports the Implementation of Privacy Protections in E-Prescribing

The MMA established an e-prescribing program to facilitate the progress of using technology to enhance quality of health care. Section 1860D-4(e) of the Act contains provisions for electronic prescription program. Section 1860D-4(e)(2) states that "an electronic prescription drug program shall provide for the electronic transmittal . . . of the prescription and information on eligibility and benefits and of the following information with respect to the prescribing and dispensing of a covered part D drug: information on the drug prescribed or dispensed and other drug listed on the medication history and information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed." After the establishment of appropriate standards, "the program shall provide for electronic transmittal of information that relates to medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved."

Section 1860D-4(e)(2) also imposes limitations on the disclosure of personal health information as it relates to this program. The section stipulates that information shall only be disclosed if the disclosure is permitted under Federal regulations concerning the privacy of individually identifiable health information promulgated under section 264(c) of HIPAA.

Unfortunately, while the regulations address the program, they do not specifically reference the collection of information or the limitations of disclosure. Proposed § 423.159 outlines the basic elements of the program, but does not include the limitations on the use and disclosure of personal health information.

Recommendation

- **Proposed § 423.159 should comprehensively reflect Section 1860D-4(e)(2) of the Act and detail the limitations on collecting and disclosing personal health information.** With the significant benefits technology brings to health also come significant risks to privacy. Beneficiaries should be assured that their personal health information is secure.

HPP Supports Strong Enforcement Provisions for Privacy Violations

By and large, the proposed rule is silent on enforcement. While the proposed rule acknowledges the authority of HHS' Office for Civil Rights in regard to violations of the HIPAA Privacy Rule[20], there are no additional penalties in place for entities that violate the provisions of the proposed rule. ***Adequate enforcement is fundamental to the success of any provision.*** If an violates in any way the privacy of Medicare beneficiaries, there should be serious recourse. Otherwise, the privacy protections set forth in the proposed rule are hollow.

Recommendation

- **The Final Rule should include a provision that penalizes for violations of privacy.** One clearly important penalty should be removal from participating in the Medicare program.

Conclusion

With the development of any new health care program, it is essential that privacy protections are built in at the outset. Like all patients, Medicare beneficiaries deserve the assurance that their personal health information will be protected. Only comprehensive privacy safeguards and strong enforcement provisions will adequately safeguard the personal health information of beneficiaries as the new prescription drug program is implemented. In order to meet this standard, the Health Privacy Project urges the following recommendations:

- **Privacy safeguards must be detailed and strengthened for Medicare beneficiaries in the Final Rule.**
- **HPP strongly urges CMS to apply specific privacy safeguards to prescription drug plans.**
- **In the Final Rule, the Secretary should not have the authority to disclose personal health information to entities interested in marketing to patients.**
- **However, if CMS chooses to disclose personal health information for marketing services, the most stringent restrictions should be in place, and the Final Rule should reflect a great deal of caution on this matter:**

[20] In the Preamble, where CMS interprets that prescription drug plans would be covered by the Privacy Rule as a "health plan," CMS confirms that OCR is responsible for the enforcement of the Privacy Rule. Preamble, Proposed Rule, Federal Register, Vol. 69, No. 148, 46666.

*Medicare beneficiaries should give authorization for disclosures related to marketing.
* The Secretary should disclose only the minimum necessary.
* The Secretary should disclose only the minimum necessary.
*****Any information shared by the Secretary can only be used to market the prescription drug plan.
*****Beneficiaries should *only* be contacted about prescription drug plan-related
*CMS should stipulate that *any* information PDP sponsors collect, cannot be shared with any other entity for any other reason.

- **There should be strong limitations on marketing activities. The current marketing limitations should remain in the Final Rule. In addition, the Final Rule should also prohibit telemarketing.**

- **The Final Rule should absolutely prohibit the marketing of services that are unrelated to the prescription drug benefit itself.**

- **The Final Rule should explicitly prohibit PDP sponsors from using beneficiary information collected by Discount Card sponsors to market prescription drug plans or any other product not related to the discount card itself.**

- **The Final Rule should prohibit Drug Discount Card sponsors from disclosing or using health information for marketing.**

- **Proposed § 423.159 should comprehensively reflect Section 1860D-4(e)(2) of the Act and detail the limitations on collecting and disclosing personal health information.**

- **The Final Rule should include a provision that penalizes for violations of privacy.**

If you have any questions about these recommendations, please contact Emily Stewart, HPP's Policy Analyst at: 202-721-5614 or estewart@healthprivacy.org.

Thank you for your consideration.

Sincerely,

Health Privacy Project
Families USA
American Association of People with Disabilities
USAction
Georgia Rural Urban Summit
Bazelon Center for Mental Health Law
Privacy Rights Clearinghouse

World Privacy Forum

Cc: Secretary Tommy G. Thompson, HHS
Richard Campanelli, Office for Civil Rights
Representative Dennis Hastert
Representative Tom Delay
Representative Nancy Pelosi
Representative Joe Barton
Representative Bill Thomas
Representative Philip Miller Crane
Representative John D. Dingell
Senator Judd Gregg
Senator Edward Kennedy
Senator Bill Frist
Senator Tom Daschle
Senator Chuck Grassley
Senator Max Baucus

CMS-4068-P-1115

Submitter : Dr. Paul Szumita **Date & Time:** 10/04/2004 07:10:12

Organization : Brigham & Women's Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

Submitter : C L Jones III **Date & Time:** 10/04/2004 07:10:30

Organization : Crescent Center Drugs

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I am concerned about the proposed rule regarding the pharmacy access standard. I recommend that the requirements be met on the local level rather than regionally.
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from the pharmacy provider of their choice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan?s network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in service costs, not the cost of the drug product. Under Medicare Part D, all rebates, discounts or other price concessions should be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements should be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

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

I appreciate that CMS recognizes that different beneficiaries will require different MedicationTherapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.
In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify.
Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

Submitter : Dr. Carol Alter **Date & Time:** 10/04/2004 07:10:31

Organization : Treatment Effectiveness Now

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

see attached

GENERAL PROVISIONS

see attached

CMS-4068-P-1117-Attach-1.doc

CMS-4068-P-1117-Attach-1.doc

Treatment Effectiveness Now

Mark B. McClellan, M.D., Ph.D.
Administrator
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-4086-P

Re: Comments to Notice of Proposed Rulemaking for Medicare Prescription Drug Benefit

Dear Dr. McClellan:

We are writing as Executive Board members of Treatment Effectiveness Now (the TEN Project). The TEN Project is a private, non-profit policy action organization, dedicated to educating public officials, advocates and professionals about the clinical and policy implications of evidence-based treatment for co-occurring medical and psychiatric disorders. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare beneficiaries. Consequently, the TEN Project is working with leaders of patient advocacy and professional organizations (mental and physical health) to provide comments on the Notice of Proposed Rulemaking (NPRM) for Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). We join others, such as the American Psychiatric Association (APA), the National Alliance of Mentally Ill (NAMI), the National Mental Health Association (NMHA) and the the National Association of State Mental Health Program Directors (NASMHPD) in bringing these issues to your attention.

The TEN Project has also assumed a role as "convener" of various advocates and experts in the area in order to better define the data required in order to best respond to the opportunities which the MMA and other policy forums might afford. As such we have worked actively with the APA, NAMI, NMHA and NASMHPD to help provide data analysis for their comments as well as work with them to continue to support efforts to address clinical and economic concerns of policy makers with appropriate and robust data. We are committed to continuing to work with these groups and CMS in what is hoped will be an ongoing dialogue about how to best address the complex needs of these beneficiaries in a clinically and economically sound way.

As you know, beginning on January 1, 2006, Medicare beneficiaries will have access to an outpatient prescription drug benefit for the first time in the program's history. This new program holds the promise of meaningful access to medically indicated medicines for Medicare beneficiaries with mental illness. This class of enrollees is a highly vulnerable population with unique medical needs. Given TEN's interest and expertise in the areas of medical and psychiatric co-occuring illness we believe that it will be critical to address the complex needs of many of these beneficiaries. As such, we would concur with the comments and proposal sent to you by the American Psychiatric Association which outlines in detail the necessity for an approach which can best address these patients' needs.

We support the comments that the APA recently sent to you on the proposed MMA rules and implementation. We wish further to underscore the following points which are of high significance to our patient constituents and professional colleagues:

The APA in its letter calls attention to the high rates of medical illness in patients with primary mental illness and raises concerns about elderly patients with primary psychiatric illness and their co-occurring medical conditions-all of which complicate treatment planning and significantly inform the need for flexibility in drug management. Of the over 18 million adults in this country with a chronic medical condition (eg. Hypertension, diabetes, cancer etc.) more than half have evidence of a mental disorder.

Patients may have evidence of mood and anxiety disorders, delirium or significant levels of psychosocial distress which greatly contribute to their health status and quality of life. Studies have shown that these patients' medical conditions appear to be worsened in the presence of mental illness and that they consequently utilize proportionately greater resources in their medical and psychiatric care. However, research indicates that when the mental illness and distress are addressed the medical conditions improve and costs are reduced. Yet, less than half of those patients presenting to their primary care physicians with evidence of a mental disorder are diagnosed, and even with diagnosis only half receive adequate treatment. We believe that the APA proposal will address the needs of *all* patients with mental illness and specifically accounts for the very common phenomenon of comorbid medical and psychiatric illness.

The APA suggests that the needs of these patients can be addressed by the implementation of an alternative formulary and management strategy for these patients:

- The APA recommends, consistent with CMS' criteria, that an alternative formulary be established for Medicare enrollees with a diagnosis as defined by the DSM-IV-TR, and cross referenced by the appropriate ICD-9 code, and for whom it has been determined that it is medically necessary that their condition be treated with a pharmacological agent.
- The alternate formulary for this class of enrollees:
    - (1) must have specific formulary management mechanisms that are defined by the unique medical needs of this population; and
    - (2) payment adjustment devices which provide incentives for PDP participation and equitable compensation for the reasonable cost of the alternative formulary.

There are four categorical reasons that this class of enrollees should be afforded special treatment through an alternative formulary.

- Medicare beneficiaries with mental illnesses are a vulnerable population with unique medical needs, highly sensitive to and less tolerant to many medications, and successful treatment requires long-term management and patient adherence.
- The medicines used to treat mental illness are therapeutically non-interchangeable and restrictions on access to the full range of needed medicines are clinically inappropriate.
- The formulary management strategies and the exceptions process promulgated by the proposed rule are unproven and will not facilitate treatment for vulnerable populations with unique medical needs.
- Beneficiary clinical outcomes will be gravely compromised and there will be negative fiscal consequences for the Medicare program if restricted formularies are permitted.

Alternative formulary cost management strategies are an essential component of their proposal.

- There are a number of developed management strategies that contain prescription drug costs while providing access to care for vulnerable beneficiaries with unique medical needs.
- It is important that the payment adjustments contemplated by the MMA are fully realized. It is also essential that PDPs be paid equitably and thereby appropriately incentivized to participate in the new Part D program. This will necessitate the development of a health status risk adjustment methodology for these enrollees that is accurate. It may also be necessary that additional pass-through payments on a reasonable cost basis be provided to these plans to assure appropriate payment.

In addition:

- We also believe that in the absence of an alternative formulary that mechanisms be devised to assure that patients can be appropriately transitioned from Medicaid or other insurers to the new benefit on January 1, 2006 and thereafter and that
- CMS create a modified exceptions process for this population which would require only a physician attestation or comparable certificate of medical necessity to accompany those prescriptions not on the PDP formulary.

There is a significant risk to health if patients are not managed appropriately as a result of limited access to needed medications. We also understand that any such program needs to be implemented in a cost-sensitive environment. We have been working with the APA and other partners to analyze and understand the numerous relationships between medical and psychiatric illness, the use of pharmaceutical and clinical services and the predictors of successful clinical and economic outcomes utilizing several states Medicaid claims data, including information on elderly and dual eligible patients. We believe this data will be critical in helping to successfully implement the promise of the new benefit.

We urge you to consider seriously the suggestion for the utilization of an alternative formulary for these vulnerable and unique patients. We welcome the opportunity to be able continue to provide important and critical information that can help guide these efforts as this considerable effort proceeds.

We thank you for your consideration and stand ready to assist you and your staff at CMS in implementation of the MMA and its associated provisions.

Sincerely,

_____ _____

Carol L. Alter, M.D.
Executive Director

Danna Mauch, Ph.D
President

cc. Robert Donnelly, Director, Health Plan Policy Group, Center for Beneficiary Choices, CMS

CMS-4068-P-1118

Submitter : Mr. Eric Reed **Date & Time:** 10/04/2004 07:10:02

Organization : Mr. Eric Reed

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please See Attached File from the Disability Community

CMS-4068-P-1118-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:

I welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am an individual with a high level spinal cord injury and would be greatly affected by the proposed rules for individuals with dual eligibilities. I am 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. I am 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), I recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. I 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. I 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. I 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.

I 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. I 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, I 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 I strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. I 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. I am 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. I 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:

I am also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. I 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. I 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. I 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 what death threats that 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 my views.

Sincerely yours,

Eric Reed
10100 Hedgerow, Apt. 25
El Paso, TX 79925
(915) 598-6429
ericreed@elp.rr.com

CMS-4068-P-1119

Submitter : Mr. Thomas Volkert **Date & Time:** 10/04/2004 07:10:01

Organization : Mental Health Association of Southeastern Pa

Category : Social Worker

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

I like thw coordiantion with states.

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

I am deeply concerned for older adults with mental health needs. The provisions allowing providers to limit drug choices to 2 within a category could spell disaster for older adults who often fail on their first psychotropic drug or can't tolerate certain drugs for health reasons. There is need for a much broader range of medicines to choose from because there are a variety of older adults with various health conditions.

You should exempt older adults with mental illness from the restrictive formularies as many states have done.

ELIGIBILITY, ELECTION, AND ENROLLMENT

It is vary unfair to allow the companies to change the drugs they could offer but not allow the beneficiaries similar choice. As I understand it companies can perform bait and switch maneuvers on a regular basis but beneficiaries have to stay in the same company. Grossly unfair and older adults and advocates won't tolerate it.

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

Don't drop people for behavioral problems. This provisiona is so brad and unfair for people with mental illness.

Submitter : Linda Rosenberg **Date & Time:** 10/04/2004 07:10:41

Organization : National Council for Community Behavioral Healthca

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BACKGROUND

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, MD 21244-8014

Dear Dr. McClellan:

On behalf of the National Council for Community Behavioral Healthcare (National Council), I am writing to furnish comments on the Notice of Proposed Rule Making (NPRM) recently published by the Centers for Medicare and Medicaid Services (CMS) to implement the new outpatient drug benefit under Title I of the Medicare Prescription Drug Improvement and Modernization Act (MMA). The National Council is the oldest and largest community behavioral health trade association, and the only entity representing the providers of mental health, substance abuse and developmental disabilities services. Our members compose the backbone of America?s public mental health system, and we serve more than 4.5 million adults, children and families each year and employ more than 250,000 staff.

The MMA is a critically important health policy breakthrough that could significantly improve the health and well-being of millions of senior citizens and people with disabilities. At the same time, if the implementation issues discussed below are not properly addressed, the new program might also be fraught with peril for its intended beneficiaries.

BENEFITS AND BENEFICIARY PROTECTIONS

Flexible Formularies Are Required (Sec. 423.120(b))

There is a policy consensus?among governors, state legislatures, and state Medicaid agencies?that restrictive cost control practices such as prior authorization, fail first, and step therapy are inappropriate when applied to the pharmacy needs of persons with mental illnesses and other chronic diseases. Here?s why. Clinicians often use diagnostic terms like ?schizophrenia? or ?bipolar disorder? to describe clusters of systems?each with their own clinical manifestations?depending upon the severity of the underlying disorder. Compounding the complexity, patients often have variable clinical responses to different drugs in the same therapeutic class. Therefore, front line clinicians must be given the flexibility to tailor drug regimens to each patient taking into account the side effect profile of the available medications, past medical history, drug interactions, and the existence of co-occurring chronic conditions.

In addition, while it might be tempting to view all drugs in a given therapeutic class such as atypical anti-psychotics or anti-depressants as clinically equivalent, the daily experiences of National Council members refutes that easy assumption. Even medications with the same mechanism of action seem to have a variable impact on brain chemistry producing (often radically) different clinical outcomes. As a result, individuals with severe bipolar disorder, for example, might be taking three (3) or more psychotropic medications from different therapeutic classes in order to make stability and recovery possible.

Carve Outs: Given these extraordinary clinical complexities, decision makers have typically responded in at least two ways when constructing formularies and preferred drug lists. Carve outs from prior authorization and related pharmacy cost control techniques for special needs populations is the first approach. On pg. 46661 of the August 3rd proposed rule, CMS specifically seeks comments ??. regarding any special treatment (for

example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs?.), we should consider requiring of plans with respect to special populations, as well as suggestions regarding particular special populations for whom we may want to make allowances.?

Thirty (30) states with restrictive Medicaid preferred drug lists?reflecting an enormous bipartisan and medical consensus?exempt special populations from prior authorization and related drug utilization management techniques. As an illustration, the State of Oregon carves out medications for people with mental illnesses, HIV/AIDS and all types of cancer. Similarly, the State of Kansas in 2002 enacted consumer protections for its Medicaid pharmacy program that states in part:

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Continuity of Care: Another approach to protect special needs populations is for CMS to guarantee continuity of care as dual eligibles make the transition from Medicaid
drug coverage to the new Part D benefit. Specifically, at a minimum, your agency should promulgate a binding rule stipulating that once dual eligibles with epilepsy, Alzheimer?s disease, severe mental illnesses, HIV/AIDS and related chronic conditions have achieved clinical stability on a particular drug regimen, PDPs are prohibited from forcing these enrollees to switch medications?irrespective of a plan?s formulary requirements. In the field of psychiatry, there is an enormous amount of medical literature detailing the catastrophic clinical consequences of forced medication switching including the onset of psychiatric crisis, adverse drug reactions, and the risk of permanent cognitive impairment.

Moreover, clear congressional intent requires ?grandfathering? coverage of mental health medications for dual eligibles in the new Part D benefit. The conference committee report states that ?[i]f a plans chooses not to offer or restrict access for 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, pgs. 769-770]

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

?No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, depression or bipolar disorder may be imposed upon Medicaid recipients. Medications that will be available under the state plan without restriction for persons with mental illnesses shall include atypical antipsychotic medications, conventional antipsychotic medications and other medications used for the treatment of mental illnesses.?

More recently, Gov. Jeb Bush in the State of Florida renewed an exemption for mental health drugs from prior authorization requirements. Instead, he directed the Medicaid agency to implement an exciting new behavioral health medication management system based upon best-practice clinical guidelines that includes truly innovative components:

? Providing feedback to providers and educating prescribers using best practice educational materials and peer-to-peer consultation.
? Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drug, and may have potential medication problems.
? Track spending trends for behavioral health drugs and deviation from best practice guidelines.
? Implement a disease management program with a model medication component for persons with severe mental illnesses and children with serious mental and emotional disturbances who are high users of care.

We believe that CMS has ample statutory authority to require plans to adopt these approaches with respect to special populations rather than the ham handed drug utilization management techniques repeatedly referred to in the proposed rule. It seems clear that state after state has avoided the use of prior authorization, fail first, coerced drug switching and step therapy because of the realization that these cost control tools will drive up psychiatric hospital utilization, reduce compliance, actually increase the risk of multiple prescriptions, reduce the quality of psychiatric care and produce exceedingly poor clinical outcomes.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Dual Eligibles: Have Special Medical Needs (Sec. 423.34)

While the National Council?s comments touch on many aspects of the MMA implementation, the dual eligible population represents a special area of concern for our members?and apparently the Congress as well. The 6.2 million low-income and disabled people eligible for both Medicare and Medicaid are among the most vulnerable patients served by these two safety net programs. According to Medpac, 38% of dual eligibles have cognitive impairments or mental illnesses (Medpac, 2004). Additionally, dual eligibles are twice as likely to have Alzheimer?s disease as other Medicare beneficiaries. These individuals also have an exceedingly high incidence of multiple chronic diseases and depend upon a wide array of medications to maintain their health and functionality.

Because dual eligibles currently receive their prescription drug benefit and related services through Medicaid, the community mental health and substance abuse providers we represent currently furnish mental health care for a very large segment of this population and, as a result, we are very well versed in their treatment needs. The MMA terminates Medicaid drug coverage for dual eligibles on Jan. 1, 2006?less than fourteen (14) months from today?and requires them to select among the private for-profit Prescription Drug Plans (PDPs) offered through the new Part D benefit. The following comments focus on this critical transition.

GENERAL PROVISIONS

Outreach and Enrollment (Sec. 423.34)

Perhaps one of the greatest challenges confronting CMS is ensuring the safe transition of dual eligibles from Medicaid to coverage under the new Part D benefit. As an illustration, it is our understanding that a large employer, say a Fortune 500 company, typically requires at least six (6) months of preparation, planning, education and outreach to successfully transition a high functioning, privately insured workforce from one health insurance plan to another. By stark contrast, your agency is charged with enrolling over 6 million people?many of whom have cognitive impairments or disabilities?in plans scattered across an unknown number of geographic regions in the United States in a highly constricted timeframe. Failure to adequately negotiate this process could result in serious programmatic difficulties and utter chaos in the lives of extremely vulnerable Americans.

CMS must engage in vigorous and specifically tailored educational efforts to assist all Medicare beneficiaries with cognitive disabilities in selecting among the array of PDPs that will be available through the MMA. It seems clear that general public service advertising campaigns will be wholly insufficient for this special health care needs population of seniors and people with disabilities. In addition, relying solely upon family members who are already struggling on a daily basis to care for their husbands, wives, sons and daughters to make the appropriate plan selections is inadequate?to say the very least.

Successful implementation of this provision requires CMS to initiate collaborative partnerships with?. and provide additional funding for?. community nonprofit mental
health organizations and agencies who would provide needed one-on-one counseling with beneficiaries and/or family members to sort out these complicated enrollment decisions. The National Council believes that community mental health and substance abuse providers could play vital role in this key process because of our frequent??often weekly?contact with beneficiaries. In addition, in their bids, PDPs should include specific plans for outreach efforts to encourage enrollment of often hard-to-reach populations, including persons with mental illnesses.

Furthermore, CMS should give very serious consideration to delaying the transfer of drug coverage from Medicaid to Medicare for dual eligibles for at least six (6) months to allow adequate time to educate and enroll these vulnerable and often hard-to-reach persons.

PAYMENTS TO PDP AND MA-PD PLANS

Involuntary`Disenrollment (Sec. 423.44)

While the proposed rule does an admirable job of balancing competing policy considerations in many areas, one of the most disturbing elements of the NPRM are

provisions allowing PDPs to involuntarily disenroll beneficiaries for behavior that is ?disruptive, unruly, abusive, uncooperative, or threatening? (Sec. 423.44(d)(2)). These
words also perfectly describe a person who is already in?or may be entering?a state of psychiatric crisis that requires an intensive intervention. Worse yet, suspended individuals would not be permitted to enroll in another plan until the next annual enrollment period, thereby guaranteeing a potentially lengthy period of time without needed drug coverage. Even worse than that, the proposed rules also create an expedited disenrollment process.

Particularly with respect to people with severe and persistent mental illnesses, it should be clear that these provisions represent an adverse selection bonanza for Medicare drug plans who would be authorized to disenroll high cost cases with near impunity. CMS must close this loophole in three ways. First, the expedited process proposal must not be included in the final rule. Second, in order to disenroll a patient for disruptive activities, the plan must making a contemporaneous showing in writing that the behavior in question is not the product of an underlying illness or condition. Third, the proposed rule should contain due process protections including advance notice to the enrollee, a notice of intent to request CMS permission to disenroll the patient, and a planned action notice advising that CMS has approved the plan?s request for approval of involuntary disenrollment.

Thank you for your attention to these comments. I am happy to meet with you and members of your staff at any time to clarify these comments. The success of this law is critical to the millions of people with disabilities we serve every day.

Issues 11-20

MEDICARE CONTRACT DETERMINATIONS AND APPEALS

Appeals Procedures: (Sec. 423.562-423.604)

There can be no serious question that CMS has a special obligation to help Medicare beneficiaries with cognitive disabilities negotiate the various appeals processes established under the MMA. As Michael Hogan, former chair of the President?s New Freedom Commission on Mental Health, has stated in a letter dated June 1, 2004 to CMS, ?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.? The proposed rules generally follow the current structure for beneficiary grievances and appeals under the Medicare Advantage program. Specifically, the NPRM sets forth a series of beneficiary rights including timely coverage determinations, the ability to request an exception to tiered cost sharing, the right to expedited re-determination of an adverse decision, reconsideration by an ?Independent Review Entity,? an Administrative Law Judge (ALJ) hearing and finally, judicial review. Timeframes for each of these processes is also stipulated.

In our view, the rules need to be modified to account for medical reality. Recent research unambiguously establishes that people with severe mental illnesses experience irreversible clinical consequences once they de-compensate and spiral into psychiatric crisis as a result of being denied access to appropriate medications. Therefore, the National Council urges CMS to issue final rules relating to grievance, reconsideration and appeals processes that take into account the special circumstances of beneficiaries living with mental illnesses and neurological diseases. Such regulatory provisions must guarantee rapid re-determinations of any denied benefits by securing a truly expedited exceptions process for persons with immediate needs, including individuals facing psychiatric crisis. It should be noted that current Medicaid law requires states to respond to prior authorization appeal requests within 24 hours.

CMS-4068-P-1121

Submitter : Dr. Trudi Renwick **Date & Time:** 10/04/2004 07:10:40

Organization : Fiscal Policy Institute

Category : Other

Issue Areas/Comments

Issues 1-10

BACKGROUND

The Fiscal Policy Institute, a nonpartisan research and education organization that focuses on the broad range of tax, budget, economic and related public policy issues that affect the quality of life and economic well-being of New York residents, respectfully submits these comments on the rules proposed by the Centers for Medicare and Medicaid Services (CMS) for the Medicare prescription drug benefit (42 CFR Part 423) as published in the Federal Register, Volume 19, No. 148, August 3, 2004. Our comments focus on two areas of concern: protections for Medicare recipients who are also eligible for Medicaid and the coordination between the Medicare prescription drug program and New York's very successful Elderly Pharmaceutical Insurance Program (EPIC).

BENEFITS AND BENEFICIARY PROTECTIONS

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

ELIGIBILITY, ELECTION, AND ENROLLMENT

CMS-4068-P-1121-Attach-1.doc

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F I S C A L P O L I C Y I N S T I T U T E
1 LEAR JET LANE / LATHAM, NEW YORK 12110 / (518) 786-3156

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]

Medicare Prescription Drug Benefit
42 CFR 423

The Fiscal Policy Institute, a nonpartisan research and education organization that focuses on the broad range of tax, budget, economic and related public policy issues that affect the quality of life and economic well-being of New York residents, respectfully submits these comments on the rules proposed by the Centers for Medicare and Medicaid Services (CMS) for the Medicare prescription drug benefit (42 CFR Part 423) as published in the Federal Register, Volume 19, No. 148, August 3, 2004. Our comments focus on two areas of concern: protections for Medicare recipients who are also eligible for Medicaid and the coordination between the Medicare prescription drug program and New York's very successful Elderly Pharmaceutical Insurance Program (EPIC).

DUAL ELIGIBLES

New York has 2.7 million Medicare beneficiaries. In New York, nearly one out of five Medicare recipients also receives Medicaid assistance. New York is home to more than 8 percent of the nation's "dual eligibles." The 537,000 "dual eligible" New Yorkers constitute the group most vulnerable during the transition from the existing Medicaid coverage of prescription drugs to the implementation of the new Medicare benefit. We believe the timing and implementation provisions of the proposed rules do not provide sufficient protections for this group.

Timing of Transition from Medicaid to Medicare Part D

The proposed rules end Medicaid coverage for prescription drugs for dual eligibles on January 1, 2006, giving dual eligibles only the six weeks from November 15, 2005 to December 31, 2005 to voluntarily enroll in a qualified Prescription Drug Plan (PDP) without losing coverage. Given the educational levels and high incidence of

mental and/or physical disabilities in this group of beneficiaries, six weeks is not sufficient to ensure that all dual eligibles will be able to complete the enrollment process.

In fact, the law and proposed rules anticipate that some of these individuals will not enroll voluntarily in a PDP. The statute and rules require that a dual eligible individual who fails to enroll in a PDP or MA-PD should be automatically enrolled into a PDP that has a monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries. If more than one such PDP serves the individual's region, the individual would be randomly assigned to one of the PDPs. The automatically assigned participant must be notified of the enrollment action and provided the opportunity to enroll in a different plan.

Unfortunately, the proposed rules do not allow automatic enrollment until the end of the initial enrollment period on May 15, 2006, which creates the likelihood that many dual eligibles will be left up to 4 1/2 months without prescription drug coverage. To protect against a gap in coverage for a significant number of beneficiaries, automatic enrollment must be completed at least several weeks before the loss of Medicaid benefits in order to provide automatically enrolled beneficiaries with notice of their enrollment in a PDP, information about the assigned plan, and an opportunity to change plans if the assigned plan does not fit their medical needs (e.g. uses a formulary which does not include a particular drug they wish to continue to use).

Recommendation #1: Extend Medicaid coverage of prescription drugs for dual eligibles through December 31, 2006 to ensure coverage during the transition to the Medicare prescription drug program.

Automatic Enrollment

In the preamble to the proposed rules (p. 46639), CMS requests comments on whether CMS or the states are best suited to perform the automatic and random enrollment functions for dual eligibles who fail to enroll in a PDP prior to the end of the enrollment period. As noted in the preamble, state officials have more readily available data identifying the dual eligibles in their state. In addition, states will already be involved in the enrollment process because they are required by both the proposed rules and the statute to make eligibility determinations for the low-income premium and cost-sharing subsidies. However, this added responsibility should include sufficient administrative payments to compensate states for the costs related to automatic enrollment. This is particularly important given the disincentives to enrollment inherent in the clawback provisions. Since the monthly amount of Medicaid savings that a state must "share" with the federal government is a function of the number of dual eligibles who have enrolled in Part D plans in any given month, a state could reduce the size of these required payments by slowing down the automatic enrollment process.

Recommendation #2: Automatic enrollment of dual eligibles should be performed by the state and CMS should reimburse the states for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.

Continuity of Access to Specific Prescription Drugs

There are significant concerns for continuity of care for dual eligibles and their access to needed prescriptions. The proposed rules would force dual eligibles 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 may not be as comprehensive as the drug coverage these individuals currently have through New York's Medicaid program. Without access to the coverage they need, dual eligibles may be forced to switch medications. For the many New York dual eligibles who are suffering from HIV/AIDS, such switches can be deadly. For these and other dual eligibles, denying them access to appropriate prescription drugs for weeks may also prove costly for the state's already overburdened Medicaid program. If dual eligibles are forced off the appropriate prescription drugs, a significant number will be forced into more expensive hospital care.

The statute and regulations include an appeals process to enable plan participants to gain access to drugs not included on a plan's formulary if a particular drug is found to be medically necessary. Unfortunately, the process proposed in these rules is extremely complex and difficult 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. Additionally, drug plans are not required to provide an emergency supply of medications until at least two weeks after the initial request for a formulary exception.

Recommendation #3: Coverage of medications for dual eligibles should be grandfathered into the new Part D benefit. 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.

COORDINATION WITH NEW YORK'S EPIC PROGRAM

Ability of SPAPs to Provide Consumer Advice

New York provides prescription drug insurance to more than 350,000 elderly New Yorkers through its very successful Elderly Pharmaceutical Insurance Program (EPIC). While the statute and the proposed rules prohibit SPAPs from discriminating based on the PDP *in which the beneficiary is enrolled,* 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. The preamble on page 46697 offers an interpretation of the nondiscriminatory provisions of the statute that would prevent SPAPS from steering participants to a one plan over another. This restrictive interpretation, which extends beyond any statutory language or intent is wrong and could

be harmful to program participants. Given the complexity of the new program and the trust and confidence that State Pharmaceutical Assistance Programs such as EPIC have gained with the elderly population, it would be wrong to ban SPAPs from providing such assistance.

Recommendation #4: Given the intense need for consumer assistance and the value of the EPIC network, we urge that the language in the preamble regarding the interpretation of "nondiscrimination" should be dropped.

SPAPS as Fallback Providers

The requirements that Subpart Q (Sections 423.851-875) imposes on entities that would be interested in providing a 'fallback plan' to serve an area not served by at least two plans are so severe that fallback plans may not, in fact, be available. The requirements in the rules exceed the requirements found in the statute making 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. Allowing SPAPs such as EPIC to serve as the fallback plan for these areas is a logical and cost effective alternative to the proposed rules. EPIC already serves more than 350,000 New Yorkers in all areas of the state and should be allowed to offer a fallback plan rather than forcing seniors to join a managed care plan.

Recommendation # 5: The requirements in this section of the rules should be scaled back to make it more certain that fallback plans will submit bids where such plans may be needed.

Recommendations #6: If no private plan is available as a fallback plan, the rules should allow SPAPs such as EPIC to offer such plans.

Respectfully submitted:

Trudi Renwick
Senior Economist
Fiscal Policy Institute

Submitter : Dr. Jean-Venable Goode **Date & Time:** 10/04/2004 07:10:33

Organization : Virginia Commonwealth University

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 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.
I would like to offer the following specific comments about this section of the regulations:
Pharmacy Access:
 If plans are only required to meet the pharmacy access standard 'on average' across the plan's service area, the plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan's pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor.

Any Willing provider:
 I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could affect my ability to continue to serve my patients.
 Allowing plans to distinguish between pharmacies could allow plans to drive beneficiaries to a particular pharmacy. This goes against Congressional intent. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice.
 Only preferred pharmacies should count when evaluating whether a plan's pharmacy network meets the pharmacy access standard. That will help patients access a local pharmacy for their full benefit.
 'Access' isn't 'access' if my patients are coerced to use other pharmacies.

Level playing field:
 If plans are allowed to charge a higher price for an extended supply obtained from a community pharmacy, CMS should clarify that the price difference must be directly related to the difference in service costs, not the cost of the drug product.
 Congressional intent, as identified in the colloquy of Senators Grassley and Enzi, opposes making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice.

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

I wouldlike to offer some general comments about this section of the regulations:

Targeted Beneficiaries
 Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS).

 Who will benefit from MTM can change, so plans should be required to identify new targeted beneficiaries on a monthly basis.
 Plans should be required to inform pharmacists who among their patients are eligible for MTM.
 Pharmacists and physicians should also be able to identify eligible beneficiaries.
 Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
 Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
 CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be

allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.
Providers
 Pharmacists, the medication expert on the health care team, are the ideal providers of MTMS.
 CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships.
Fees
 Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
 CMS must carefully evaluate each plan?s 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.
Services
 MTM services are independent of, but can occur in conjunction with, the provision of a medication product.
 I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as performing a health assessment, formulating a medication treatment plan, monitoring and evaluating a patient?s response to therapy, etc.
 Face-to-face interaction between the beneficiary and the patient is the preferred method of delivery whenever possible. The initial assessment should always be face-to-face.
 I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004.

Thank you for the opportunity to stress these points
 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 at Ukrop's Super Market Pharmacies. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications. Additionally, I am a faculty member at Virginia Commonwealth University School of Pharmacy and a key component of the curriculum is teaching pharmacy students to help patients manage their medications for better outcomes.

CMS-4068-P-1123

Submitter : Mr. John Arlotta **Date & Time:** 10/04/2004 07:10:33

Organization : NeighborCare, Inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

NeighborCare, Inc.'s extensive and specific comments regarding the proposed rules implementing Medicare Part D are included in the attached letter. Thank you for the opportunity to submit these comments.

CMS-4068-P-1123-Attach-1.doc

CMS-4068-P-1123-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

601 East Pratt Street, 3rd Floor Baltimore, Maryland, 21202-6000
Tel 410.528.7300 **Fax** 410.528.7377

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.

[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.

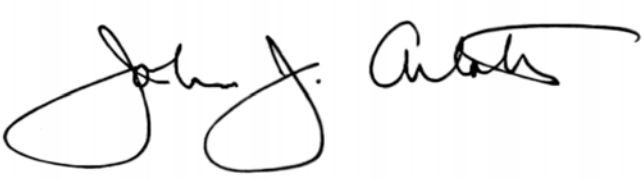
14. Prompt Payment – There is no provision in the rule requiring plans to pay providers promptly.

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.

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

601 East Pratt Street, 3rd Floor Baltimore, Maryland, 21202-6000
Tel 410.528.7300 **Fax** 410.528.7377

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.

[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.

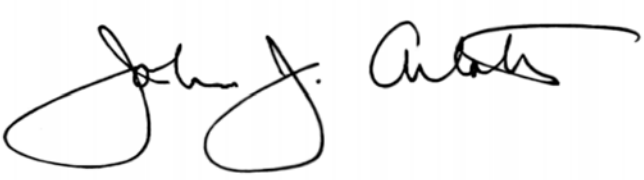
14. Prompt Payment – There is no provision in the rule requiring plans to pay providers promptly.

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.

CMS-4068-P-1124

Submitter : Ms. Michelle Plasari **Date & Time:** 10/04/2004 07:10:19

Organization : RetireSafe

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Via E-mail: wherecanIsendcomments@cms.hhs.gov

Dear Doctor McClellan:

On behalf of RetireSafe?s 300,000 senior supporters, we urge you to consider the attached comments we submitted last month to United States Pharmacopeia (USP) regarding the proposed Draft Model Guidelines for the Medicare Prescription Drug Benefit, Drug Categories and Classes in Part D. We believe every effort should be made to ensure patient access to critical medications, just as we know President Bush and the Congress intended when the Medicare Modernization Act (MMA) was enacted.

In addition to our comments on the USP Guidelines, we also urge the Centers for Medicare and Medicaid Services (CMS) to be sure all patients are adequately protected so that changes in coverage are not detrimental to their treatment, especially when their medication is no longer covered by their chosen provider. By the same token, we urge you to standardize an appeals process that will be timely and easy for seniors to use. And, we urge every effort to bring newer, more effective drugs into the program as quickly as possible to save lives and dollars.

Finally, we urge CMS to continue reform policies that make the reimbursement fairer and more affordable for older Americans covered by Medicare.

Thank you for your consideration of our comments.

Sincerely,
Michelle Plasari
Vice President

see attachement

CMS-4068-P-1124-Attach-1.doc

September 16, 2004

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790
Attention: Lynn Lang

Via E-mail: lfl@usp.org

Re: RetireSafe Comments to the Draft Model Guidelines for the Medicare Prescription Drug Benefit, Drug Categories and Classes in Part D.

RetireSafe represents nearly 300,000 senior-supporters across America, and has been especially active as a strong supporter of the Medicare Modernization Act (MMA), both before and after its passage into law. Keeping with our mission of securing the best possible individual health and financial options for older Americans, and in helping them to make informed choices, RetireSafe has continuously encouraged seniors to explore the many potential benefits of the MMA Prescription Drug Benefit. That effort has included thousands of letters, well over a hundred radio talk show interviews, and the use of our popular website, RetireSafe.org. While we continue to educate seniors regarding the great new Medicare options they might use to their advantage, we also note with concern the limiting factors of U. S. Pharmicopeia's Draft Model Guidelines for the Medicare Prescription Drug Benefit, Drug Categories and Classes in Part D. It is those limiting factors that we wish to comment on today.

First and foremost, there are far too few Pharmacologic Classes to ensure the appropriate treatment options and choices for all of the beneficiaries the MMA Prescription Drug Benefit Part D is intended to serve.

The Medicare Discount Drug Cards now in effect cover 209 therapeutic classes giving seniors and their doctors a broad range of options in choosing the best treatment options. The Draft Model Guidelines for Part D only cover 146 classes. While the Draft Guidelines carry the disclaimer that they are not intended as a formulary, it seems clear to us that the limited number of classes will act just as a formulary, severely limiting choices for patients and their doctors.

Congress and the President, in their creation of the new Part D Medicare Prescription Drug Benefit, intended for beneficiaries and their physicians to have the widest range of possible choices for the best available treatment. Doctors today often try many different drugs (and/or combinations of drugs) to establish the best treatment for their patients. That fact is especially true as it applies to older individuals. Having exactly the right treatment choice available for patients not only portends the best medical outcome, with the fewest side effects, it also provides most cost effective remedy. Avoiding expensive surgeries and extended hospital stays will be critical if Medicare is to be financially viable in the future.

To reach that goal, we recommend the expansion of the Draft Guidelines to include as many of today's pharmaceutical treatment choices as possible.

Since the Proposed Rule for the Drug Benefit only requires that two drugs per class be covered, we would first recommend that the Centers for Medicare and Medicaid Services (CMS) require coverage for more than two drugs per class, if those drugs are clinically appropriate. For example, as patient groups have noted, in the case of anti-epileptic drugs used to treat seizures, the Draft Guidelines failed to divide the category of anti-convulsants into any classes whatsoever. This means that health plans would only be required to cover two drugs, or as little as 10 percent of the currently available seizure medications.

Next, we would urge the expansion of the proposed Recommended Subdivisions to include the broadest range of possible medications available, as well as a dual listing of drugs with more than one applicable usage. Not listing drugs that may be beneficial to more than one Class could easily be used to thwart coverage.

Finally, the expanded Recommended Subdivisions should be listed as individual Classes, thus replacing the current Pharmacological Classes, and ensuring the availability of the best available treatment options for all Medicare patients.

RetireSafe is also concerned that the use of overly restrictive Classes and Categories will discourage the development of new and more effective drugs by tilting coverage to older, cheaper drugs. The development of better and more innovative medications is a top priority for seniors, thus the broadest and most flexible Drug Categories and Classes for Part D coverage is critical.

Thank you for the opportunity to comment.

Michelle Plasari
Vice President

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

Organization : Pharmacy Consultants

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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.
Additionally, there should be a provision for "any willing provider". This should assure that any pharmacy or pharmacist that wants to participitate, should be able to, and be able to provide services to their patients.

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."

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

Medication Therapy Management Program:

I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer. This way pharmacies and pharmacist can decide if they want to participitate, and will know the requirments of participation.
In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I feel pharmacist, as medication "experts" based upon their unique training and education, are qualified to provide these clinical services to all patients. Additionally, there are numerous studies, which show that Clinical Medication Management Services, are cost effective. I believe if these services are properly implement, there will be a real "cost savings" for Medicare, and that our patient will greatly benefit from these services.

RetireSafe.org

Protecting Your Retirement, Securing Your Benefits

September 16, 2004

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790
Attention: Lynn Lang

Via E-mail: lfl@usp.org

Re: *RetireSafe Comments to the Draft Model Guidelines for the Medicare Prescription Drug Benefit, Drug Categories and Classes in Part D.*

RetireSafe represents nearly 300,000 senior-supporters across America, and has been especially active as a strong supporter of the Medicare Modernization Act (MMA), both before and after its passage into law. Keeping with our mission of securing the best possible individual health and financial options for older Americans, and in helping them to make informed choices, RetireSafe has continuously encouraged seniors to explore the many potential benefits of the MMA Prescription Drug Benefit. That effort has included thousands of letters, well over a hundred radio talk show interviews, and the use of our popular website, RetireSafe.org. While we continue to educate seniors regarding the great new Medicare options they might use to their advantage, we also note with concern the limiting factors of U.S. Pharmicopeia's Draft Model Guidelines for the Medicare Prescription Drug Benefit, Drug Categories and Classes in Part D. It is those limiting factors that we wish to comment on today.

First and foremost, there are far too few Pharmacologic Classes to ensure the appropriate treatment options and choices for all of the beneficiaries the MMA Prescription Drug Benefit Part D is intended to serve.

The Medicare Discount Drug Cards now in effect cover 209 therapeutic classes giving seniors and their doctors a broad range of options in choosing the best treatment options. The Draft Model Guidelines for Part D only cover 146 classes. While the Draft Guidelines carry the disclaimer that they are not intended as a formulary, it seems clear to us that the limited number of classes will act just as a formulary, severely limiting choices for patients and their doctors.

Congress and the President, in their creation of the new Part D Medicare Prescription Drug Benefit, intended for beneficiaries and their physicians to have the widest range of possible choices for the best available treatment. Doctors today often try many different drugs (and/or combinations of drugs) to establish the best treatment for their patients. That fact is especially true as it applies to older individuals. Having exactly the right treatment choice available for patients not only portends the best medical outcome, with the fewest side effects, it also provides most cost effective remedy. Avoiding expensive surgeries and extended hospital stays will be critical if Medicare is to be financially viable in the future. To reach that goal, we recommend the expansion of the Draft Guidelines to include as many of today's pharmaceutical treatment choices as possible.

Since the Proposed Rule for the Drug Benefit only requires that two drugs per class be covered, we would first recommend that the Centers for Medicare and Medicaid Services (CMS) require coverage for more than two drugs per class, if those drugs are clinically appropriate. For example, as patient

groups have noted, in the case of anti-epileptic drugs used to treat seizures, the Draft Guidelines failed to divide the category of anti-convulsants into any classes whatsoever. This means that health plans would only be required to cover two drugs, or as little as 10 percent of the currently available seizure medications.

Next, we would urge the expansion of the proposed Recommended Subdivisions to include the broadest range of possible medications available, as well as a dual listing of drugs with more than one applicable usage. Not listing drugs that may be beneficial to more than one Class could easily be used to thwart coverage.

Finally, the expanded Recommended Subdivisions should be listed as individual Classes, thus replacing the current Pharmacological Classes, and ensuring the availability of the best available treatment options for all Medicare patients.

RetireSafe is also concerned that the use of overly restrictive Classes and Categories will discourage the development of new and more effective drugs by tilting coverage to older, cheaper drugs. The development of better and more innovative medications is a top priority for seniors, thus the broadest and most flexible Drug Categories and Classes for Part D coverage is critical.

Thank you for the opportunity to comment.

Michelle Plasari
Vice President

2915 Hunter Mill Road, Suite 23 • Oakton, VA 22124 • Phone: 703-319-0009 • Fax: 703-319-8842 • www.RetireSafe.org
RetireSafe.org is a project of the Council for Government Reform

CMS-4068-P-1126

Submitter : Mr. Michael Cantrell, R.Ph., Esq **Date & Time:** 10/04/2004 07:10:58

Organization : Longs Drug Stores California, Inc

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Longs Drug Stores California, Inc. ("Longs) is providing its comments to the proposed regulation published August 3rd that would implement Title I of the Medicare Modernization Act of 2003. This Title established the voluntary Medicare Part D prescription drug benefit program that will begin in 2006.

Longs is one of the most recognized retail drug store chains on the West Coast and in Hawaii. Through more than 470 stores in California, Hawaii, Washington, Nevada, Colorado, and Oregon, Longs serves the health and well being needs of consumers with customer-oriented pharmacy services. We are a major provider of pharmacy services to elderly and disabled Medicare beneficiaries, and will continue to be such under this new benefit program. We are providing comments to select sections in the proposed regulations, which we feel significantly impact our ability to provide premier pharmacy services to our patients.

CMS-4068-P-1126-Attach-1.pdf

Longs Drugs

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

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:

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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 continued use of its prescription pricing website that it established for the Medicare-endorsed prescription drug discount program. The purpose of this website was to help beneficiaries select a Medicare-endorsed discount card by comparing negotiated prices that were being offered by various card sponsors.

We agree that Medicare beneficiaries should take the most cost effective prescription medications, but price point is but one factor to be considered in determining the most cost effective therapy. Therapeutic considerations, as well as convenience, should also be considered in this analysis. Comparing the prices of medications is one way to help beneficiaries make Part D plan decisions, but our experience related to the current website indicates is it very confusing for patients. Seniors are overwhelmed with thousands of prescription drugs, different dosage forms and strengths and package sizes, whose retail prices change frequently due to manufacturer price increases. In addition, prices for the same dosage form and strength of a drug may change depending on the number of dosage units ordered, thus making it more difficult for beneficiaries to determine exactly how much they might pay for a prescription.

As previously mentioned, prescription price should not be the exclusive factor influencing a beneficiary's decision. Beneficiaries should be choosing plans based on other criteria as well, such as the pharmacy network, 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 price as only one of the factors in determining which Part D plan best fits their needs. Failure to do so is a disservice to the beneficiary and unfair to pharmacy. Seniors will look to pharmacy for guidance as to which program is the best for them. Given that Part D is a coverage program, beneficiaries will also have to know how to compute their out of pocket cost, since cost sharing will apply.

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 using the pricing website should be able to learn this information without having to involve multiple website navigation clicks. This will encourage the use of less expensive generics in therapeutic categories where alternative molecules might be available.

Posting the actual retail prices is problematic for Longs because it could reveal confidential proprietary information about our negotiations with plans regarding prices and may be impossible, or impractical, to determine. 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 confidential information from pharmacies. If the posted prices for a particular plan were to include negotiated price concessions from manufacturers (which is allowed under the regulation, since plans can pass these through in the form of lower prices), drug specific manufacturer discounts, which are not supposed to be revealed under the statute, would be disclosed.

Website prices may lead to disappointment and confusion among some seniors who expect that they will be charged a certain price for their prescription, only to find that the price has changed only a week later due to a manufacturer's price increase. Resolution of these pricing issues would divert pharmacy resources away from care. We recommend that patients obtain prices from their pharmacies by telephone or in person. We believe that this is the most expeditious and least confusing means for patients to obtain this information. It would also encourage patients to use a single pharmacy in accord with one of your goals.

Section 423. 100 - Definition of Covered Part D Drugs

In Section 423.100, the proposed regulation defines covered outpatient drugs. 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). Based on the foregoing, Longs supports the definition of covered outpatient drugs specified in the statue and the regulation.

Medically accepted indications of these drugs will be covered as well, consistent with these indications appearing in the listed published compendia. However, pharmacists are seldom aware of the specific diagnosis. We are concerned that retrospective review of the use of a drug may indicate that it was not used for a medically accepted indication. 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 reasonably 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 indication.

Instead, the pharmacist should be able to reasonably rely on the prescriber's compliance with the compendia.

We recommend that plans be instructed 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 of their Part B drugs under that Part of the program. We would 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.

Options for Dispensing Fees: In its discussion of covered outpatient drugs at 69 CFR 46647-48, the proposed regulation presents different options for payment of dispensing fees for covered Part D drugs. Longs expects Part D and MA-PD plans will pay pharmacists a reasonable dispensing fee for providing these medications. The statute and regulation clearly envisions that such a fee will be paid by plans. We encourage CMS to monitor the scope and nature of dispensing fees paid by plans to pharmacies to ensure there is appropriate community-based access for Medicare beneficiaries to pharmacy services.

We believe that the plan should pay a dispensing fee suitable to cover the pharmacy's routine cost of dispensing, overhead, and fair profit. However, additional payments should be made for compounding prescriptions (which may be different from "mixing" or "reconstitution" of an antibiotic) as well as other services, such as delivering prescriptions to a beneficiary's home. We also believe that plans should consider the use of differential fees to encourage the use of less expensive generic drugs. Therefore, to facilitate beneficiary access to retail pharmacies, we urge that you monitor the adequacy of the dispensing fees paid by Part D plans.

For the purpose of defining a dispensing fee for Part D oral drugs, Longs believes 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. The definition of dispensing fee, as envisioned in the statute and the regulation, does not appear to 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, as required under state and federal law. The act of providing medication to the patient is an important part of dispensing, but a basic component of such provision involves helping the patient take the medication correctly, store it properly, and understand possible side effects. This information, of which pharmacists are uniquely qualified to deliver, provides a critical component of patient care.

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. Under these requirements, plans cannot require pharmacies to accept insurance risk as a condition of participating in these plans. The legislation defines "insurance risk" as 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.

Consistent with the 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 burdensome payment terms might take the form of 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 arising from the plans' failure 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.

Plans should be required contractually 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 a program. For example, plans should indicate whether they are using First Data Bank, Medi-Span, or another pricing source, and pricing files to be updated daily. Changes in data sources and other contractual terms should be prohibited without mutual consent of the parties. Plans should also be required to publish their Maximum Allowable Cost (MAC) list for generic drugs, provide sufficient notice prior to implementing a change, and use the list to reimburse both for retail prescriptions and mail order prescriptions. Plans should also reveal the criteria used for amending MAC lists.

Section 423.120(a)(6) – Level Playing Field between Mail Order and Network Pharmacies

This section implements statutory requirements relating to plans allowing enrollees to obtain covered Part D drugs from retail pharmacies in the same amount, scope and duration that they do from mail order pharmacies. We believe that it was the intent of Congress to ensure that Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from their pharmacy provider of choice. We believe plans must 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.

Plans must use the same drug cost basis to determine the reimbursement rate for mail order and retail, and not use artificially inflated or repackaged product costs for mail service. Additionally, reimbursement rates for generic drugs should be the same whether provided through retail or mail. Similarly, MAC for generics should be the same for mail order and retail pharmacies.

Given that subsidy-eligible low income individuals cannot have any difference in co-payment amounts for their medications (i.e. $1 for generic; $3 for a brand) 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.

The final rule must specify that plans cannot use differential cost sharing to steer beneficiaries to mail order pharmacies. The final rule should require that, in calculating the difference between the negotiated price for the same quantity of medication dispensed through retail versus mail, 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 patient for a prescription obtained from a retail pharmacy versus a mail service pharmacy, or vice versa, should be considered an "incurred cost", and count toward the beneficiary's out of pocket spending thresholds.

Section 423.132 - Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

This section requires that plans require 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. The pharmacist will be dispensing the product that is stocked in the pharmacy when a prescription is written for a multiple source drug. Therefore, in actuality, this provision requires the pharmacist to tell the patient if they are dispensing a higher cost version of a generic that they stock in the pharmacy rather than the lowest cost version in stock. The use of the term "lowest" can imply that there are more than one version of a generic drug 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.

This section creates disparity between retail and mail service pharmacies. Retail pharmacies are required to provide pricing 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 placed on mail service are consistent with those imposed on retail pharmacies.

In keeping with the interpretation of a similar provision in the Medicare approved discount card program, retail pharmacies should be permitted to provide general information to the beneficiary at the time the prescription first arrives at the pharmacy, if requested, regarding the general price difference between the brand name drug and generic drug if one is available. However, the ability of a Longs pharmacy to provide the actual price difference in print will be extremely difficult, since the current NCPDP 5.1 retail pharmacy claims processing standards cannot support this application. A requirement such as this would require extensive programming at a prohibitive expense to our company.

Section 423.159 – Electronic Prescription Programs

The use of electronic prescribing allows for effective multi-tasking and supports the efficiencies of system-mediated workflow. The use of standards promotes a consistent implementation for stakeholders. The industry widely supports the use of the NCPDP SCRIPT Standard. The SCRIPT Standard has been in continuous use in some regions of the country for over three years providing efficiencies and a level of security heretofore unavailable. The key to successfully implementing electronic prescribing is to obtain critical mass in both the systems used by prescribers and dispensers. Naming NCPDP SCRIPT as the standard for retail pharmacy will ensure that a significant portion of this section of the industry will be able to meet the statutory time frame and eliminate the need for pilot programs.

Electronic prescribing offers a cost efficient method of communicating prescription orders between the prescriber and the pharmacy. However, this opportunity to develop and implement such a valuable aspect of prescribing could be lost without a mandate of uniformity. Longs supports electronic prescribing using the NCPDP Script Standard.

Section 423.452-464 - Coordination Under Part D Plans with Other Prescription Drug Coverage

Section 1860D-23(a) of the Act discusses methods of handling Coordination of Benefits for Medicare Part D patients. The concept of enrollment file sharing and sequencing is a step in the right direction. However, this needs to be expanded to provide even more effective coordination for patients, providers and payers. Coordination of benefits is a complicated task that in a medical center requires specialized staff. It is no less difficult to coordinate for prescription coverage and may be more so since each prescription is a single claim that must be coordinated. We feel that the costs of this coordination need to be shared among the entities that will benefit.

As proposed, the enhancements require extensive software development within Longs' pharmacy computer systems and will adversely affect the workflow of our pharmacies. While Section 1860D-23(a) facilitates providers in determining Coverage and Billing sequence and augments what occurs today. The development surrounding this feature, along with the resulting multiple transmissions and the labor and training required, present a costly barrier to pharmacy for the following reasons:

- Requirement to develop the 270/271 Eligibility transaction. This transaction type is not used by pharmacies today because it is not a real-time transaction. Additionally, if this were enhanced to be a real-time transaction, software development must occur to add this to our existing prescription processing systems.
- Using the 270/271 requires an additional transmission (staff time and cost) *prior* to submission of a claim to determine coverage and sequence. This presents a significant adverse effect on the current workflow in our pharmacies. An eligibility inquiry would not be required for non-Medicare patients, but would be necessary for Medicare beneficiaries.
- Once the payers and sequence is determined, multiple billings must take place with this effort falling on our store personnel, adding to our cost of operation, and extending waiting times for beneficiaries.
- It is not uncommon for various payers to have conflicting coverage rules that require attention by pharmacy staff. For example, payer 1 has a preferred product that is not the preferred product of payer 2, resulting in the need to supply clarification or prior authorization.
- In the prescription-processing arena, each prescription is a separate claim. If a patient is receiving multiple prescriptions, each prescription must be coordinated individually.

Section 1860 D-2 (e) 2(B) indicates the complexity of coverage between Part A, Part B and Part D coverage. In order for individuals to receive their prescribed benefits, Medicare 2006 requires simplification. To accomplish this, we suggest that Part B and Part D covered drugs and medical supplies be processed on-line in real-time by the Part D processor using prescription processing standards common to the industry and in place today. By having all medications processed at a central entity, we provide better patient care, as many of the Part B drugs are complex in nature. For example, many medications are supplied by specialty pharmacies, and are unknown by the local pharmacy or by the PBM processor. The result is those medications are not included in Drug Utilization Review that could identify a potential drug interaction or adverse health event.

The 'Enrollment file Sharing' concept should be developed into a single point of contact where a central entity accepts a claim from a provider containing the Medicare ID number and required patient identifying data, along with prescribed product information. This central entity uses the enrollment file data to populate claims to payers in the appropriate order. As a payment is returned, the central entity transmits the next claim to the next payer. Enrollment rejections are handled by the central entity since the most up-to-date enrollment information is there. Coverage rejections are returned to the provider for follow up. When all payers have processed and made appropriate payments on the claim, the central entity returns final claim payment to the provider who initiated the claim. We recognize the need to modify the NCPDP 5.1 payment response record to provide multiple payer identification and their

associated pricing response so providers can create receivables for the portions of the payment due from the various entities.

Section 1860D-2(b)4(C)(ii) of the Act requires determination of TrOOP, 'true out of pocket' dollars. While the Part D processor will know the TrOOP reported when they processed the claim, if another payer exists and pays on that same claim, the TrOOP is reduced. The Act discusses payers providing updates to TrOOP, but CMS should be aware that it is not uncommon for a patient on one day to receive multiple prescriptions, where each prescription is treated as an individual claim requiring coordination. Under the concept of a single point of contact, when all billings for a claim are completed, the out of pocket amount to be collected from the patient is returned to the provider. Referring to Option 2 mentioned within the Act, the central entity would serve as the 'TrOOP facilitation contractor'. After claim processing the central entity, acting in this capacity, could update the Medicare enrollment file in real-time to set the *accumulated* TrOOP so this amount is available for the next prescription claim – whether it comes in seconds later, or weeks later. By use of on-line real-time coordinated processing, the out of pocket to collect from the patient at time of dispensing would be accurate and up to date.

As noted in the Preamble on page 46707, there is concern regarding cancellation of claims. With on-line real-time processing, the central entity would receive a modified cancel request (modified to provide the payer id of those who need to receive the cancel notification as well as the final out of pocket reported for collection on the claim). This would allow the central entity to perform the cancellations to the various payers, as well as updating the accumulated TrOOP.

By simplifying the Medicare prescription process via a central point of contact, payers will be billed in the proper order, thus paying the correct amount. Patients will only need to carry ONE card -- their Medicare card. Patients will receive their medication with minimal issues due to coordinated claims processing and will be better served by professionals who can assist them with their medication therapy and overall health concerns. Longs supports changes that will assist patient, provider and plans to coordinate coverage and which will avoid unnecessary workflow and operational costs to providers.

Conclusion

Title I of the Medicare Modernization Act presents the opportunity to improve health care for many Americans. Through thoughtful integration of various participants within industry and oversight by the federal government, this opportunity may be achieved in a cost effective manner, yielding significant therapeutic advantages. Longs looks forward to its participation in this endeavor.

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.

Michael L. Cantrell, R.Ph., Esq.
Vice President, Professional Services

Submitter : James Firman **Date & Time:** 10/04/2004 07:10:04

Organization : Access to Benefits Coalition

Category : Other

Issue Areas/Comments

GENERAL

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October 4, 2004

Mark B. McClellan, MD, Ph.D
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-4068-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Re: Medicare Prescription Drug Benefit, Proposed Rule (CMS-4068-P)
Dear Dr. McClellan:

On behalf of the Access to Benefits Coalition (ABC), which includes 92 national organizational members and 52 local coalitions, we wish to offer the following comments and recommendations regarding the August 3rd proposed rule on the Medicare Prescription Drug Benefit (CMS-4068-P).

Outreach, education, decision-support, enrollment and notification issues
Section 423.48 of the proposed rule concerns transmission of information about the new Part D benefits to beneficiaries. We are very concerned that this section does not adequately address the need for targeted and hands-on outreach, education and decision-support and enrollment services, particularly outreach to lower income, rural, and disabled beneficiaries, as well as those who have low literacy or for whom English is not their primary language. Many of these beneficiaries will need personalized, one-on-one assistance to access benefits (i.e. sign up for the Part D low-income subsidies) as well as to make wise choices among the competing Part D plans. ABC can and should play an important partnership role in a major outreach, education and enrollment campaign for the Part D subsidies as well as in decision-support to help people choose the best plan for them.

Although the preamble suggests that such campaigns should occur, the regulations do not. The preamble discussion focuses largely on support through the Internet sources and the 1-800-Medicare number. Both are necessary and helpful but insufficient to meet the needs of many of those eligible for both Medicare and Medicaid (dual eligibles) as well as those eligible for low-income subsidies. To answer the many confusing, detailed, time-consuming questions that beneficiaries with low incomes will have about the new program, an extensive network of local counseling services will be needed. The local affiliates of national ABC members, as well as local ABCs and State Health Insurance Counseling Programs (SHIPs), can provide the kind of detailed help needed, but they will need additional resources to do so. The regulations should be more specific about how CMS, the Social Security Administration (SSA), Prescription Drug Plans (PDPs), states, and community-based organizations should work together in a coordinated fashion to reach and enroll these beneficiaries.

There are also important notification issues involved in these efforts. For example, as early as possible, CMS or the states should mail simple, standardized notices to dual eligibles that: (i) inform them of their eligibility to receive the low income drug benefit if they enroll in a PDP or MA plan; (ii) list choices of PDPs in their area (clearly denoting those that meet the benefit premium assistance limit) and contact information for them; and (iii) explain that individuals will be randomly assigned into a PDP by [X date] if they fail to enroll themselves. Similar notification should be provided to those receiving assistance under Medicare Savings Programs (MSPs).

When individuals are notified of their eligibility or ineligibility for the low-income subsidy, they should be notified of the level of subsidy and of their right to appeal both ineligibility and the level of the subsidy. SSA and states should notify CMS within 24 hours of the date when a beneficiary is determined subsidy eligible. Under section 423.773, those who are deemed subsidy eligible need to be notified of that status and how to enroll in a PDP to use the subsidy. If the states provide this information, CMS should reimburse 100% of their administrative costs.

CMS should direct both states and SSA

CMS-4068-P-1127-Attach-1.txt

October 4, 2004

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Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-4068-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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CMS should direct both states and SSA that individuals applying for Medicaid who have a spend-down period, either under a medically needy program or in a 209(b) state, should be informed of their likely eligibility for a low-income subsidy and given the direction to enroll. After they have spent down, they should be informed of their entitlement to a lower co-payment, if applicable. Once they are determined to be subsidy eligible, they should retain that status for a full year, until the next redetermination for the low-income subsidy, regardless of whether they are no longer eligible for Medicaid. Otherwise, individuals who go in and out of medically needy status, depending on the length of their state's budget period, will experience confusing changes – for pharmacy networks and PDPs plans, as well as beneficiaries – regarding the status of their low-income drug subsidies.

In addition, to facilitate outreach and enrollment efforts, CMS should provide data on enrollment rates by state and county on a monthly basis in electronic form for use by analysts and researchers. A centralized database should be developed and made available that allows CMS, SSA, the states, and PDPs to view real-time beneficiary information and make timely updates to information. The real-time, shared database could be utilized by states to determine whether dual eligibles or MSP beneficiaries have enrolled in a PDP or whether they should be automatically assigned into a plan. CMS should also generate ongoing reports on best practices and the results and cost effectiveness of outreach and enrollment efforts. More of this data for decision-making should be placed into the public domain.

Consumers are going to be required to make choices among competing plans that could have serious consequences for their health and health care. In addition to providing information about the features, coverage and costs of competing plans on Medicare.gov and through print publications, CMS should also make detailed information about plans available electronically to others in accessible formats that would enable them to conduct independent analyses about what plan would be best for a particular individual. As we are seeing from the current efforts on Medicare-approved cards, the private sector can offer

information in ways that can support informed decision-making and enrollment in ways that can complement and extend government efforts.

Uninterrupted Coverage for Dual-Eligible Beneficiaries

Under section 423.34 the initial enrollment period for the drug benefit begins on November 15, 2005, and extends for six months. However, Medicaid prescription drug coverage for dual eligible beneficiaries is scheduled to end on January 1, 2006. It is not clear, however, whether they will all have Medicare drug coverage by then. The current schedule leaves only 45 days to notify, educate and counsel dual eligibles about their PDP choices; identify those who have failed to enroll in a drug plan and auto-assign them into a PDP; and educate those who have been auto-assigned about their new coverage.

There are both timing and operational issues surrounding the enrollment process. Given the difficulty of reaching this population, coupled with inadequate provisions for outreach and education, 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 assignment. This completely foreseeable situation is untenable. We must ensure that none of these 6.4 million beneficiaries confronts a loss of benefits or gap in drug coverage, either of which would have disastrous consequences. Absent a statutory change which extends Medicaid prescription drug coverage beyond January 1st, dual eligibles must all be automatically assigned before their Medicaid coverage ends.

Automatic assignment for Medicare Savings Program (MSP) beneficiaries

As described above, dual eligible beneficiaries will be assured that they will receive Medicare prescription drug coverage through an automatic assignment process. Unfortunately, this is not the case for the almost 2 million MSP beneficiaries with incomes below 135% of poverty who currently receive help with their Medicare premiums. We applaud and support the decision under 423.773 to deem MSP beneficiaries as full subsidy eligible individuals. The ABC also supported the recent decision to automatically enroll this group in the Medicare discount card program, with the $600 annual credit. Making MSP beneficiaries eligible for low-income subsidies is not sufficient; they must be assured that they will actually receive the available subsidies by automatically assigning them through the same process as that for dual eligibles.

Screening for MSP, Medicaid, and other low-income program eligibility

Under section 423.904, in processing applications for low-income subsidies, states and SSA should screen for MSP and full Medicaid eligibility, as well as for other low-income benefits, such as Food Stamps and SSI. The opportunity to enroll in these other programs should be made available during the same visit or contact (whether in person, by phone or by some other contact), without providing any further documentation or completing any additional forms, so that that they do not need to take further action that requires an additional trip to the agency.

CMS should specify that the eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the benefits for which they qualify. For example, outreach materials should contain

information about other low-income benefits. Applications and data should be easily shared between SSA, states and CMS so that they are available to all agencies and duplication of effort can be avoided. Other federal agencies administering low-income programs should be encouraged to simplify their rules to promote easier access. A model may be the SSA Combined Application Projects that now operate in a handful of states where SSI applicants are asked only a couple of additional questions and are certified automatically for food stamps based on their SSI applications.

Treatment of resources

Under section 423.772, we strongly support CMS's decision to count only liquid assets. In addition, the definition of "resources" should be clarified concerning what it means to be able to be converted into cash in 20 days. Resources should not include burial plots, burial funds or life insurance of any value, nor should they include any officially designated retirement account, such as an IRA or 401(k). Resource assessments should not include any consideration of transferred assets.

In addition, several states that have less restrictive income and resource methodologies under their current MSP programs should be permitted to use them in determining subsidy assistance eligibility. While national uniformity may be a desirable goal, uniformity within states is also desirable because it would be unduly cumbersome for states to develop yet another resource methodology to apply to a certain group, who is probably also MSP eligible. In addition to states, SSA should also apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy. 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 is permitted under Section 1860D-14(a)(3)(E)(iv) of the Medicare Modernization Act. SSA has the capacity to apply different resource methodologies in the few states where this applies, as we understand that they currently apply different rules when determining eligibility for state supplements.

Redeterminations for low-income subsidy eligibility

If seniors and people with disabilities are required to fill out lengthy forms or mail in re-enrollment forms every year, large numbers of low-income, frail beneficiaries will likely lose their subsidies. Preprinted renewal forms should be mailed to enrollees on an annual basis with instructions that they should return the preprinted postcard only if corrections about their eligibility status are needed.

Section 423.774(c)(1) refers to redeterminations and appeals under the state Medicaid plan. It should make clear that determinations are for one year and that redeterminations should 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. Under section 423.774(c)(2) the Secretary should direct the SSA Commissioner to create an annual, passive, simple redetermination process under which an individual 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. Section 423.774 (c) should also provide for a

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. Section 423.774(d)(2) 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.

Treatment of Drug Patient Assistance Programs (PAPs) and TrOOP

Under section 423.104, both donated prescription drugs and payments made under private sector, state, and federal PAPs should be counted in calculating beneficiaries' true-out-of-pocket costs towards meeting the catastrophic thresholds. If assistance from these sources is not permitted to count as true out-of-pocket (TrOOP), lower income beneficiaries (typically those with incomes between 150% and 200% of poverty, or those whose assets disqualify them for low-income subsidies) will lose the help they are now getting through access to free or low-cost drugs. These programs have the potential to fill the "doughnut hole" for those in great need. If PAPs and other assistance programs are liable for costs incurred without any back-end protection from the law's catastrophic coverage, there will be strong incentives to drop the assistance programs completely. The regulations should provide incentives for these important programs to continue.

Thank you for this opportunity to share our views. We look forward to working with CMS to ensure that all lower income Medicare beneficiaries receive the assistance they need and to which they are entitled.

Sincerely,

James Firman, Chairman
Access to Benefits Coalition

CMS-4068-P-1128

Submitter : Mr. Thomas McCormack **Date & Time:** 10/04/2004 07:10:36

Organization : Title II Community AIDS National Network

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file comments.

CMS-4068-P-1128-Attach-1.doc

• T. II C.A.N.N. •

TITLE II COMMUNITY AIDS NATIONAL NETWORK

1775 "T" Street, NW **Washington, D.C. 20009**
Phone: (202) 588-1775 **Fax: (202) 588-8868**

Email: Weaids@ix.netcom.com

A Not for Profit 501(C) (3) Policy & Program information Exchange &
Service Organization for AIDS/HIV Education, Advocacy, Support & Action .

Comments on Medicare Part D proposed regulations:

1. CMS' final regulations should more clearly and explicitly require and *actually list* the SSI income disregards which states and SSA must use in determining eligibility for the very low income and low income Medicare Part D subsidies. Among these are:

*$20 monthly per case of any income (apply to unearned first)
*$65 and half the rest of gross monthly earnings per case
*$1370 monthly (up to $5,520 yearly) of earnings, not otherwise disregarded, of each student under 21 in 2004
*Earnings, not otherwise disregarded, which are actually spent by the recipient *himself* (and not by Medicare, Medicaid or another benefit program) on Impairment Related Work Expenses ("IRWEs" are medically-related costs which enable a disabled person to work; they include the costs of at-work or go-to-work attendants and assistive devices, Medicare and health insurance deductibles and copays, cash medical purchases, over-the-counter drugs, bus, taxi, subway and auto gas mileage costs of travel to medical care and even extra/special impairment-necessitated costs of commuting to work, such as vans for wheelchair users or the very frail.)
*Earnings of the blind, not otherwise disregarded, which is spent on work-related expenses (e.g., taxes, other payroll deductions, union dues, carfare, guide dog food and care, Braille-related costs, uniforms, etc.)
*One third of *actually received* child support payments
*State or local government welfare or vendor payments based on need (including AFDC and TANF; state-paid child care fees; state-paid supplements to SSI; General and Emergency Assistance and Home Relief)
*The value of medical, housing, energy and food assistance.
*Amounts of assets or income placed in SSA- or state-approved Plans to Achieve Self Support (PASSes) to ready a disabled person for employment—including PASS money spent on medical care or travel to medical care that aids the PASS employment goal.

2. We support the suggestions made by other commentors that assets such as pre-paid funerals, pre-paid cemetery plots, life insurance policies and separate accounts designated for burial simply be totally disregarded and exempted in the interest of eased program administration and a lessened burden on potential recipients. And we support CMS' apparent---but still far too-vague---proposal in the NPRM to effectively ignore vehicles totally. If these routes can't be taken, then CMS should recall that the statute explicitly requires that applicants for the very low and low income subsidies be accorded *triple* the non-general liquid asset levels that are allowed by SSI (i.e., they must be given three times the asse6t allowances of the SSI program, excerpt for the $6,000/$9,000 and $10,000/$20,000 general liquid asset levels that are explicitly set forth in the MMA for the very low and low income subsidy groups). While a literal reading of the statute here would even require exempting *three* homes per case, we don't have the temerity to demand that absurd result. But, should CMS not adequately exempt vehicles or totally disregard all pre-paid funerals, cemetery plots, life insurance policies and separate burial accounts, then this literal statutory mandate *must*, in fact, compel the exempting of at least *three* vehicles per case and at least $4500 (triple SSI's $1500 allowance) *per family member* (including, of course, Medicare-*in*eligible spouses and children) in burial-related assets and life insurance policies from which cash can immediately be raised.

• T. II C.A.N.N. •
TITLE II COMMUNITY AIDS NATIONAL NETWORK
1775 "T" Street, NW **Washington, D.C. 20009**
Phone: (202) 588-1775 **Fax: (202) 588-8868**
Email: Weaids@ix.netcom.com
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Service Organization for AIDS/HIV Education, Advocacy, Support & Action .

3. We applaud CMS' decision to allow for the use of family-sized income levels that recognize the presence of non-Medicare-eligible family members such as spouses and children for whom the beneficiary pays over half of support. This commitment to the appropriate family-sized income level must be matched, however, by a like use of *full family-sized general liquid asset and supplementary asset levels that also recognize the presence of non-Medicare-eligible spouses and children in the assistance unit.* This means, that if CMS fails to meet our preferred suggestions to simply totally disregard all vehicles and burial-related and life insurance policies as assets, it must explicitly allow not only three vehicles per case, but also at least $4500 in supplementary burial-related and life insurance policy cash-available assets *per family member, including not only Medicare-ineligible spouses but also children in the home.* **And moreover, in any case, the $6,000/$9,000 and $10,000/$20,000 general liquid assets levels must have added to them an additional $3,000 or $10,000, as the case may be, to allow for the presence in the family of any children.**

4. While we support the various suggestions by other commentors on the best methods for proactively and easily enrolling very low income and low income subsidy eligibles in Part D (as well as full Medicaid, MSP-only, SSI and/or food stamps, as appropriate) CMS should recall that the low income subsidized group also includes those above the 135% FPL MSP income level but below 150% FPL. Surely a number of the Medicare patients cases in that income range---even before the deducting of their incurred medical bills---have had their eligibility status evaluated, and have been somehow inputted into state systems in some sort of pending status, already by state Medicaid eligibility staff where they've applied for spend down coverage as either medically needy or under Section 209(b). These would include not only those Medicare patients who *successfully* have spent down to Medicaid eligibility in a current or recent eligibility budget period (one, three or six months, depending on the state), but also those inputted into the state eligibility system who haven't yet or may not at all *successfully* spend down. Both kinds of Medicare beneficiaries have countable incomes (prior to the deducting of incurred medical bills) under 150% and have been already "worked-up", for eligibility purposes, by states in anticipation of a potentially successful current, prospective or recent spend down. CMS should arrange to gather lists of such cases---including not just current and prospectively current successful and pending spend downers, but also successful and unsuccessful spend downers form recent past eligibility spend down budget periods (e.g., perhaps all spend down cases, successful and unsuccessful, "worked up" by state eligibility workers within the last two years or so). Amassing such lists from states—and adding them to the lists of full dual eligibles and "MSP-onlies" who are to be targeted by methods suggested by CMS itself and other commentors would thus include a significant portion of those needy beneficiaries over the 135% MSPFPL level but below the maximum 150% FPL Part D subsidy level.

Thomas P. McCormack
Public Benefits Policy Consultant
(202) 479-2543

CMS-4068-P-1129

Submitter : Dr. Margaret Giannini **Date & Time:** 10/04/2004 07:10:34

Organization : Office on Disability

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached from the Office on Disability

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1130

Submitter : Mrs. Susan Schwarz **Date & Time:** 10/04/2004 07:10:12

Organization : CV Medical Solutions

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

CV Medical Solutions

CMS-4068-P-1130-Attach-1.doc

CMS-4068-P-1130-Attach-2.doc

CV Medical Solutions 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.

CV Medical Solutions is based in Oklahoma City, Ok. We are an independently owned company and have been servicing home infusion patients for over 12 years. We have provided home infusion to many Medicare patients during this time, including, TPN patients, Inotropic patients, pain patients, and other misc. therapies.

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

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

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

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying coverage of the services, supplies. Section 642 of the MMA created limited coverage of home administration of intravenous immune

globulin (IVIG) for patients with diagnosed primary immune deficiency disease (PIDD) under Medicare Part B. According to the Immune Deficiency Foundation, which represents patients the PIDD community, his new coverage under Part B has not resulted in additional access to home IVIG under Medicare. We see this as an important "demonstration project" of what is likely to happen under Medicare Part D if drugs are covered without adequate coverage, reimbursement, and standards for the critical services, supplies, and equipment that comprise the basic standard of care for home infusion therapies.

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

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

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

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

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

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

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

Sincerely,

Susan Schwarz, D.Ph.
VP Clinical Operations
CV Medical Solutions

CMS-4068-P-1131

Submitter : Mr. P. STEPHEN McDowell **Date & Time:** 10/04/2004 07:10:42

Organization : Mr. P. STEPHEN McDowell

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter with my comments.

CMS-4068-P-1131-Attach-1.doc

P. Stephen McDowell
1403 Cross Valley Dr
Sugar Land TX 77479-6934
281-937-1922 (H) • 281-937-9187 (O)

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 the parents of an adult daughter with Autism, Mental Retardation and Epilepsy, I am very concerned about the effect of proposed rules on the ability to properly treat my daughter's needs with appropriate and effective medications. Specifically, we join with those who are advocating critical changes to the proposed rule: "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The recommendations, in brief, include:

- Delay the implementation of the Part D program for dual eligibles
- Expand outreach to Medicare beneficiaries with disabilities
- Designate special populations who will receive affordable access to an alternative formulary
- Impose new limits on cost containment tools
- Strengthen and improve inadequate and unworkable exceptions and appeals processes
- Require plans to dispense a temporary supply of drugs in emergencies

Thank you for your attention to our concerns.

P. Stephen McDowell
Eileen D. McDowell

CMS-4068-P-1132

Submitter : Dr. John Cronin **Date & Time:** 10/04/2004 07:10:16

Organization : California Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See attached comments

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

See attached comments

CMS-4068-P-1132-Attach-2.pdf

CMS-4068-P-1132-Attach-1.doc

CMS-4068-P-1132-Attach-2.pdf

CMS-4068-P-1132-Attach-1.doc

October 1, 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:

The California Pharmacists Association (CPhA) is the largest state pharmacy association in the nation, with more than 5000 members. We welcome the opportunity to offer the following comments on the proposed rule for the Medicare Prescription Drug Benefit.

CPhA is an affiliate of the American Pharmacists Association, the National Community Pharmacists Association and several other national pharmacy groups. We are aware of the comments provided by these professional associations with regard to this proposed rule and join with them in those comments. Our comments should be considered in addition to the comments provided by those organizations, particularly as their comments apply to the portions of the proposed rule other than Part 423, Subpart D, which is the primary focus of our comments.

Part 423, Subpart C – Dispensing Fees
CPhA believes the appropriate definition to use for "dispensing fee" is found in Option 1 in the proposed rule: 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 or any activities for entities other than the pharmacy.

CPhA believes more clarity is needed in this definition with regard to medications that are "compounded" in the pharmacy. It is clear that the typical costs associated with the simple dispensing of prescription drug are not representative of costs associated with the extemporaneous compounding of prescription medications from raw ingredients. The definition should allow for these additional costs, either in the form of an enhanced dispensing fee, or, more properly, as a separate fee based on the reasonable costs for providing the enhanced professional services associated with compounding of the particular prescription preparation.

Further, emphasis needs to be placed on the fact, which is clearly stated in the proposed rule, that the dispensing fee does not include the costs associated with the services mandated by OBRA 90. Pharmacies must be compensated for these costs outside of

4030 Lennane Drive
Sacramento, California 95834
916.779.1400 ● Fax 916.779.1401
www.cpha.com ● cpha@cpha.com

the proposed concept of a dispensing fee as included in the rule. This however begs the question as to how payment for OBRA 90 counseling might occur. Since OBRA 90 counseling is required for every new and changed prescription, it would fall out of the scope of medication therapy management programs (many people receiving new or changed prescriptions will not have multiple chronic conditions, be taking multiple medications, or exceed a defined cost threshold). Further clarification on how PDPs and MA-PDs are to pay pharmacists for OBRA 90 counseling services is needed.

CPhA believes that any approach to establishing a dispensing fee must be based on sound actuarial data, updated at least annually to incorporate changing costs and increases in costs of living and including an amount for reasonable profit or return on investment. In addition, the dispensing fee must take into consideration local requirements for pharmacy operation with may increase the costs of providing service. Absent such a basis, the dispensing fee can easily be the subject of contracting abuse by the prescription drug plan (PDP) or Medicare Advantage prescription drug plan (MA-PD). We have substantial concerns that the Medicare Part D program may result in contracting activity that reflects monopsony power exerted by the plans.

Subpart C – 423.104(h) Negotiated Prices
CPhA agrees that enrollees should receive the benefit of negotiated prices and we support the provisions of the proposed rule that ensure this will be the case. However, the precise mechanism of how any discounts are provided to enrollees is not nearly as clear. One concern that exists under the current prescription drug discount program is whether pharmacies may be required to bear the carrying costs of these discounts while the PDP or MA-PD is collecting negotiated rebates. The profession considers this to be a major flaw in the discount card program and we recommend that the proposed rule be amended to ensure that these costs be borne by the PDP or MA-PD rather than imposed on the pharmacy provider network.

Subpart C – 423.120 Access to covered Part D drugs
CPhA specifically joins APhA and other national pharmacy organizations with regard to their comments on the TRICARE pharmacy access requirements and the establishment of preferred pharmacy networks. We refer CMS to those comments with this notation of our support for them.

Subpart C – 423.132 Public disclosure of pharmaceutical prices for equivalent drugs
CPhA recognizes the desire to make this information available to enrollees. However, it may become impractical for pharmacies to provide this information to enrollees. We envision that in the large majority of cases in which this cost differential may be a factor the enrollee or their prescriber either will be requesting a particular brand of drug or may have little or no interest in the information. To impose this requirement on pharmacies without some indication that the enrollee is seeking the information amounts to an inefficient use of resources. We recommend that any requirement imposed on pharmacies to provide this information should be limited to circumstances when the enrollee asks the pharmacy for this information.

CPhA also has concern about the nature by which the proposed rules impose the disclosure requirement on mail order pharmacies. The rule states that notification must occur at the time of delivery which we believe is too late. By the time a patient received a 90 day supply of medication in the mail, there is nothing they can do to obtain a lower

cost product in lieu of whatever they were shipped. If this requirement is left in place, CPhA would like to see that price disclosure occur at the time of ordering.

Subpart D – 423.153 Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

General Comment:

CPhA appreciates the fact that Congress and CMS has recognized that a well designed prescription drug benefit must include services that extend beyond the simple dispensing of medications. Subpart D recognizes four distinct areas in which cost control and quality improvement can be achieved from these additional, non-dispensing services. The most significant of these to pharmacists is the medication therapy management services, but pharmacists can play a valuable role in ensuring that each of the service areas achieves its desired end. CPhA applauds the promotion of flexibility in the design of programs to see that the benefits of these components of Medicare Part D are realized.

CPhA believes pharmacists and pharmacies should embrace the opportunities created in the new requirements; we equally believe that payers, including the Medicare Program, should recognize the value received from the efforts of the pharmacy profession and provide for proper compensation to pharmacists and pharmacies for the value delivered. These two concepts must be realized together – the only way for the Medicare Program to achieve its desired end is to appropriately reward those who perform in response to the opportunity provided.

Subpart D – 423.153(b) Cost Effective Drug Utilization Management

CPhA supports the use of cost effective drug utilization management tools such as those identified by CMS in the background provided for the proposed rule. We strongly agree that such tools must include incentives if they are to be successful. While we agree that any type of "therapeutic substitution" should always require prescriber notification and approval, we believe the rule should make clear that such activities are appropriate when provided in accordance with protocols or procedures accepted by the prescriber. Under such protocols, approval of the prescriber may not be as "explicit" as is suggested in the materials that accompany the proposed rule.

The proposed rule recognizes the need to address both overutilization and underutilization of prescription drugs in the drug utilization management programs. We agree. In doing so, we point out that correcting underutilization will certainly result in increased drug costs to the program. These increased costs will likely be offset by savings in areas outside the drug benefit, resulting in the need to properly align the incentives needed to realize the potential benefit of improving utilization. The proposed rule needs to require PDPs and MA-PDs to compensate pharmacists and pharmacies for the value of efforts to improve utilization even if these efforts result in higher drug costs.

The proposed rule notes consideration of the use of Pharmacy and Therapeutics Committees in this area. We agree and further suggest that such P&T Committees should place a high level of importance on coordination of prescriber and pharmacy providers. This can be achieved by requiring the majority of the members of the P&T Committees to be providers within the PDP or MA-PD. Such a requirement not only assists in improved relationships between physicians and pharmacists but will also serve

to exert a higher level of peer pressure on prescribers and pharmacies that fall outside the performance norms of their respective provider networks.

Subpart D – 423.153(c) Quality Assurance
CPhA supports inclusion of this component in Medicare Part D. California has had a quality assurance requirement to reduce prescription errors in pharmacies for several years. Although we have not seen any studies of the impact of this requirement, we have received anecdotal reports from members, non-members and the California State Board of Pharmacy that the emphasis on quality assurance has made pharmacists more aware of potential problem areas and has resulted in greater scrutiny of dispensing practices.

However, the proposed rule goes farther in this section than simply seeking to reduce medication errors. In addition, the rule seeks to reduce adverse drug interactions and improve medication use. In total, the goals of this provision are consistent with the provisions of OBRA 90. Although these provisions have been widely incorporated into pharmacy practice, CPhA believes the potential benefits from these activities have not been fully realized. This is due in large part to the fact that pharmacy reimbursements have not compensated pharmacies for the increased costs of providing these services. As noted in our general comments on this section, the reward to providers for meeting the new requirements must be adequate to secure the benefit of those requirements.

The proposed rule has recognized the fact that these (and other) services are separate and distinct from the function of drug distribution. The rule should incorporate this recognition more forcefully by requiring payment for these services separately from payment of a dispensing fee. This is particularly true in light of the proposed definition of a medication error included in the background of the proposed rule. CMS should either adopt a less broad definition of medication error or establish some mechanism to compensate pharmacists and pharmacies for the costs associated with the level of quality assurance required by this definition.

With regard to the various types of QA mechanisms, CMS has mentioned a variety of elements, including electronic prescribing, clinical decision support systems, bar codes and adverse event reporting systems. These examples of desired elements are "mechanical" in nature in that they involve collection and analysis of data. Other elements mentioned include educational interventions and provider and patient education – elements that are much more part of the "art" aspect of health care practices. Because of the distinct differences involved in these two types of elements, the value, the costs, and hence, the payment, for them should be handled differently. The final rule should recognize the distinctions in how elements of QA programs are implemented and should require payment systems to incorporate those distinctions.

Subpart D – 423.153(d) Medication Therapy Management Programs (MTMP)
CPhA 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.

CPhA views the MTMP section of the proposed rule as the most interesting and exciting for pharmacists. We note with approval the following language from the proposed rule:

> We [CMS] are particularly interested in the most effective steps to make valuable, proven MTMP services available to beneficiaries ***to improve health care quality and reduce costs***. We are mindful of the importance of ***stimulating the evolution*** of the most appropriate and efficient form of MTMPs, ***without stifling innovation*** or prematurely locking-in specific attributes [emphasis added] 69 Fed. Reg. 46668.

CPhA believes these characteristics - the goals of improving health care quality and reducing costs in an environment of growth and evolution that encourages innovation – should serve as the principle guidelines for MTMPs offered by PDPs, MA-PDs and the Chronic Care Improvement Programs. Along with these attributes, the programs should be based on the now broadly recognized fact, demonstrated in several studies, that these programs result in significant savings to overall health care costs.

With these basic characteristics in mind, we make the following additional comments:

"Targeted Beneficiaries"
It is understandable that the Medicare Program would want to focus it's financial resources on those activities that will result in the most economical and efficient utilization of those resources. However, the goal of improving health care quality and reducing costs is of benefit to all Medicare beneficiaries, not only a defined group or groups of beneficiaries that meet certain diagnostic criteria. As such, CPhA believes the concept of "targeted beneficiaries" should be interpreted in as broad a manner as allowed under the statute. We also believe that, because of the benefits that will result from MTMPs, every effort should be made to include beneficiaries in the target beneficiary definition rather than to use that definition to exclude coverage. In addition, we believe PDPs, MA-PDs and the CCIPs should strive to extend MTMPs to all participants in their programs, not because it is mandated under this new provision of the law, but because it does result in the most efficient and economical use of resources and will preserve a consistent level of access to care for all Medicare beneficiaries – standards that have long been recognized as part of the Medicare program.

Multiple Chronic Diseases; taking Multiple Part D covered drugs; likely to incur annual costs that exceed a pre-determined level.
Consistent with our comments above, as well as with the overall characteristics of stimulating evolution without stifling innovation, we believe these three criteria should be interpreted in manner that is as inclusive as possible.

In our view, "multiple chronic diseases" should incorporate current health issues and should be extended to include anticipated changes in health condition. For example, beneficiaries being treated for high cholesterol should be eligible for MTMPs in order to prevent conditions such as hypertension and cardiovascular disease that often result from failure to control high cholesterol but which may not be present currently. This is a particularly relevant example because of the high level of effectiveness of current medications used to treat high cholesterol and the often bothersome side effects

associated with the use of those medications. Programs to improve compliance with this class of drugs will improve long term health and result in significant overall cost savings to the Medicare Program. It makes no sense to exclude these beneficiaries from MTMPs based on an overly restrictive definition of who qualifies for coverage.

In the same way, "taking multiple Part D covered drugs" should be broadly interpreted. In our view any beneficiary taking more than one medication should be seen as meeting this qualification. We believe it is likely than MTMPs in many cases will result in beneficiaries taking fewer medications. As a result, we foresee that at least some beneficiaries who initially are taking multiple drugs may, as a result of the MTMP, find they can reduce those medications to a level that is below the qualifying threshold, however it is defined. CPhA believes it is in the best interest of the patient and the Medicare program to continue coverage for MTMPs once a beneficiary has been found to qualify for that coverage.

The final qualification is "likely to incur annual costs that exceed a certain level that we [CMS] determine." CMS has asked for comments on legal and policy aspects associated with delegating this determination to the private drug plans. CPhA believes that, although there are good reasons for delegation of this determination to the drug plans, both legally and as good policy CMS should retain oversight of this decision.

Many of CPhA's pharmacist members would opine that the drug plans cannot be trusted with this determination. This opinion is based on the history of their dealings with pharmacy benefits managers (PBMs) and managed health care plans, many of which are or will be participating in the Medicare Part D programs. In addition, the basic business relationship between pharmacies, pharmacists and the PDPs and MA-PDs will be much the same as currently exists: the payers have an extreme advantage in negotiating power can essentially dictate terms to providers. This type of relationship is currently being challenged in two separate lawsuits and represents the type of monopsony power that many antitrust experts believe needs to be curtailed. Some level of oversight needs to be in place to assure that abuses of the type feared by pharmacy providers do not occur. The responsibility for that oversight needs to lie with an entity that can quickly respond to claims of abusive contracting and administrative behavior.

There certainly are roles for the PDP and MA-PD sponsors to play in determining these criteria, and we believe CMS can appropriately explore delegation of those roles to the PDPs and MA-PDs. However, we believe CMS needs to retain the final authority to approve or reject a drug plans recommendation. One step CPhA suggests to aid CMS in that oversight is the involvement of pharmacy and therapeutics committees[*] in any role that is delegated to the drug plans. Further, an action by CMS in this area should be based on the basic characteristics that have been identified in the proposed rule: improve health care, reduce costs, and promote the evolution of MTMPs without stifling innovation.

In light of those basic characteristics, we believe that the annual cost issue can be resolved simply: that any level of annual costs should qualify a beneficiary for coverage for any MTMP that has been shown to reduce overall health care costs. It is widely acknowledged that MTMPs will, in some cases, increase drug expenditures but will be cost effective because these increases are offset by greater savings in other medical

[*] See our comments on Pharmacy and Therapeutics Committees below

costs. We believe CMS needs to consider this reality as it finalizes a rule that appears to treat MTMPs as impacting only the drug benefit "silo." Recognition of the true impact of MTMPs needs to occur if the benefit of these programs on overall health care costs is to be realized.

In sum, CPhA believes the concept of "targeted beneficiaries" and the related definitions of "multiple chronic diseases," "multiple covered Part D drugs" and level of annual costs at which coverage is triggered should be driven by the overall characteristics of the MTMPs that are being sought. Because MTMPs will improve health care and reduce costs, the interpretation of these statutory limitations should be as inclusive as possible. By adopting a broad interpretation, CMS will best achieve the goal of promoting the evolution of MTMPs without stifling innovation. Regardless of how the limitations are ultimately defined, the rule should encourage expansion of MTMPs to all beneficiaries in the interests of promoting economy, efficiency and access to better and more cost effective health care.

MTMP Provider Networks

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 a 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. It is for this reason 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.

The proposed rule acknowledges that pharmacists will be the primary providers of MTMP services. CPhA and its members appreciate the confidence placed in the profession in this area and we believe that confidence is not misplaced. We believe among the health professionals, pharmacists are in the best position to provide the MTMP services that will best benefit Medicare beneficiaries. We also believe that the best approach, as recognized in the proposed rule, is for beneficiaries to utilize existing beneficiary-provider relationships in the provision of MTMP services.

CPhA 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 to 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.

Because of the ready accessibility of pharmacists and the presence of existing beneficiary-provider relationships, we not only agree that pharmacists should be recognized as primary providers, we believe that MTMPs should actively promote pharmacists as the preferred provider of MTMP services. CPhA strongly believes that personal, face-to-face interaction between pharmacists and beneficiaries is the best way to realize the potential benefits of MTMP services. We acknowledge that our suggested "preferred" status may have require meeting special criteria related to qualifications and performance and we believe certain criteria are appropriate. We again recommend that the pharmacy and therapeutics committees* play an integral role in establishing these criteria.

Alternative providers of MTMS services may be appropriate for certain aspects of MTMP services, but CPhA believes that qualified pharmacists can provider equivalent levels of expertise with a higher level of access. Regardless of who provides the services, providers of all types should meet the same general requirements. Allowing different levels of qualification for the same types of services in order to save costs at the expense of outcomes should not be allowed under the proposed rule. Any MTMP should be designed to ensure the improved health outcomes and reduced costs that are the goals of this new benefit. Drug plans should be required to monitor performance of their MTMPs and those that fail to meet the goals as described in the proposed rule should be required to address any deficiencies.

MTMP Fees

A major concern of CPhA involves the issue of fees for MTMP services. We strongly agree that any such fees should be separate and distinct from dispensing fees associated with the drug distribution portion of the Part D benefit. Our primary concern relates to the level of oversight by CMS as to the appropriateness of these fees.

* See our comments on Pharmacy and Therapeutics Committees below

The proposed rule states "in establishing fees for pharmacist or others providing MTMP services, . . . a PDP sponsor must take into account the resources and time associated with implementing the MTMP." In implementing this requirement, CMS proposes to 1) require PDP sponsors to describe their plan in establishing fees for pharmacists and others for providing MTMP services, and 2) to investigate complaints that PDP sponsors are not paying pharmacists or others in accordance with the fees discussed as described above. While CPhA agrees with both of these provisions, we believe CMS has an obligation to do more. Specifically, we believe CMS should be providing oversight of the fee setting process to ensure that the fee is fair and reasonable in light of the resources needed to provide the MTMP services. It is not enough for CMS to investigate only when the plans are not in compliance with the payment standards they set. There needs to be review of those payment standards for appropriateness consistent with the standards for provider payments established elsewhere in the Medicare program.

CPhA believes this to be a major weakness in the proposed rule. CMS states in the proposed rule that

> [W]e do not believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services. We also would not adjudicate any specific disputes between PDP sponsors or MA organizations and pharmacists or other providers regarding the specific fees due for MTMP services.

69 Fed. Reg. at 46669-46670. CPhA asks that CMS re-examine this issue to identify the extent of CMS's authority to review the adequacy of contracted fees for MTMP services. At a minimum, CPhA believes some grievance process needs to be established to ensure that fees for these services meet some minimal stand to ensure access to quality MTMP services that meet the goals expressed for the Part D benefit. Absent some process for review, providers will have no means of challenging the adequacy of compensation offered to them on a take-it-or-leave-it basis by a PDP or MA-PD.

Pharmacy and Therapeutics (P&T) Committees

The discussion of section of 423.153(b) of the proposed rule suggests the use of Pharmacy and Therapeutics Committees as a useful tool in dealing with drug cost and utilization issues. CPhA believes these committees can also serve a vital role in the development and execution of MTMPs.

A substantial factor in a successful MTMP will be the cooperation, collaboration and communication between treating physicians and pharmacists or other providers of MTMP services. As recognized in the proposed rule, there are several possible elements of a MTMP, including:

- enhanced enrollee understanding of drug therapy,
- increased enrollee adherence to drug therapy regimens,
- detection of adverse drug events and misuse of medications,
- health status assessment,
- formulation of drug treatment plans,
- management of specialty medications,
- evaluation an monitoring of patient response to drug therapy,
- specialized patient education and training,
- coordination of drug therapy with other health care services and

- participation by pharmacists and physicians in collaborative practice agreements as allowed under existing state law.

Each one of these components, as well as others that are not mentioned, rely on effective cooperation and coordination of care between physicians and those providing the MTMP services. An effective P&T Committee can provide essential help in development of protocols and guidelines for implementation of these types of health care services. As mentioned previously, we believe not only that P&T Committees should be involved, but also that members of these committees should be providers participating in the program.

In addition to their role in developing protocols and guidelines, we believe P&T Committees should be involved in the development of standards for beneficiary participation in MTMPs offered as part of the Medicare Part D benefit. The use of the P&T Committee in oversight of the MTMP enrollment process, we believe, will result in the most effective and consistent process for identifying beneficiaries who would benefit from these services. At the same time, the involvement of the P&T Committee will maximize the coordination of these services with the drug cost and utilization efforts. Further, we believe physician and pharmacy providers should be a key resource for identifying beneficiaries who should enroll in the MTMPs. Together, we believe this type of involvement of P&T Committees will result in improved provider compliance with cost and utilization controls, will provide a rational and consistent basis for beneficiary enrollment in MTMPs and will enhance the pharmacist-physician interaction that will be necessary for the full benefits of MTMPs to be realized. PDPs and MA-PDs should be strongly encouraged to promote and support strong provider collaboration in the implementation of MTMPs.

Other Comments on MTMPs

In addressing some final comments we draw once again on the basic characteristics of MTMPs: improving health care quality and reducing costs in an environment of growth and evolution that encourages innovation. In promoting growth, evolution and innovation in these programs, CPhA believes a wide range of approaches should be considered. One such approach is the use of shared risk or at-risk models for MTMPs. We are aware of several MTMP proposals where compensation to pharmacists is based on sharing of cost savings realized from the programs. We believe these types of approaches will be useful in finding the most effective ways for providing incentives for committed participation and performance in MTMPs and we encourage CMS to incorporate into the proposed rule a means for using this type of approach.

Likewise, CPhA recognizes that these types of services are undergoing almost constant change. We encourage CMS to include language in the proposed rule that allows for a high level of change so that new approaches can be incorporated without an undue level of regulatory hurdles. The advances in this area of health care will certainly be accelerated at the Medicare Part D benefit goes into effect and these MTMPs are implemented. The entire process will certainly be one of trial and error and the final rule should neither promote inefficient and ineffective programs nor stifle new approaches. We believe the proposed rule reflects an appreciation of this concern; we hope the final rule will provide the highest level of flexibility while protecting beneficiaries and providers from unscrupulous plan operators.

CPhA has some concerns about the degree of utilization that will be observed in the MTMPs for the following reasons:

- 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 is 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.

Subpart D – 423.153(e) Fraud, Abuse and Waste

CPhA supports a requirement for PDPs and MA-PDs to provide a program to control fraud, abuse and waste. We believe such programs are essential for program integrity and represent a "win-win-win" for taxpayers, beneficiaries and providers.

We note with approval that section 423.153(e) of the proposed rule requires these programs to "evaluate, prevent and investigate fraud, abuse and waste." We strongly believe a major emphasis should be placed on the "prevent" portion of this requirement. Too often we have seen health plans take few steps to detect potential fraudsters until after the fraud has occurred. Our experience has been that the reaction to this "pay and chase" approach has routinely resulting in overly severe and abusive audit practices. The result often is financial disaster for pharmacies as they try to defend themselves against these abusive and unjust practices. We have also seen "pay and chase" result in overly restrictive network participation standards as payers attempt to gain greater control over the pharmacies in their networks. The result is decreased access for beneficiaries and an absence of competition and innovation.

A more reasonable approach is to develop reasonable participation standards as the program begins. This, coupled with regular and noticed review of performance, will result in better provider relations and better service to beneficiaries. CPhA does not support overly restrictive networks; however, we do support an "any willing *and qualified*" provider standard that ensures providers meet (and continue to meet) reasonable standards designed to address legitimate concerns to prevent fraud, abuse and waste. We also support inclusion of an effective grievance and appeal process to ensure that any requirements that are in place meet a reasonableness standard and do not result in preferential treatment based on inappropriate inducements. CPhA believes inclusion of these types of reasonable steps for network screening should be encouraged in PDPs and MA-PDs. To protect providers and beneficiaries, we believe plans should provide full disclosure of their network participation standards and that CMS should exercise active oversight of these standards where appropriate.

We cannot end our comments in this area without a response to a specific example mentioned by CMS in the proposed rule. At 69 Fed. Reg. 46670, the following appears:

> One area of concern is inappropriate switching of prescriptions by a PDP or MA-PD plan without consulting a prescribing physician. For instance, switching from brand to generic may be appropriate, but switching brands, e.g. Lipitor to Zocor, may not without consultation.

First, we appreciate this apparent recognition by CMS of the common practices engaged in by pharmacy benefits managers and mail order pharmacies of switching brand name drugs with little or no notice or communication to the prescriber and/or the patient. CPhA agrees that this type of activity truly belongs in a section addressing fraud, abuse and waste.

Second, we note the many qualifiers in the CMS's statement, which we assume are present to distinguish this type of switching without prescriber notice from appropriate substitution practices which routine occur in many practice settings pursuant to policies and procedures to which the prescriber has agreed. This latter practice is authorized as part of collaborative practice agreements in many states and should be available as part of the drug utilization and cost containment strategies described in 423.153(b). The key component is prescriber notice, which often is accomplished in by way of the collaborative practice agreement. It is our assumption that CMS agrees that such agreements (as encouraged in the discussion of 423.253(d)) meet the "explicit prescriber notification and approval" standard included in the discussion of 423.153(b).

Conclusion

In conclusion, the California Pharmacists Association appreciates the opportunity to provide these comments. We are available for further clarification and to respond to any questions that may arise as a result of these comments.

Respectfully Submitted,

John A. Cronin, Pharm.D., J.D.
Senior Vice-President and General Counsel

Submitter : Mr. Christopher Decker **Date & Time:** 10/04/2004 07:10:56

Organization : Pharmacy Society of Wisconsin

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Thank you for the opportunity to comment on the proposed rule to implement the Medicare pharmacy and prescription drug benefit. The Pharmacy Society of Wisconsin (PSW) represents more than 2,000 Wisconsin pharmacy practitioners and PSW?s mission is to provide leadership in advocacy, education and pharmacy practice that improves the safe and effective use of medications. Our organization?s mission is congruent with the action of Congress and the interest of CMS to create a meaningful pharmacy benefit within Medicare; a benefit that works.

The proposed rule establishes a Medicare prescription drug benefit as mandated by Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Developing regulations to implement the prescription drug benefit is an awesome task. PSW commends the Centers for Medicare and Medicaid Services (CMS) for its stated commitment to develop regulations and implementation guidelines for a workable benefit within less than a year.

We are pleased the regulations recognize the valuable role of the pharmacist and the benefit pharmacist services can have on patient outcomes. The final structure of this new Medicare benefit will likely serve as a model for the entire health care industry, as Medicare often has. It is imperative, for both the success of the program and the structure of programs that will model Medicare, that the benefit be designed right from the beginning. PSW has considerable experience in working with both private and public health care purchasers in Wisconsin in the design, administration and evaluation of pharmacy benefit plans. We commit to assisting CMS in any manner desired by the Administration to ensure that the new Medicare benefit be cost effective and work for both recipients and providers.

There are several areas of the regulation as published in the August 3rd Federal Register that need further clarification and improvement in order to ensure that the drug benefit is implemented as effectively as possible.

BENEFITS AND BENEFICIARY PROTECTIONS

Under the proposed rule, plans are required to offer beneficiaries ?access to negotiated prices for covered Part D drugs included in the plan?s formulary.? Requiring plans to negotiate with manufacturers for lower prices should result in lower co-payments for beneficiaries and lower overall drug costs for the Medicare program. However, because the regulation fails to establish minimum requirements for the amount of the discount or price concession that the plan must pass on to beneficiaries, plan sponsors may use negotiated rebates or discounts for the plan?s benefit and not the recipient?s. There is no guaranteed minimum discount for the recipient. The amount of the discount shared with beneficiaries can vary greatly from plan to plan and from product to product. Plans could meet the requirement to offer access to negotiated prices by simply passing on one cent to enrollees.

To ensure that beneficiaries receive the negotiated manufacturer price, the final regulation should specify that the savings must be passed through to beneficiaries either directly or indirectly through the pharmacies. CMS should add a requirement to the regulation that the manufacturer rebates or discounts be passed through to beneficiaries.

The regulation is also silent on how the negotiated manufacturer discounts will move from the plan, to the pharmacy, and ultimately to the patient. The regulation requires plans to provide access to negotiated prices by negotiating price concessions but fails to explain how the price concessions will be passed through to the pharmacy.

Further, it is possible, without further directive, that plan sponsors will receive rebates and payment from manufacturers for drugs dispensed to Medicare recipients during the ?donut hole period? where the plan sponsor will not be making any payment for the medication and when the recipient is responsible for 100% of the medication cost. This is further reason that the plan be required to pass forward all rebates and concessions provided to the plan for purchases made and services received by the recipient. Allowing plans to maintain any portion of rebates provided on a recipient?s behalf will create the possibility (and financial incentive) for plans to maximize rebates when it can benefit and minimize rebates when the recipient is responsible for the cost.

It is also important to note that a pharmacy?s cost to obtain and provide the product to a Medicare recipient is independent of price concessions that a plan sponsor may negotiate with a manufacturer. Plans should be required to reimburse pharmacies in a manner that is consistent with a pharmacy recovering its cost in purchasing and handling the product, as well as the costs associated with dispensing the product to a Medicare recipient. CMS should direct plans to provide a detailed analysis on how the plan determines its pharmacy provider reimbursement policies and assures that the reimbursement levels are sufficient to meet the provider?s cost of doing business.

Although the regulation does not provide a specific definition for the term dispensing fee, it does propose three different options for the definition. Option one limits the dispensing fee to the ?transfer? of the product from the pharmacy to the beneficiary and it is most related to the dispensing related activities in practice. However, if this option is selected, it will be important to delineate the activities involved in the transfer.

The preparation and dispensing of a drug product is a multi-step process that contains several different components that each add a cost to the process. There are also indirect costs associated with the dispensing process such as overhead costs related to cost of operating.

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

The proposed regulation includes a list of possible MTM program elements such as performing patient health status assessments, formulating prescription drug treatment plans, managing high cost ?specialty? medications, evaluating and monitoring patient response to drug therapy, providing education and training, and participating in collaborative drug therapy management. These are all areas that may benefit from intensive medication management services provided by pharmacists to both recipients and prescribers of therapies.

Eleven national pharmacy groups joined together, subsequent to the passage of the MMA, to develop a definition of medication therapy management services that is accepted profession-wide (appendix A). While this definition does not specify individual MTM services, it does provide a framework for the delineation of such services for Medicare.

The proposed regulation states that plans can customize MTM programs. However, it is critical that all plans be required to provide a minimum set of standard services so that there is commonality among programs and that all beneficiaries are afforded a common minimum benefit. This is particularly important because stand alone PDP?s will not have an economic incentive, in fact they have a disincentive, to pay for MTM services.

CMS should develop a minimum package of MTM services that plans must provide. The minimum package should include a broad range of professional services designed to optimize therapeutic outcomes for individual patients. A panel of experts including practicing pharmacists, physicians, and representatives from involved health care organizations could be convened to advise the Agency on the services a plan must, at a minimum, include in its MTMP. CMS could also enlist the help of the panel of experts when evaluating plan bids related to MTM services and measuring MTM service outcomes.

Eligibility and Enrollment in MTMP

Under the proposed regulation, plans are not required to provide MTM services to every beneficiary enrolled in the plan. Instead, plans are allowed to target beneficiaries most at need for MTM services. ?Targeted beneficiaries? would include beneficiaries who have multiple chronic diseases, are taking multiple covered Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines. CMS should not allow individual plans to set the parameters for eligibility or at least CMS should provide a minimum eligibility requirement. Beneficiaries with two or more chronic diseases and taking two or more medications should be eligible for MTM services. Need for MTM services will be highly variable from recipient to recipient, as any medical service varies, however, all recipients should be eligible for such a service and health care providers should be vested with the ability to determine whether MTM services are warranted or not.

In addition to the CMS defining criteria of multiple chronic diseases and multiple chronic medications, there may be instances where a recipient has a single area in need of intensive medication management. While most of these patients could be diagnosed with more than one chronic problem, a single area of complexity may require specialized MTM services. For example, patients using potent medications for anticoagulation purposes require intensive monitoring and medication dosage adjustment.

For these purposes, CMS should specify that a prescriber be authorized to order and a plan required to pay for individualized MTM services. Any licensed pharmacist within the plan?s region that receives an order from an authorized prescriber should be allowed to provide the MTM service and be compensated by the plan for the service provided.

Plans should also be required to pay for necessary MTM services even if the recipient happens to be in the financing donut hole.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Pharmacists and pharmacy providers can serve as a resource for Medicare recipients as they consider enrolling in a particular Medicare pharmacy program. To that end, CMS should consider either directing plan sponsors to pay pharmacies an administrative fee for assisting individuals in determining whether they are eligible to participate in a program and to assist in their enrollment. A flat administrative fee of $25-35 could be required to be paid by the plan sponsor to each pharmacy for enrolling a recipient in the program.

GENERAL PROVISIONS

This section describes the general framework for the new benefit and outlines some areas of prohibition for health plans that will offer the benefit. We believe that this area of the regulations could be strengthened, and the program enhanced, by including additional specific requirements plan sponsors must meet. For example, plan sponsors should all be required to meet certain contracting requirements when developing a pharmacy network. Concentration of market power with plan sponsors will otherwise enable them to dictate terms that are of benefit to the plan sponsor and not to the Medicare recipient or the network?s pharmacy providers. Plan sponsors should be prohibited from directing or creating incentives for recipients to use a pharmacy service owned or operated by the plan sponsor over that of another pharmacy provider. The commercial market has developed in such a manner that this practice has become epidemic and CMS should not allow such activity within Medicare. Plan sponsors or their subcontractors should be prohibited from using internal incentives, rebates or kickbacks from pharmaceutical manufacturers or other vendors to steer recipients to a business that provides financial benefit to the sponsor or its subcontractors.

In addition, it would be helpful to provide further direction in this section to plan sponsors on the expectations of CMS with regard to fair contracting procedures. It has become commonplace in the commercial market for insurers and pharmacy benefit managers to offer a contract to pharmacy providers on a take it or leave it basis. There is often no interest on the part of the insurer or PBM to negotiate terms of participation or reimbursement what so ever. This practice has led to provider cost shifting to other programs where possible and/or unprofitable business for the pharmacy practice. With the enormity of the Medicare program, it is critical that plan sponsors be required to deal fairly with pharmacy providers in order to prevent a complete disruption in the market through the displacement of pharmacies. With the rapid growth in the number of Medicare recipients over the next decade it is critical that the pharmacy provider infrastructure not be dismantled due to one-sided contract terms. CMS can and should play a valuable role in bringing about stability and equity in the pharmacy contracting process.

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CMS-4068-P-1133-Attach-1.doc

October 1, 2004

Centers for Medicare & Medicaid Services
Department of Health & 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 rule to implement the Medicare pharmacy and prescription drug benefit. The Pharmacy Society of Wisconsin (PSW) represents more than 2,000 Wisconsin pharmacy practitioners and PSW's mission is to provide leadership in advocacy, education and pharmacy practice that improves the safe and effective use of medications. Our organization's mission is congruent with the action of Congress and the interest of CMS to create a meaningful pharmacy benefit within Medicare; a benefit that works.

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We are pleased the regulations recognize the valuable role of the pharmacist and the benefit pharmacist services can have on patient outcomes. The final structure of this new Medicare benefit will likely serve as a model for the entire health care industry, as Medicare often has. It is imperative, for both the success of the program and the structure of programs that will model Medicare, that the benefit be designed right from the beginning. PSW has considerable experience in working with both private and public health care purchasers in Wisconsin in the design, administration and evaluation of pharmacy benefit plans. We commit to assisting CMS in any manner desired by the Administration to ensure that the new Medicare benefit be cost effective and work for both recipients and providers.

There are several areas of the regulation as published in the August 3rd *Federal Register* that need further clarification and improvement in order to ensure that the drug benefit is implemented as effectively as possible. We offer the following comments on those areas:

SUBPART A: GENERAL PROVISIONS

This section describes the general framework for the new benefit and outlines some areas of prohibition for health plans that will offer the benefit. We believe that this area of the

regulations could be strengthened, and the program enhanced, by including additional specific requirements plan sponsors must meet. For example, plan sponsors should all be required to meet certain contracting requirements when developing a pharmacy network. Concentration of market power with plan sponsors will otherwise enable them to dictate terms that are of benefit to the plan sponsor and not to the Medicare recipient or the network's pharmacy providers. Plan sponsors should be prohibited from directing or creating incentives for recipients to use a pharmacy service owned or operated by the plan sponsor over that of another pharmacy provider. The commercial market has developed in such a manner that this practice has become epidemic and CMS should not allow such activity within Medicare. Plan sponsors or their subcontractors should be prohibited from using internal incentives, rebates or kickbacks from pharmaceutical manufacturers or other vendors to steer recipients to a business that provides financial benefit to the sponsor or its subcontractors.

In addition, it would be helpful to provide further direction in this section to plan sponsors on the expectations of CMS with regard to fair contracting procedures. It has become commonplace in the commercial market for insurers and pharmacy benefit managers to offer a contract to pharmacy providers on a take it or leave it basis. There is often no interest on the part of the insurer or PBM to negotiate terms of participation or reimbursement what so ever. This practice has led to provider cost shifting to other programs where possible and/or unprofitable business for the pharmacy practice. With the enormity of the Medicare program, it is critical that plan sponsors be required to deal fairly with pharmacy providers in order to prevent a complete disruption in the market through the displacement of pharmacies. With the rapid growth in the number of Medicare recipients over the next decade it is critical that the pharmacy provider infrastructure not be dismantled due to one-sided contract terms. CMS can and should play a valuable role in bringing about stability and equity in the pharmacy contracting process.

SUBPART B: ELIGIBILITY AND ENROLLMENT

Pharmacists and pharmacy providers can serve as a resource for Medicare recipients as they consider enrolling in a particular Medicare pharmacy program. To that end, CMS should consider either directing plan sponsors to pay pharmacies an administrative fee for assisting individuals in determining whether they are eligible to participate in a program and to assist in their enrollment. A flat administrative fee of $25-35 could be required to be paid by the plan sponsor to each pharmacy for enrolling a recipient in the program.

SUBPART C: BENEFITS AND BENEFICIARY PROTECTIONS

Negotiated Prices

Under the proposed rule, plans are required to offer beneficiaries "access to negotiated prices for covered Part D drugs included in the plan's formulary." Requiring plans to negotiate with manufacturers for lower prices should result in lower co-payments for beneficiaries and lower overall drug costs for the Medicare program. However, because the regulation fails to establish minimum requirements for the amount of the discount or price concession that the plan must pass on to beneficiaries, plan sponsors may use negotiated rebates or discounts for the plan's

benefit and not the recipient's. There is no guaranteed minimum discount for the recipient. The amount of the discount shared with beneficiaries can vary greatly from plan to plan and from product to product. Plans could meet the requirement to offer access to negotiated prices by simply passing on one cent to enrollees.

To ensure that beneficiaries receive the negotiated manufacturer price, the final regulation should specify that the savings must be passed through to beneficiaries either directly or indirectly through the pharmacies. CMS should add a requirement to the regulation that the manufacturer rebates or discounts be passed through to beneficiaries.

The regulation is also silent on how the negotiated manufacturer discounts will move from the plan, to the pharmacy, and ultimately to the patient. The regulation requires plans to provide access to negotiated prices by negotiating price concessions but fails to explain how the price concessions will be passed through to the pharmacy.

Further, it is possible, without further directive, that plan sponsors will receive rebates and payment from manufacturers for drugs dispensed to Medicare recipients during the "donut hole period" where the plan sponsor will not be making any payment for the medication and when the recipient is responsible for 100% of the medication cost. This is further reason that the plan be required to pass forward all rebates and concessions provided to the plan for purchases made and services received by the recipient. Allowing plans to maintain any portion of rebates provided on a recipient's behalf will create the possibility (and financial incentive) for plans to maximize rebates when it can benefit and minimize rebates when the recipient is responsible for the cost.

It is also important to note that a pharmacy's cost to obtain and provide the product to a Medicare recipient is independent of price concessions that a plan sponsor may negotiate with a manufacturer. Plans should be required to reimburse pharmacies in a manner that is consistent with a pharmacy recovering its cost in purchasing and handling the product, as well as the costs associated with dispensing the product to a Medicare recipient. CMS should direct plans to provide a detailed analysis on how the plan determines its pharmacy provider reimbursement policies and assures that the reimbursement levels are sufficient to meet the provider's cost of doing business.

Dispensing Fee

Although the regulation does not provide a specific definition for the term dispensing fee, it does propose three different options for the definition. Option one limits the dispensing fee to the "transfer" of the product from the pharmacy to the beneficiary and it is most related to the dispensing related activities in practice. However, if this option is selected, it will be important to delineate the activities involved in the transfer.

The preparation and dispensing of a drug product is a multi-step process that contains several different components that each add a cost to the process. For example, after the beneficiary presents a prescription at the pharmacy, the pharmacist processes the prescription (entering informing into the pharmacy's computer system, complying with third party requirements,

resolving conflicts with pharmacy benefit managers, correcting clinical conflicts, etc.), prepares the order (retrieving the drug, counting/preparing the correct amount, preparing the label, etc.), and delivers or dispenses the product to the patient (transferring the product to the patient, counseling the patient, handling the financial transaction, etc.) Each of these activities are essential and require dedication of pharmacy resources in order to complete.

There are also indirect costs associated with the dispensing process such as overhead costs related to cost of operating (pharmacist and pharmacy staff salaries, computer equipment and robotics, rent, utilities, etc.).

All of these activities must be considered when establishing a dispensing fee. If the Agency will not set a specific dispensing fee, we urge CMS to add a requirement to the final regulation that plans must consider all of the costs associated with the processing, preparation, and delivery of the prescription drug product, including basic professional services such as patient counseling and overhead costs.

In addition, a single dispensing fee may not adequately or appropriately compensate for dispensing of certain products that have additional complexity associated with either their preparation or dispensing. For example, compounding a product for delivery to the patient requires additional time, effort, and resources that may include specialized equipment. This should be recognized in the form of a higher dispensing fee. CMS should require that plans create a separate and higher dispensing fee for pharmacy compounding. This is especially relevant given the significant number of emerging biotechnology products that will require specific pharmacist preparation prior to dispensing.

Lastly, plan sponsors and/or a plan's pharmacy benefit manager should be prohibited from charging pharmacies to submit claims for payment. It has become customary in the commercial market for this practice to occur and the pharmacy provider incurs the expense of administration for the plan. Recently, some PBM's have unilaterally quadrupled the charge to pharmacy providers for claim submission without regard for the costs associated the activity. Claims administration is one component of the plan sponsor's responsibility and plans should not be allowed to use their market dominance to shift these costs to providers or recipients.

Pharmacy Access Standards

Congress included several provisions in the Act intended to preserve Medicare beneficiaries' access to the pharmacist of their choice. Both the Act and the proposed regulation prohibit plans from restricting beneficiaries to mail service pharmacies. That's good. Allowing beneficiaries to utilize the pharmacist and pharmacy of their choice – whether it is a community or mail service pharmacy – is crucial to protect existing patient-pharmacist relationships and enable Medicare recipients to receive the services they need from the provider they know and trust. The patient-pharmacist relationship is an important link in ensuring appropriate and safe medication use.

There are many technical aspects included in the proposed rule related to pharmacy access. These provisions could be interpreted by plan sponsors one-way and by recipients or providers another. If plan sponsors are allowed to determine which providers are allowed to serve recipients enrolled in a program, it is critical that the plan sponsor meet the recipient's needs. The bottom line is that the recipient should be able to select their pharmacy provider. It's that simple. If plan sponsors are allowed to create restrictive networks that don't allow Medicare recipients to select their own pharmacy provider, not only would such an action be the exact opposite of the intent of Congress, it would be disruptive to the care so important to this group of individuals. The any willing provider provision of the statute requires plans to permit any pharmacy willing to accept the plan's terms and conditions to participate in the plan's pharmacy network. It is important that the terms offered to the pharmacies by the plan be a realistic offer to gain the pharmacy's participation.

Under the Act, plans must allow beneficiaries to obtain their benefits at a network community pharmacy instead of a mail service pharmacy. This provision, similar to the pharmacy access standard and the any willing provider requirement, is designed to ensure that beneficiaries are able to access their benefit from the pharmacist and pharmacy of their choice. This requirement will allow beneficiaries to obtain benefits such as an extended 90-day supply of medications – a benefit that is typically only available through a mail service pharmacy – and medication therapy management services from local pharmacy providers. It is important, in each case, that CMS disallow any promotion or incentive for the use of one provider over another, except for the creation of preferred pharmacies or pharmacists based upon quality measures.

Standard ID Card

All plans should be required to issue beneficiaries a standard identification card that complies with the criteria and standard established by the National Council for Prescription Drug Programs (NCPDP). By requiring that plans meet this standard, Medicare beneficiaries will present an ID card at the pharmacy that contains the information required by the NCPDP standards displayed in the appropriate location on the card. Adherence to such a standard will benefit both Medicare recipients and pharmacy providers through increased efficiencies.

Out-of-Network Pharmacies

The proposed regulation includes special rules for beneficiary access to medications at out-of-network pharmacies. If a beneficiary chooses to use an out-of-network pharmacy, the pharmacy is limited in its ability to serve the beneficiary under the terms of the beneficiary's prescription drug plan. Therefore, the pharmacy can only charge the beneficiary its usual and customary price for a medication. The beneficiary will have to seek reimbursement directly from the plan for what they paid or a percentage of what they paid based upon the plan's specifications. Pharmacies should not be expected to determine network pricing formulas, covered drugs etc. if the pharmacy does not participate in the particular plan.

Skilled Nursing Facility Needs

Medicare recipients residing in nursing homes or assisted living centers have unique medication needs, with particular emphasis on special medication packaging needs for medication

administration within a particular facility. Pharmacy providers have traditionally dispensed medications to nursing home residents in these organized medication distribution systems and plans should all be required to compensate pharmacy providers for the additional cost of these needed packaging systems.

SUBPART D: COST CONTROL & QUALITY IMPROVEMENT REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Medication Therapy Management Program

Background for comments

The Act and the proposed regulation include a requirement that plans establish a medication therapy management program (MTMP). This provision of the program is perhaps the most important aspect of the program for pharmacy providers and for CMS leading innovation in health care system design.

In spite of the technological advances of the past 50 years, the quality of health care remains inadequate and highly variable, with errors and suboptimal practices occurring far too frequently and advances in clinical knowledge finding their way into practice far too slowly.

A 1999 report by the Institute of Medicine (IOM) estimates that medical errors in the inpatient setting cause between 44,000 and 98,000 avoidable deaths each year, and even more injuries. While experts debate the precise number of deaths and injuries, it is important to realize that even if the true figure is at the low end of the IOM's range, an unacceptably large number of people still die each year in the United States from inpatient medical errors.

Hospitals are not the only setting in which quality shortfalls occur; additional deaths and injuries occur in other settings. Nor is poor quality exclusively the result of medical errors. Suboptimal use of medications and avoidable adverse events related to medication therapies constitute a large number of the health care events that could be improved. Furthermore, in many cases, prescription drug therapy is the primary modality to be used in correcting health care problems.

>Drug misuse, broadly defined, results in more than 200,000 deaths and as much as $300 billion in expenditures each year. Many of these deaths and costs are likely avoidable.

>Overuse of antibiotics results in as much as $5 billion in unnecessary expenditures each year.

>Overuse of inpatient care for medical treatments that can be performed safely in an outpatient setting unnecessarily raises costs.

> Preventable hospital-acquired infections claim at least 20,000 and perhaps more than 60,000 lives each year, and result in up to $18 billion in unnecessary expenditures each year.

>The direct and indirect costs of diabetes are $132 billion annually.

The statistics illustrating avoidable costs in health care and the data illustrating the need for system redesign go on and on. The Medicare medication therapy management program has the potential of being the first landmark public policy initiative to bring about a system-wide change that addresses the need for more attention on how medications are used and in the application of known best medical practices.

Scope of MTM Services

The proposed regulation includes a list of possible MTM program elements such as performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training, and participating in collaborative drug therapy management. These are all areas that may benefit from intensive medication management services provided by pharmacists to both recipients and prescribers of therapies.

Eleven national pharmacy groups joined together, subsequent to the passage of the MMA, to develop a definition of medication therapy management services that is accepted profession-wide (appendix A). While this definition does not specify individual MTM services, it does provide a framework for the delineation of such services for Medicare.

The proposed regulation states that plans can customize MTM programs. However, it is critical that all plans be required to provide a minimum set of standard services so that there is commonality among programs and that all beneficiaries are afforded a common minimum benefit. This is particularly important because stand alone PDP's will not have an economic incentive, in fact they have a disincentive, to pay for MTM services.

CMS should develop a minimum package of MTM services that plans must provide. The minimum package should include a broad range of professional services designed to optimize therapeutic outcomes for individual patients. A panel of experts including practicing pharmacists, physicians, and representatives from involved health care organizations could be convened to advise the Agency on the services a plan must, at a minimum, include in its MTMP. CMS could also enlist the help of the panel of experts when evaluating plan bids related to MTM services and measuring MTM service outcomes.

Eligibility and Enrollment in MTMP

Under the proposed regulation, plans are not required to provide MTM services to every beneficiary enrolled in the plan. Instead, plans are allowed to target beneficiaries most at need for MTM services. "Targeted beneficiaries" would include beneficiaries who have multiple chronic diseases, are taking multiple covered Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines. CMS should not allow individual plans to set the parameters for eligibility or at least CMS should provide a minimum eligibility requirement. Beneficiaries with two or more chronic diseases and taking two or more medications should be eligible for MTM services. Need for MTM services will be highly variable from recipient to recipient, as any medical service varies, however, all recipients

should be eligible for such a service and health care providers should be vested with the ability to determine whether MTM services are warranted or not.

In addition to the CMS defining criteria of multiple chronic diseases and multiple chronic medications, there may be instances where a recipient has a single area in need of intensive medication management. While most of these patients could be diagnosed with more than one chronic problem, a single area of complexity may require specialized MTM services. For example, patients using potent medications for anticoagulation purposes require intensive monitoring and medication dosage adjustment.

For these purposes, CMS should specify that a prescriber be authorized to order and a plan required to pay for individualized MTM services. Any licensed pharmacist within the plan's region that receives an order from an authorized prescriber should be allowed to provide the MTM service and be compensated by the plan for the service provided.

Plans should also be required to pay for necessary MTM services even if the recipient happens to be in the financing donut hole. MTM services must be able to be provided when they are needed and plans should be required to pay for those necessary services accordingly.

Provision of MTM Services

Pharmacists are the ideal providers of MTM services under the Medicare prescription drug benefit. Pharmacists have the education and training to help patients manage their medication use and learn how to control their disease. Any pharmacist that is willing to provide MTM services should have the option to do so. If a beneficiary needs highly specialized services beyond their expertise, pharmacists can refer the patient to another pharmacist specialized in that disease or area. While we recognize that other "qualified health care professionals" may also provide MTM services, MTM services must fall within the providers' scope of practice to deem them "qualified."

It is imperative that all pharmacists able to provide MTM services be eligible to provide MTM services and that Medicare recipients be allowed to select their MTM service provider. While there are some population-based services that plans may provide from a centralized system, individual patient-specific services should be provided locally. This is where there is an opportunity for CMS to change the current fragmented health care delivery system to one that is coordinated among providers. However, once again CMS must provide a directive to the plans in order for the system design to change.

MTM Services Fees

The proposed regulation includes a discussion of "pharmacy fees" related to MTM services. According to the regulation, plans must reimburse pharmacists and other qualified providers for the provision of MTM services to targeted beneficiaries. While CMS did not establish a specific fee plans must pay pharmacists for these services, the regulation directs plans to take into account the resources and time associated with implementing the MTM program. CMS should expand upon this requirement and provide plans with additional guidance in determining fees for

MTM services. At a minimum, plans should be directed to base fees on the time and resources required to implement and deliver the MTM services. A mandate to provide the service without a corresponding mandate to adequately fund the service will lead to failure. Plans should be required to disclose, in their bids to CMS, the level and system of payment for MTM services. If the payment is insufficient to warrant provision of the service, CMS should reject the bid.

Likewise, pharmacists must know the amount of the MTM fees and plans must be required to include the MTM fee rate in its contracts with pharmacists and/or pharmacies.

CMS should also require standards for the billing of MTM services. Billing for MTM services should be conducted electronically and follow the requirements established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In order to be HIPAA compliant, MTM services should be billed using the Accredited Standards Committee (ASC) X12N 837, the standard government form for billing provider services, in conjunction with Current Procedural Terminology (CPT) codes.

In conclusion, we wish to thank CMS for this important opportunity to offer comments on the proposed regulations for the impending Medicare pharmacy benefit. Done right this new program has the potential to not only benefit millions of Americans for years to come but to also establish a new, progressive model for pharmacy benefit plan design. We have provided one page of actionable recommendations for CMS to consider from the above comment letter (appendix B) and we encourage your consideration of each as the final Medicare regulations and pharmacy program guidelines are completed.

Our organization and its members have considerable experience in development, administration and conduction of pharmacy benefit programs. Practicing pharmacists have first-hand experience in what works and what doesn't. We offer our assistance to CMS as you finalize the regulations and begin the development and offering of this new benefit. It is critical to the pharmacy profession's future that this benefit be designed in such a way that it is long lasting and we pledge our support to assist CMS in that regard.

Sincerely,

Christopher J. Decker
Executive Vice President and CEO

Appendix A

Medication Therapy Management Services
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. * In some situations, Medication Therapy Management Services may be provided to the caregiver or other persons involved in the care of the patient.

Approved July 27, 2004 by the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the 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 Pharmacy Association Executives.

*** Organization policy does not allow NABP to take a position on payment issues.**

Appendix B

Recommendations to CMS for Action re CMS-4068-P

1. Strengthen plan requirements for the provision of medications to Medicare recipients:
    a. Require plans (and any plan subcontractor) to provide each recipient the ability to choose their pharmacy provider.
    b. Require plans to forward all rebates and discounts provided by a pharmacy or pharmaceutical manufacturer to the recipient.
    c. Require plans to provide adequate and fair payment to pharmacy providers in the form of a dispensing fee for dispensing Medicare prescriptions.
    d. Prohibit plans from charging recipients or providers for administrative costs associated with the plan or the submission of claims.
    e. Prohibit plans from providing economic incentive for using one pharmacy provider over another, including mail order pharmacies.
    f. Require plans to issue recipient ID cards in conformance with the NCPDP national standard.
    g. Plans should be required to meet the special medication needs of Medicare recipients residing in skilled nursing facilities or assisted living centers.

2. Detail plan requirements for the offering of medication therapy management programs (MTM):
    a. Define a minimum set of MTM services that all plans will be required to provide.
    b. Provide a minimum set of eligibility criteria that all plans will be required to follow.
    c. Require all plans to cover MTM services ordered by a MD or other qualified Medicare Part B provider.
    d. Require all plans to enroll all pharmacists in the plan region as MTM providers (the plan may specify other MTM providers as well.)
    e. Allow Medicare recipients to select their MTM provider.
    f. Require that all plans provide fair and sufficient payment for MTM services based upon the provider's time and resources required to deliver the necessary MTM service.
    g. Require that all plans use the X12 837 standard for electronic billing of MTM services, as developed by the Accredited Standards Committee.

3. Create an expert panel to advise CMS on the final pharmacy benefit operational guidelines and CMS directives for plans offering the pharmacy benefit:
    a. Appoint practicing pharmacists and physicians expert in the area of plan design and operation.
    b. A majority of those serving on the expert panel should be practitioners.
    c. Practitioners should be from both ambulatory and institutional practices that serve Medicare recipients.

CMS-4068-P-1134

Submitter : Pamela Parker **Date & Time:** 10/04/2004 07:10:52

Organization : Minnesota Department of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Extensive comments have been submitted through our Medicaid Director, Mary Kennedy. We would like to provide a further clarification of our comments on the Part D bid process impact on Minneosota's dual demonstration (MSHO/MnDHO) and on special needs plans through the word file attachment below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1135

Submitter : **Date & Time:** **10/04/2004 07:10:02**

Organization :

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Comments from Missouri Senior Rx Program (Missouri SPAP) attached.

CMS-4068-P-1135-Attach-1.doc

Missouri Senior Rx Program
Missouri Department of Health and Senior Services
205 Jefferson Street, Room 1310 P.O. Box 570
Jefferson City, MO 65102-0570
Phone: 573-522-3070 Toll Free: 1-866-256-3937 Fax: 573-522-3073
Bob Holden
Governor

October 4, 2004

Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Comments from the Missouri Senior Rx Program regarding Medicare Prescription Drug Benefit Proposed Rules

The Missouri Senior Rx Program, Missouri's State Pharmacy Assistance Program (SPAP) for seniors requests to go on record with CMS and provide the following comments relative to the proposed Medicare Modernization Act of 2003 rules governing the transition to Medicare Part D – Prescription Drug Plan. Suggested changes, adaptations and additions to the rules are outlined below in bold print, followed by information supporting the suggestion.

- **The Missouri Senior Rx Program recommends the rules be revised to allow SPAPs to partner with one PDP.**

It is anticipated that for cost effectiveness and/or providing continuity of care regarding formulary coverage for an SPAP's members, partnering with one PDP may be desirable. Requiring SPAPS to coordinate benefit with all PDPs may be so technically cumbersome or expensive to facilitate that the SPAPs continued existence is threatened as the benefits it provides must be pared back to accommodate the risk. We recognize the need for non-discrimination regarding eligibility determinations and benefits, and request CMS' assistance in identifying methods for SPAPs to cost effectively work with MA-PDs.

- **The Missouri Senior Rx Program recommends the regulations allow and encourage PDPs to adopt SPAP's formularies to ensure continuity of care and to limit the need for appeals regarding drug coverage.**

Continuity of pharmaceutical treatment is of great importance to effective disease management and appropriate healthcare. Especially for older individuals, it is often therapeutically counter-productive, or even dangerous, to abruptly change medications. We are deeply concerned about the requirement to coordinate with PDPs, whose formulary may be much less inclusive than ours. Typically, SPAPs' formularies are more inclusive and we believe it would be beneficial for all states and SPAP members for PDPs to adopt the SPAPs' formularies. We disagree with the allowance of PDPs to have closed formularies or formularies that may be therapeutically counter-productive to Missouri Senior Rx beneficiaries by not offering the same prescription drugs that are currently available through our Program.

- **The Missouri Senior Rx Program recommends the rules provide maximum flexibility for SPAPs to wrap around benefits of Medicare Part D, while providing protection from any cost shifting from PDPs to SPAPs.**

Flexibility to meet the needs of States will vary with the laws governing the care for its citizens. Providing maximum flexibility with protection will provide a safer platform for states to craft their legislative policy.

- **Missouri Senior Rx requests that the regulations include some form of protection for SPAPs regarding members' possible dis-enrollment in Part D due to non-payment of premiums or changes in assets.**

Depending upon how our Program determines to coordinate with PDPs, we have a concern regarding the SPAP's responsibility for pharmaceutical coverage of a member should the member become dis-enrolled in Part D. We would recommend that CMS provide direct notification to the SPAPs as well as the PDPs should a member become dis-enrolled.

- **The Missouri Senior Rx Program recommends the rules governing auto-enrollment be drafted to allow states to execute the application on the individual's behalf.**

We assisted many of our members in the application process for the Medicare-approved drug discount card. We expect that our members will encounter the same level of confusion and need for assistance with enrollment into Part D. To ensure our members are timely enrolled, we request CMS include language allowing the states to submit application on the individual's behalf. We believe it is strongly advisable to facilitate the participation of the SPAP's (and other state agencies) in assisting beneficiaries with their enrollment in a PDP. Further, we encourage this flexibility to ensure that our members are enrolled in a PDP that most closely meets our current formulary prior to the implementation of a random, auto-enrollment process.

- **The Missouri Senior Rx Program requests that the establishment of PDP regions be defined by individual State boundaries, or SPAP boundaries.**

The proposed rule seems to acknowledge that existing SPAPs will play a critical role in coordinating benefits with the PDPs for the most vulnerable populations. These individuals will be served under the Part D program, as well as providing "wrap around" coverage for beneficiaries within these populations. Our membership is limited to Missouri residents, and coordination with PDPs would be more easily effected if the PDP's boundaries were consistent with our boundaries. The administrative complexities and burden of effectuating these goals will be enormously and unnecessarily increased if PDP regions are not consistent with the State boundaries.

- **Missouri Senior Rx recommends that regulations not be established to restrict rebate agreements between manufacturers and PDPs and/or SPAPs.**

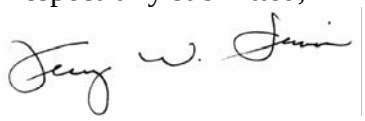
Restriction of the rebating process may complicate state's ability and funding sources for methods of providing wrap-around coverage. We understand that other entities are commenting to CMS to include regulations limiting rebates, and we strongly disagree with their request.

- **Development of a network of user groups to identify and share "Best Practices".**

In addition to the above recommendations, the Missouri Senior Rx Program would advocate for CMS to implement a network of user groups and identify "Best Practices". This information could be shared on the CMS website for review. Best practices utilized by SPAPs may provide insight and assistance for the many challenges during this ongoing transition to Part D.

As the first State to introduce legislation to address the coverage gap in Medicare Part D, we continue our commitment to providing Missouri's seniors with consistent, comprehensive, and affordable prescription drug coverage. The Missouri Senior Rx Program trusts you will take our recommendations, concerns, and comments with serious consideration.

Respectfully submitted,



Jerry Simon
Interim Executive Director

JS/bb

CMS-4068-P-1136

Submitter : **Date & Time:** **10/04/2004 07:10:56**

Organization : **Medicare Payment Advisory Commission**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4068-P-1136-Attach-1.pdf

MEDPAC Medicare Payment Advisory Commission

601 New Jersey Avenue, N.W. • Suite 9000
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

October 4, 2004

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
Room 443-G
200 Independence Avenue, SW
Washington, D.C. 20201

Re: File Code CMS-4068-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled *Medicare Program; Medicare Prescription Drug Benefit*. We appreciate that your staff has an enormous task in implementing the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), particularly given the agency's competing demands.

MedPAC's comments aim to help CMS strike a balance among policy goals that sometimes compete with one other. Part D will only provide the outpatient prescription drug benefit that Medicare beneficiaries need if CMS is able to encourage private plans to enter the market and offer competitive benefits at affordable premiums. At the same time, CMS must ensure that Part D enrollees have access to the drug therapies they need. We appreciate the complexity of CMS's task in striking this balance, and MedPAC intends for its comments to help CMS in that mission.

Many important details relating to CMS's implementation of Part D fall outside of these proposed rules yet is critically important for the decision making of beneficiaries and private plans. Examples include specification of the boundaries of regions in which Part D plans will operate, publication of risk adjustors that will apply to drug plan payments, and CMS guidance on formulary structure and operations, on the process for grievance and appeals, on evaluating actuarial equivalence, and on the process for obtaining employer or Medicare Advantage plan waivers. We look forward to timely decisions about these and other details, and we may provide further comments once they become available.

As you requested, our comments are organized and identified by the corresponding sections in the proposed rule.

Background

Eligibility and Enrollment (B)

Limiting direct marketing to beneficiaries

The MMA provides that prescription drug plans (PDPs) are able to market directly to beneficiaries to encourage enrollment and that CMS provides contact information to PDP sponsors to facilitate efficient marketing. You ask whether you should limit this practice, for example, by allowing beneficiaries to choose not to be contacted, restricting contacts to certain times of the year or to written materials instead of telephone contacts.

Allowing PDPs to contact Medicare beneficiaries directly has the potential to lower the marketing costs of Prescription Drug Plans (PDP) which, in turn, may reduce beneficiaries' premiums for Part D coverage. However, such efficiencies should be balanced with other program goals, such as protecting beneficiaries' privacy and reducing beneficiary confusion about the new program. Allowing beneficiaries to choose not to be contacted and restricting contacts too before and during the annual open enrollment period would seem to be reasonable limits consistent with these program goals.

Marketing services other than PDP services to beneficiaries

CMS states in the preamble that it is interested in the possibility of allowing PDP sponsors to market other products including financial services to beneficiaries as well.

We appreciate CMS's interest in providing additional incentives to entities to participate as PDPs, thereby spurring competition and offering beneficiaries choices among plans. With the introduction of the drug benefit under Part D, beneficiaries will have to learn about a new benefit and make choices among a number of plans with different kinds of cost-sharing structures, formularies, and pharmacy networks. Adding the marketing of other products by PDP sponsors would only add to the potential confusion and would also add to CMS's burden in reviewing marketing materials. We strongly oppose this option at this time but believe the policy could be reviewed at a later date.

Timing of the auto-enrollment period for dual eligible beneficiaries in the first year

The initial enrollment period extends from November 15, 2005, through May 31, 2006. The auto-enrollment processes for full dual eligible beneficiaries who do not enroll in some plan starts after this period. Medicaid coverage for full duals ends on December 31, 2005, leaving a potential five-month gap in coverage for the poorest beneficiaries.

There are several possible solutions to this problem: The choice should rest on which solution is the least administratively burdensome for states and the federal government and best ensures continuous coverage for this vulnerable population. Perhaps the simplest solution would be to start the auto-enrollment process when the initial enrollment period begins. Although this approach would have the potential disadvantage of enrolling beneficiaries in plans they would not have chosen for themselves, it would ensure continuous coverage for all dual eligibles. To preserve choice, these beneficiaries could then have the option of changing plans once before the end of the initial enrollment period. We anticipate that few beneficiaries would change plans. A second solution could be to begin and end the initial enrollment period earlier for dual eligibles, but this would be administratively complex for both CMS and the states.

Disenrollment of beneficiaries by PDPs

At the plan's discretion, PDPs may disenroll a beneficiary involuntarily if he or she does not pay premiums or is disruptive. In other circumstances, PDPs are *required* to disenroll beneficiaries, such as when they withhold information to PDPs about third-party coverage. There is no special election period that allows involuntarily disenrolled beneficiaries to enroll in another PDP.

As CMS points out, in the Medicare Advantage context, the beneficiary, who is dropped from a plan for nonpayment of premiums or other bad behavior defaults to fee-for-service Medicare coverage. However, for Part D drug coverage, there is no default. CMS describes its intentions to provide re-enrollment guidelines, and proposes regulations that require plans to give a proper notice and due process, review the case, and document their efforts to resolve issues leading to disenrollment. Because of the lack of default Part D coverage, CMS should also consider including a warning to beneficiaries enrolling in plans about involuntary disenrollment and its consequences.

Under the Medicare Advantage program (which forms the basis for many enrollment and disenrollment provisions in the statute and regulations for PDPs), a beneficiary who is out of a PDP service area for more than six months must be involuntarily disenrolled. CMS asks for comments on whether this regulation should also apply to PDPs.

Because the scope of benefits in a PDP is much more limited than the Medicare Advantage program, and enrollees may be able to get prescription drugs through mail order or through nationwide retail pharmacy networks, MedPAC agrees with CMS that automatic disenrollment for people out of the service area for more than six months is not necessary. Instead, PDPs should be allowed to structure pharmacy excess rules specifically for beneficiaries who are out of the service area for extended periods of time. Indeed, in subpart C of the regulation text, CMS considers pharmacy excess rules (such as mail order) that PDPs may impose on beneficiary members who have extended out-of-network travel.

Educating beneficiaries

The preamble reviews how Medicare provides comparative information to beneficiaries on www.medicare.gov and through the 1-800-Medicare line but provides little guidance on the range of activities that will be necessary for beneficiary education. Research consistently has shown that web-based resources are not sufficient to explain to some beneficiaries the complex choices they will face. Many beneficiaries will require individual counseling. State SHIPs and other volunteer groups must be adequately prepared to enable them to perform this task.

It would be useful to devote some resources to developing educational materials for pharmacists and physicians on the Part D drug benefit. CMS might provide the same kinds of educational materials that it has developed to help SHIPs advise beneficiaries about their choices. MedPAC's research on drug benefit implementation issues, included in our June 2004 Report to Congress, shows that pharmacists and physicians, as trusted intermediaries, are often in the position of explaining plan benefits and benefit changes to their patients. Yet, they rarely have sufficient information available to do so quickly, accurately, and efficiently. We found that despite considerable efforts by employers to inform their employees about changes in their drug benefit plans, many plan recipients first became aware that their plan had changed when they were in a physician's office or attempted to fill a prescription at a pharmacy.

While plans must take several measures to educate participating pharmacists and physicians affected by formulary changes, Medicare should also educate them on beneficiary needs and Medicare requirements under the new drug benefit. Recent studies indicate that many beneficiaries, particularly those receiving drug benefits from Medicaid, are unaware that they will be affected by the Medicare drug benefit. Knowledgeable pharmacists and physicians may often be required to explain benefit options to many members of this population.

Benefits and Beneficiary Protections (C)

Formulary regulations

Plans participating in the Medicare drug benefit may develop and use formularies to manage the cost and utilization of prescription drugs. The MMA charged the United States Pharmacopeia (USP) with developing a model classification system. Plans have the flexibility to use USP's model, or to develop their own classification system. In either case, plans must list at least two drugs in each therapeutic category and class, if available. If a plan uses USP's model, CMS cannot find its classification system to violate regulations against discrimination of beneficiaries. However, CMS may continue to scrutinize other components of the plan's formulary and utilization management programs (e.g., specific drugs listed, prior authorization requirements) for such discrimination. If a plan decides *not* to use USP's final model, it will need to show that its departure from the model is not designed to discourage certain beneficiaries from enrolling.

In MedPAC's June 2004 Report to Congress, we examined formulary implementation issues for the upcoming Medicare drug benefit. Specifically, we outlined competing demands on plans'

classification systems to be broad enough to enable plans to manage drug costs, but specific enough to ensure adequate drug coverage for beneficiaries.

The MMA affords plans the flexibility to develop and use their own tools to manage drug costs, within limits. For the success of the new drug benefit, plans will need to keep premiums relatively low, which requires them to have the ability to rely on many of the utilization management tools that are available in current practice. And ultimately, whether formularies are broad or narrow, CMS will still need to ensure that plans have effective exceptions processes so that beneficiaries can get the drugs that are medically necessary for their specific conditions.

One issue we see pertaining to CMS's proposed formulary regulations is the lack of clarity on the cost-sharing status of drugs in each therapeutic category. Although the regulations state that plans must list at least two drugs (if available) per therapeutic category and class, they do not explicitly address cost-sharing levels of the required drugs. That is, will one or more of these drugs need to be at the preferred level, or could plans provide only nominal coverage in an entire category? Could plans vary cost-sharing structures between categories? If so, CMS will need to closely scrutinize plans' cost-sharing structures, *per category and per drug*, to rule out beneficiary discrimination. To do so, CMS could estimate plan cost sharing (as a percent of total drug spending) for selected groups of beneficiaries, and compare those to average ranges. In any case, CMS will need to review all PDP bids to assess whether formularies and cost-sharing structures are in keeping with those used in current practice by most health plans.

Pharmacy & Therapeutics (P&T) committee role

By statute, a plan's formulary must be "developed and reviewed" by a P&T committee. CMS proposes strengthening the committee's role to make its decisions binding on the plan. CMS also expects that P&T committees will be involved in designing formulary tiers and clinical programs implemented to encourage the use of preferred drugs (for example, prior authorization, step therapy, and generics programs).

MedPAC is concerned that CMS's proposal to make P&T committee decisions binding on the plan extends the role of P&T committees beyond current practice. Our research on drug benefit implementation issues, included in our June 2004 Report to Congress, shows that a plan's P&T committee typically serves as an advisory body to the plan. While plans usually accept their P&T committee's recommendations, plans have the final say on formulary decisions. Also, we found that P&T committees are often tasked with recommending preferred drugs, but do not establish the actual cost-sharing structure. This component of benefit design is usually under the plan's purview. Our research also showed that P&T committees may recommend which drugs should require other utilization procedures, such as prior authorization to improve patient safety. However, as in formulary decisions, plans ultimately oversee the implementation of such utilization management programs.

P&T committee independence

Among other membership conditions, P&T committees must include one practicing physician and one practicing pharmacist who are "independent and free of conflict with respect to the sponsor and plan" – meaning that they have no stake, financial or otherwise, in formulary decisions. CMS proposes strengthening the independence requirement in two ways: first, by increasing the number of independent members, and second, by adding pharmaceutical manufacturers to the list of entities from which independent members must be free of conflict.

MedPAC strongly supports CMS's overall desire to increase the independence of P&T committee membership. Defining the number of members who are independent may be somewhat arbitrary, however. MedPAC agrees with CMS that those members who are designated as "independent" should be free of conflict from drug manufacturers (in addition to plans and sponsors). CMS should, at a minimum, require plans to establish a disclosure and recusal process for all P&T committee members who have any type of arrangement or relationship with drug manufacturers. Under this process, P&T members would recuse themselves from decisions that involve specified therapeutic categories or classes that may pose a conflict of interest for them. Our research found that this course of action was common among plan P&T committees.

Out-of-network pharmacy access

Under the MMA, plans must guarantee enrollee access to covered drugs from out-of-network pharmacies when they cannot reasonably be expected to get their drugs from network pharmacies. CMS proposes four conditions that may grant enrollees coverage at out-of-network pharmacies. CMS also proposes that plans can limit out-of-network access to encourage in-network use, including limiting amounts of covered drugs dispensed, requiring use of mail-order for extended time out of service area, and requiring plan notification for out-of-network fills.

CMS's proposals for granting enrollees coverage at out-of-network pharmacies are reasonable, but CMS needs to ensure that plan rules meant to encourage in-network use are not so burdensome and complex that they obstruct beneficiary access to needed medications in a timely manner. In particular, the prior notification requirement may be problematic for many beneficiaries. Nursing home patients in a facility without a network pharmacy, for example, cannot be expected to notify their plan of each type of drug they intend to use in the nursing home. Also, if plans require prior notification for out-of-network fills, plans should be required to provide a customer service line 24 hours a day, seven days a week, to answer the calls.

Rural pharmacy access

The MMA requires plans to provide enrollees with at least the same access to retail pharmacies as is provided by the Department of Defense's TRICARE program. In rural areas, therefore, plans must ensure that at least 70 percent of Medicare beneficiaries have access to a participating

retail pharmacy within 15 miles. CMS is proposing that PDPs serving more than one region meet excess requirements within each region.

Because CMS has not yet defined the plan regions, it is difficult to evaluate the impact of TRICARE standards on access to pharmacies. If the regions are relatively small, beneficiaries are less likely to encounter pharmacy excess problems, but if the regions are large, multi-state areas, access may be more problematic, especially in rural areas. In these cases, up to 30 percent of Medicare beneficiaries living in large portions of rural state may not have access to a participating pharmacy within 15 miles of their home. We note that these beneficiaries will be able to receive some drugs through a mail-order option and access a limited supply of medication at out-of-network pharmacies in the event of an emergency. In either case, we recommend that CMS monitor network adequacy in its review of plan bids to ensure that certain geographic areas are not subject to systematic discrimination.

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

E-prescribing

The MMA includes several provisions to encourage the use of e-prescribing. MA plans and PDPs may pay physicians differentially based on their use of e-prescribing as long as these arrangements are in compliance with A Stark self-referral and antitrust statutes. E-prescribing is one important step toward broader use of information technology and has been shown to lead to reductions in medication errors. MedPAC strongly supports moving toward greater use of electronic health information systems.

The MMA directs HHS to develop a safe harbor from the anti-kickback statute and an exception from the Stark self-referral rules. The Secretary should proceed expeditiously to issue such guidance.

Submission of Bids and Monthly Beneficiary Premiums (F)

Tradeoffs associated with the late enrollment penalty

Part D's late enrollment penalty would be the greater of two amounts: one determined by CMS to be actuarially fair, or 1 percent of the base beneficiary premium for each uncovered month. That penalty would apply every month for as long as the beneficiary was enrolled in Part D. CMS expects to use the 1 percent per month approach until it has collected enough data to do an actuarial estimate. For 2006, this would be about $0.36 per month—so someone who waited a year to enroll would pay an extra 12*$0.36=$4.32 per month forever. CMS suggests this approach because it does not yet have enough data to know what additional costs the program would incur if beneficiaries delay enrollment.

MedPAC urges CMS to collect data as quickly as possible to calculate a penalty amount that fairly reflects any higher costs associated with beneficiaries who delay their enrollment. Ideally, CMS would begin using this actuarially fair penalty after, say, one year of the program. Beneficiaries on long-term drug therapies for managing chronic conditions can often predict their prescription drug spending quite well, making this market especially susceptible to adverse selection. The role of the late enrollment penalty is to encourage high levels of enrollment in Part D, since otherwise plans should expect that beneficiaries with the greatest use of prescription drugs would be among the earliest to enroll. Indeed, plans may not choose to enter the market to deliver Part D benefits at all if their only likely enrollees are those with the highest drug expenditures. Nor should all enrollees subsidize the decision of others to delay their enrollment. The penalty should be as high as is fair to encourage enrollment and thereby promote participation by plans, but no higher so as to avoid unduly penalizing lower income beneficiaries, since some or all of those penalties will not be covered by low-income subsidies.

CMS'S role in reviewing PDP price information

The MMA gives CMS authority to negotiate bids and benefits similar to that of the Office of Personnel Management (OPM) for administering the Federal Employees Health Benefits Program (FEHBP). CMS interprets this to mean authority to determine whether bids reasonably reflect the cost of benefits provided, whether bids and trends in premiums are in keeping with those charged in other insurance contexts, whether the level of benefits reflects reasonable minimum standards for health plans, whether administrative costs are reasonable, and whether plans are taking reasonable steps to control costs and otherwise manage the plan well.

CMS's position is appropriate: it would not set the price for any individual drug or even an average discount across a group of drugs. However, the agency would look for justification from plans if aggregate price levels for groups of drugs were higher than prices observed among peer plans. This is due diligence and a reasonable course of action short of direct price regulation. However, CMS must allocate sufficient levels of staffing to ensure that it can credibly accomplish this oversight role. As one basis of comparison, CMS could look to OPM's staffing levels for administering FEHBP.

Coordination Under Part D Plans with Other Prescription Drug Coverage (J)

Tracking true out-of-pocket costs

Part D's true out-of-pocket provision holds that only the enrollee's own spending, or that of a close relative on behalf of the enrollee, qualifies for purposes of satisfying the Part D benefit's out-of-pocket threshold. In other words, coverage that wraps around the Part D benefit—such as through retiree drug benefits—would not count when plan sponsors calculate whether an enrollee had reached $3,600 in out-of-pocket spending during 2006. This provision was included as a mechanism to restrain Medicare's program payments for Part D benefits. But its effectiveness can only be as successful as CMS's ability to monitor whether Part D enrollees have supplemental drug coverage.

CMS invites comments on options for facilitating the exchange of data needed to track true out-of-pocket spending. Managing this information flow is an especially challenging task because of the need for data on a real-time basis at the point of sale in order to accurately calculate enrollee cost sharing. CMS proposes three options: making PDPs and MA-PDs solely responsible for tracking true out-of-pocket costs, awarding a contract to a facilitator that would become the single point of contact between primary and secondary payers and pharmacies, or establishing its own query system that would provide billing information to pharmacies about the order of payers. Although the latter two options pose technical challenges for CMS, MedPAC does not support the first option. PDPs and MA-PDs who contract with third-party payers may not enforce this provision too stringently, since it reduces the likelihood of receiving federal reinsurance payments. CMS should also explore other ways to monitor reporting of third-party coverage.

Employer/union group waiver authority

One option available to employers or unions is to contract with a PDP sponsor or MA-PD organizations and request permission to waive requirements under Part D that hinder the design or offering of plans for their retirees. Such waivers allow drug plans to furnish employer/union groups with Part D benefits and establish separate premiums for them, similar to authority used by MA organizations under Part C. CMS would make separate payments to such plans. A goal of these waivers is to facilitate efficient administration and integration of enhanced Part D benefits with other retiree health benefits.

While we understand the important role that waivers can play in encouraging employers and union groups to continue providing drug benefits to their retirees, we also hope that CMS will use its authority judiciously. In particular, it may be difficult to distinguish between bid costs for standard versus supplemental benefits, thereby complicating the monitoring and enforcement of the MMA's true out-of-pocket provision.

Grievance, Coverage, Reconsideration, and Appeals (M)

Non-formulary and non-preferred exceptions process

Plans must have an exception process for enrollees to request coverage for non-formulary drugs and for obtaining preferred cost-sharing status for non-preferred drugs. To obtain such exceptions, the prescribing physician must determine that a formulary or preferred drug would not be as effective for the enrollee, would have adverse effects, or both. Plans may determine the standards for documenting and concluding that an exception is necessary. Such standards may include step therapy, which requires that the enrollee first tried the preferred drug.

In reviewing plan proposals, CMS must ensure that plans have effective exceptions processes so that beneficiaries can access medically necessary drugs for their specific conditions.

As a drug utilization management tool, step therapy can be appropriate for some drugs and some populations, but risky for others. As we discussed earlier, MedPAC believes that P&T committees should provide guidance and recommendations to plans with regard to policies for specific drugs for given therapeutic indications. In doing so, P&T committees should take into account clinical effectiveness, patient safety, and cost considerations. Also, CMS has the responsibility to assess plans' drug utilization management tools, including step therapy, to ensure that they are not designed to discourage enrollment by certain beneficiaries, such as those with high expected drug costs.

While the MMA requires that beneficiaries themselves initiate the process exceptions, CMS proposes to also allow physicians to initiate the process exceptions. However, CMS clarifies that physicians could only initiate the process for their individual patients, not for their patients as a group. MedPAC agrees that physicians should be able to initiate the exceptions process for their individual patients because it could increase beneficiary access to needed medications.

Grievances and appeals procedures

Plans must have grievances and appeals procedures in place for beneficiaries to obtain coverage for medically necessary drugs. The regulations proposed for Part D generally follow the timetables and procedures outlined in the Medicare Advantage appeals process. However, denied appeals and requests for reconsideration will not be forwarded automatically to an independent review agency, as they are for A/B benefits in MA plans. Rather, enrollees must request such a review. Under certain circumstances, physicians may appeal on their individual patients' behalf. Plans are not required to cover drugs that are pending appeal.

In general, the proposed regulations on grievances and appeals procedures are not prescriptive and allow plans to establish the criteria and the standards for approving or denying appeals. Further clarification on the standards by which Part D plans and external appeal's reviewers can deny appeals would be helpful. Also, MedPAC believes that physicians should be allowed to appeal on behalf of their individual patients throughout the entire exceptions and appeals process. Considering that appeals would not be automatic, allowing increased physician involvement may be helpful for beneficiaries who require access to non-formulary drugs, but who have difficulty navigating through the multi-step appeals process themselves. Finally, CMS could consider requiring plans to cover a beneficiary's drug that is pending an appeal. However, in doing so, CMS should include maximum time limits on the coverage, such as a defined, short-term emergency supply.

Intermediate Sanctions (O)

For poor plan performance, CMS is inclined not to close enrollment and to use civil monetary penalties instead to maximize choice for beneficiaries, particularly in the case when there are only two PDPs in a region. This is different treatment than that of MA plans, where suspending enrollment has been used.

CMS should not rule out closing enrollment if plans are harming or misleading beneficiaries. If engaged in activities that harm beneficiaries, it is not a good choice and enrollment should be suspended. Civil monetary penalties of no more than $100,000 may be insufficient in such a case to penalize poor behavior.

Guaranteeing Access to A Choice of Coverage (Qualifying Plans and Fallback Plans) (Q)

Review of drug prices for fallback plans

In evaluating bids by fallback plans, CMS intends to negotiate price-related performance targets. Options include tying performance payments to the average discounts plans are able to negotiate with manufacturers including rebates. CMS proposes using a benchmark to determine if a drug plan is negotiating reasonable prices from manufacturers and asks for comments on whether this violates the noninterference provisions of the law.

We support CMS's use of a benchmark in its negotiations and believe it represents due diligence on the part of the agency to ensure that beneficiaries and the Medicare program are not penalized with high prices in areas in which there are no choices among plans. CMS suggests that the benchmark could be based on a number of sources including the average wholesale price (AWP), the average sales price, or the prior year's negotiated price. We agree with CMS that it would be best not to use a benchmark based on AWP. Use of AWP in determining payments for drugs under Medicare Part B resulted in inaccurate payments, unrelated to acquisition costs by purchasers. We support the use of a benchmark based upon actual transaction prices.

Availability of fallback plans

Many elements of the regulation related to fallback plans appear designed to make the fallback an unattractive business proposition for firms. For example, CMS would establish a separate bidding process for fallback plans. Plans would submit bids in the first half of 2005 to offer fallback plans in one or more regions in 2006. Any plan submitting a bid as a fallback plan could not submit a bid as a risk plan in any area of the country. Awards would be made but plans would only be used if necessary and plans awarded fallback contracts could not offer risk plans for at least three years. Further, contracts could be amended at any time to reflect the exact regions or counties to be included in the fallback service area.

While the Commission fully appreciates the goal of encouraging plans to take risk so as to provide incentive for controlling Part D spending, the goal of providing all beneficiaries with access to drug coverage also is important. These fallback regulations may be so burdensome that no plan applies. CMS may wish to consider relaxing some of its requirements in the event that neither fallback nor risk-taking PDPs bid to cover an area.

Payments to Sponsors of Retiree Prescription Drug Plans (R)

Valuing employer subsidies

Employers with drug coverage at least as generous as that offered under Part D can receive subsidy payments if they continue to provide primary coverage for a Part D-eligible retiree. CMS is considering several tests of actuarial equivalence. The "single prong" approach is that total/gross value of the employer's benefit package must at least equal that of the standard Part D benefit, without regard to who pays the premium. Another option is to combine the first with a provision that would limit the subsidy to the amount paid by the sponsor. A third option would use "two prongs": gross benefit payouts would have to be at least as great as those for Part D, plus an additional test on net benefits—the value of benefits net of enrollee premiums.

MedPAC supports either of the approaches that would take an employer's subsidy of the premium into account. Calculating actuarial equivalence only on the benefits and not the subsidy could lead to windfall payments to employers. For example, in the most extreme case, an employer might offer a benefit that met the requirements for actuarial equivalence under the first test and charge a beneficiary the entire premium. In this case, the employer would receive a payment but incur no benefit costs. While we understand the goal of maintaining employer- or union-sponsored retiree drug coverage, in order to administer the Medicare program's resources responsibly, it is incumbent upon CMS to prevent windfall payments.

MedPAC appreciates this opportunity to comment on these proposed regulations. The Commission values the willingness of CMS staff to provide relevant data and to consult with us concerning technical policy issues.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

CMS-4068-P-1137

Submitter : Ms. Judith Mears **Date & Time:** 10/04/2004 07:10:26

Organization : Kaiser Permanente

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comments

CMS-4068-P-1137-Attach-1.doc

KAISER PERMANENTE®

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-4068-P
RIN0938-ANO8
Medicare Program: Medicare Prescription Drug Benefit

Thank you for the opportunity for the Kaiser Permanente Medical Care Program ("Kaiser Permanente") to comment on this proposed rule. Kaiser Permanente is the nation's largest non-profit integrated health care system. A prepaid group practice health maintenance organization, Kaiser Permanente consists of three closely coordinated organizations in each geographic region where it provides care – Kaiser Foundation Health Plan, Inc. (or one of its Health Plan subsidiaries) ("Health Plan"), a non-profit health maintenance organization; Kaiser Foundation Hospitals ("Hospitals") a non-profit hospital company that provides or contracts for hospital services; and one of eight independent Permanente Medical Groups that provide or contract for all medical services required by Health Plan members.

Kaiser Permanente has more than 8.5 million members in nine states and the District of Columbia. More than 850,000 of these members are Medicare beneficiaries, and 96% of them receive prescription drug benefits through Kaiser Permanente. In 2003, Kaiser Permanente owned and operated 425 pharmacies and filled approximately 65 million prescriptions, of which approximately 19 million were for Medicare members. The Health Plans hold contracts with the Centers for Medicare & Medicaid Services (CMS) pursuant to Sections 1876 and 1852 of the Social Security Act to serve Medicare members. The vast majority of these members are enrolled under Medicare Advantage (MA) contracts. Kaiser Permanente supports the goals of the MMA legislation authorizing a new Medicare Part D drug benefit, and is committed to partnering with CMS to administer Part D constructively and in the best interest of Medicare beneficiaries.

Our attached comments are directed at many of the provisions of this proposed rule. As CMS considers all the comments it receives, and strives to finalize the rule in a timely manner, we believe it should bear in mind the following objectives that will serve the stability and thus the success of the Part D marketplace.

A. MA organizations should have the maximum benefit design flexibility permitted by law to offer MA-PD plans that fill in the "donut hole" of Part D and otherwise provide comprehensive coverage. CMS should aggressively use its regulatory authority to implement the MMA in a way that maximizes opportunities for beneficiaries to obtain prescription drug coverage that enhances the standard Part D benefit. We believe such enchanced coverage is crucially important to serve continuity of care and facilitate the best clinical outcomes.

B. Some highly efficient organizations could offer standardized, risk adjusted Part D coverage for substantially less than the national average bid amount, possibly sufficiently low that the national average bid amount less the base beneficiary premium would exceed the organization's bid. As written, the necessary mathematical result of the statutory payment formula in this case would be a negative premium. Accordingly, in the final rule we believe CMS should provide for the possibility of-and recognize the legitimacy of - a negative premium. This could be done without inappropriately compensating such bidders if CMS requires them to return the value of the negative premium to the beneficiary in the form of enhanced drug benefits. If CMS does not follow the statute in recognizing the legitimacy of negative premiums, it will discourage organizations from seeking to achieve maximum efficiency and discourage beneficiaries from enrolling in very efficient plans. Disclaiming the possibility of a negative premium, as the proposed rule does, is inconsistent with the plain language of the statute and long-standing Medicare payment policy.

C. CMS says (p.46633) it is considering establishing a demonstration "to evaluate possible ways of achieving…extended coverage", and welcomes suggestions in this regard. We believe it is possible to design an appropriate demonstration that would encourage the provision of enhanced coverage while complying with applicable cost constraints. We believe such a demonstration would encourage beneficiaries to enroll in efficient MA plans providing enhanced coverage, with significant savings for Medicare. Like other entities wishing to offer such demonstrations, we look forward to working collaboratively with CMS as soon as possible in order to be able to offer CMS-approved demonstration Part D coverage as of January 1, 2006.

D. The MMA establishes three new entities – Regional MA organizations, Regional PDP Sponsors, and Fallback Plans. The first two types of entities will, and the third type of entity may, compete with local MA organizations and local Section 1876 cost contractors to offer qualifying Part D coverage. CMS must finalize the rule so that it creates a level playing field in which all types of organizations in the Part D marketplace can compete fairly and efficiently, and afford beneficiaries with good choices for obtaining Part D coverage.

E. Section 1876 cost HMOs have a small, but valuable, role to play in offering qualifying Part D coverage to their members. CMS should extend to Section 1876 cost HMOs, at least with respect to their Part D products, the same regulatory flexibility and access to employer group waivers and preemption from State law as is afforded to local MA-PD plans.

F. The MMA recognizes that MA organizations with integrated delivery systems that include owned and operated pharmacies operating at the same sites as medical offices and hospitals are structured differently than other MA organizations and PDP Sponsors. We hope that CMS will acknowledge these structural differences in the final rule, and accord these organizations with the regulatory flexibility necessary for them to continue providing value to nearly a million beneficiaries.

The attached comments represent the work product of several Kaiser Permanente personnel. If readers have questions or require further information, please contact the undersigned at 510-271-5964, (Judith.Mears@kp.org) or Anthony Barrueta at 510-271-6835 (Anthony.Barrueta@kp.org) and we will direct inquiries to the appropriate person.

Very truly yours,

The Kaiser Permanente Medical Care Program

Judith M. Mears

By: _____
Judith M. Mears
Vice President and Assistant General Counsel

cc: Anthony Barrueta
Vice President, Government Relations

Comments on the Proposed Rule on the Medicare Prescription Drug Benefit

CMS – 4068 – P

by

The Kaiser Permanente Medical Care Program

October 4, 2004

Contacts: Judith M. Mears (510) 271-5964 (Judith.Mears@kp.org)
Anthony Barrueta (510) 271-6835 (Anthony.Barrueta@kp.org)

II. Provisions of the Proposed Rule

A. General Provisions

2. Discussion of Important Concepts and Key Definitions (§423.4)

c. Definitions of Frequently Occurring Terms (P. 46637)

CMS does not use the terms defined in this section consistently throughout the proposed rule. Specifically, CMS does not consistently indicate whether any particular Part D requirement or option applies only to PDP sponsors or to PDP sponsors and MA organizations offering MA-PD plans and §1876 cost HMOs offering qualifying Part D coverage that are to be "treated" as local MA-PD plans. Such inconsistency generates questions about the meaning of other provisions in the rule. For example, Subpart M of the proposed rule, which governs grievances, coverage, reconsiderations and appeals, is written only in terms of PDP sponsors, without any mention of the provisions being applicable to MA organizations or cost HMOs. However, CMS staff have unofficially stated that the term "PDP sponsor" includes MA organizations that offer MA-PD plans, with the result that Subpart M would apply to MA organizations offering MA-PD plans. We disagree with both this interpretation of the definitions and this conclusion. We believe that "PDP sponsors" and "MA organizations" that offer MA-PD plans are distinct and mutually exclusively entities and that CMS should clarify the definitions to reinforce this distinction. We suggest the following:

> "PDP sponsor means a non-governmental entity that is certified under this part as meeting the requirements and standards of this part for that sponsor. An MA organization offering an MA-PD plan is not, by virtue of offering such a plan, a PDP sponsor".
>
> "Prescription Drug Plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under Subpart K. An MA-PD plan is not a prescription drug plan or PDP."

We offer these proposed revisions to clarify that MA organizations are not PDP sponsors even though CMS has the authority to apply to MA organizations offering MA-PD plans the same Part D requirements that apply to PDP sponsors. The task for CMS is to be very clear in every provision of the final rule to delineate those provisions applicable to PDP sponsors and their PDPs that also apply to MA organizations and their MA-PD plans and/or cost HMOs and their qualifying Part D coverage, and those that do not.

II. Provisions of the Proposed Rule

B. Eligibility and Enrollment (P.46637)

1. Eligibility to Enroll (§423.30) (P. 46637)

This section (at P. 46638) specifies that with minor exceptions for MA private fee-for-service plans and MSAs, "[a] Part D eligible individual who is enrolled in an MA-PD plan must obtain prescription drug coverage through that plan." However, CMS does not discuss here or clarify in the proposed rule whether a Part D eligible individual who is enrolled in a §1876 cost HMO that offers qualifying Part D coverage must obtain prescription drug coverage through that cost HMO. We believe that when a cost HMO offers qualifying Part D coverage, a cost HMO enrollee must obtain prescription drug coverage through the Part D plan offered by the cost HMO. CMS should foster integration of Part A, B, and D benefits whenever possible.

2. Part D Enrollment Process (§423.34)(P.46638)

In this section (at P. 46638) CMS proposes automatic enrollment of "a full benefit dual eligible who fails to enroll in an MA-PD" into an MA-PD plan offered by the same MA organization offering his or her MA plan unless the basic premium for such plan exceeds the low-income benchmark premium amount. In that case, CMS would not permit automatic enrollment. We believe automatic enrollment would still be the better course in such cases if the full benefit dual eligible could disenroll from the MA-PD plan if he/she were unwilling to pay for the portion of the MA-PD plan premium that exceeded the low-income benchmark.

We also question the applicability of such automatic enrollment to full benefit dual eligibles who would otherwise be subject to proposed §422.66 (P. 46956). This section provides that an individual enrolled in a MA plan as of December 31, 2005 that offers any prescription drug coverage "will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006." CMS should clarify that when a full benefit dual eligible individual is enrolled in a MA plan that as of December 31, 2005 offers any drug coverage, he/she will be automatically enrolled in an MA-PD plan offered by that MA organization as of January 1, 2006, irrespective of the premium for that MA-PD plan. CMS may wish to specify that the automatic enrollment only applies to the MA-PD plan with the lowest premium offered by the MA organization.

8. Part D Information that CMS Provides to Beneficiaries (§423.48) (P.46642)

CMS recalls (on P.46643) that it established a price comparison website to provide beneficiaries eligible to enroll in the Medicare Drug Discount Card program with information "for the purpose of comparing negotiated prices across approved card programs." CMS says that it proposes "extending 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…" on the Medicare website. CMS says that doing so will broadly disseminate information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees. However, CMS exempted MA organizations that qualified as

exclusive drug discount card sponsors from being required to publish their negotiated prices on the Medicare website because it recognized that enrollees of such organizations could only obtain the card offered by their MA organization. There was little point in publicly posting the negotiated prices of the drug discount cards offered by such MA organizations because MA plan enrollees could not beneficially compare the drug prices with those of other drug card sponsors unless they first disenrolled from their MA organization.

The situation under Part D is analogous. A Medicare beneficiary who is enrolled in an MA-PD plan must obtain Part D coverage through that plan, and may only obtain Part D coverage from another entity if he/she first disenrolls from the MA organization. Consequently, an MA-PD plan's negotiated drug prices are of interest only to its enrollees or to prospective applicants to that plan who have questions about the negotiated prices for the particular drugs they are taking. We believe that CMS should not require (but could make optional) the website posting of negotiated prices available to the enrollees of MA-PD plans. Instead CMS should require MA-PD plans to make their negotiated prices easily available and accessible to their own enrollees, and on a reasonably excerpted basis to prospective applicants.

10. Information Provided to PDP Sponsors and MA Organizations (P. 46644)

In this section, CMS asks for comments about whether and how it should provide PDP sponsors and MA organizations with information about Part D eligible individuals to facilitate marketing and outreach to these beneficiaries, and to encourage their participation in Part D. We believe that CMS should not exercise its statutory authority to provide such information, at least not without evidence that current methods of outreach are inadequate.

In the past few years, CMS has significantly increased its outreach efforts and has developed several vehicles that beneficiaries can easily access, including the 1-800 MEDICARE call center, the Medicare website, the *Medicare & You* handbook, national advertising campaigns, and partnership efforts with SHIPs and other beneficiary advocacy groups. Continuing these outreach efforts should be adequate to inform beneficiaries about Part D, making CMS' provision of beneficiary information to PDP sponsors and MA organizations unnecessary.

Many Medicare beneficiaries will react negatively to the fact that CMS is sharing their most personal information (name, address, phone number, date of birth, HIC number, etc.) with commercial entities competing to offer Part D coverage. Beneficiaries may well wonder what happens to their personal information once CMS sends it off to Part D entities. How long will the entities maintain this information? What type of privacy and security safeguards will protect this information? Which employees or consultants of the entities will have access to this information? In the current climate of great concern about identity theft, CMS' provision of personal information to Part D providers could easily inspire beneficiary anxiety and undermine the success of the program.

If CMS does provide identifying information to PDP sponsors and MA organizations in very competitive markets, beneficiaries in those markets could be inundated with mail and perhaps even phone calls from Part D competitors. Beneficiaries who are already enrolled in an

MA organization and who will get mailers and/or calls from Part D competitors do not need to be informed by these competitors about the necessity of enrolling in Part D. The MA organizations in which these beneficiaries are enrolled must offer one or more MA-PD plans in 2006, and therefore must inform their own members about their MA-PD offerings. (And in many cases, these MA members will be automatically enrolled in their organizations' MA-PD plans as of January 1, 2006).

Lastly, while CMS says HIPAA does not apply, and therefore is not a bar to its provision of information to Part D providers, CMS does not mention state and/or federal "Do Not Call" laws and "opt-out" lists maintained pursuant to them. Would the Part D providers who receive beneficiary information from CMS be subject to these laws, or would CMS send Part D providers “scrubbed” information pertinent only to those beneficiaries who have not "opted out"?

We believe that CMS' provision of personal information about beneficiaries to Part D competitors would generate more problems and incite more negative beneficiary reaction than the value it would produce in enhanced outreach. We believe CMS should maintain and enhance the outreach vehicles it now has, because information it provides through these vehicles will have greater credibility than "marketing disguised as outreach" done by Part D competitors.

11. Procedures to Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56) (P. 46644)

On P. 46645, CMS notes that entities seeking to offer creditable prescription drug coverage must “disclose the creditable status of their prescription drug coverage to us [CMS] and to each Part D eligible beneficiary enrolled in such coverage.” CMS further says that the “initial notice of creditable status could be coordinated with the first Annual Coordinated Enrollment Period for Part D which begins November 15, 2005 to ensure that beneficiaries have this information when making decisions regarding their Part D coverage.”

We understand and agree with the need for beneficiaries to know whether any prescription drug coverage they will be receiving <u>in 2006</u> qualifies as “creditable coverage”. We also believe that PDPs and MA-PD plans are, by definition, offering creditable coverage, a statement we think CMS should confirm in the final rule. However, proposed §423.56 provides a very confusing statement of when and to whom notices of creditable coverage must be given. For example, §423.56 (b) says that “with the exception of PDPs and MA-PD plans…, each entity that offers prescription drug coverage under any of the types described…, must disclose to all Part D eligible individuals…whether such coverage meets the requirements of actuarial equivalence…” Does the clause “with the exception of PDPs and MA-PD plans” mean that an employer group that will, as of January 1, 2006, offer an MA-PD plan need <u>not</u> notify its retirees that such an MA-PD plan constitutes “creditable coverage”? Does this exception clause mean that an MA organization that intends to offer MA-PD plans to its direct pay (individual) MA members as of January 1, 2006 need not inform these members that the MA-PD plans constitute creditable coverage? CMS should clarify the meaning of “with the exception of PDPs and MA-PD plans” with respect to the duty to furnish notices of creditable coverage.

The same clarity is needed with respect to cost HMOs offering qualifying Part D coverage. Because CMS says such coverage is to be treated as an MA-PD plan, we assume (and we ask CMS to confirm) that the exception clause in §423.56(b) also relieves cost HMOs offering qualifying Part D coverage from having to issue notices of creditable coverage.

Because this new and wide-ranging requirement to furnish notices of creditable coverage imposes a very heavy administrative burden on employer groups, unions, trust funds and other organizations that provide prescription drug coverage, CMS must be particularly clear in the final rule about which entities have the duty to furnish such notices, under which circumstances, and to whom.

CMS also requests comments "regarding the types of materials that could provide an appropriate vehicle" for notices of creditable coverage, especially vehicles that would be "conspicuous and readily identified by recipients…." We believe that if MA organizations and cost HMOs must send out notices of creditable coverage to members who would be automatically enrolled in their MA-PD coverage as of January 1, 2006, they should be permitted to include the notice of creditable coverage in the Annual Notice of Change (ANOC). MA plan and cost HMO members are familiar with the ANOC; they read it carefully to ascertain changes in benefits and cost-sharing for the coming year. This document would be an ideal vehicle to notify members about creditable coverage. Moreover, the ANOC for 2006 will summarize any MA-PD plan coverage offered by the MA organization or cost HMO in 2006, and therefore, information about the creditable coverage status of the MA-PD plan would be a natural part of the information to be provided in the ANOC.

On P. 46646, CMS notes that the MMA requires "entities to disclose the creditable status of this [drug] coverage to us, and we invite comments on the possible methods of providing such disclosure". We assume that this requirement – formal disclosure of the creditable status of drug coverage to CMS - does not apply to MA-PD plans because it would be automatically satisfied when CMS accepts the MA organization's bid to offer one or more MA-PD plans.

CMS asks on P. 46646 "whether it would be a significant administrative burden for group health plans and other sponsors to include in disclosures [of creditable coverage] an indication of the value of their drug benefit, the total amount of the annual premium for their drug benefit, and the amount of the annual drug benefit premium that the beneficiary will be required to pay." It is not clear if this suggestion applies to MA organizations or PDP sponsors, since they are apparently excepted from the notice requirements set forth in §423.56. If this suggestion does apply to them, it is not clear whether it applies only to employer group members enrolled in MA-PD plans or to all MA-PD plan enrollees. In either case, indicating the "value" of the drug benefit would inevitably confuse members who have never received this information in the past, because they could easily confuse or mistake the "value" of their drug benefit for the "coverage" limits of their drug benefit. Moreover, we doubt it helps MA plan members to have "value" information: it is unclear to us how members could beneficially use this information.

An MA-PD plan could easily provide to its direct pay (individual) members the "total amount of the annual premium for their drug benefit" in the ANOC. However, providing the same information to employer group members would be meaningless because they rarely pay the

total annual premium. Moreover, disclosing the total annual premium could produce disputes between employer groups and their retired members. Whether and how to disclose the total premium should be the employer group's decision and not a requirement on the MA-PD plan. CMS should seriously rethink what it is trying to accomplish with this suggestion. The "value" information is largely meaningless, and the total premium and premium-sharing information is subject to a large and multi-varied number of different employer group, union and trust fund interpretations and arrangements. No one regulation can do justice to all these situations.

II. Provisions of the Proposed Rule

C. *Voluntary Prescription Drug Benefit and Beneficiary Protections*

1. Overview and Definitions (§423.100) (P. 46646)

a. Covered Part D Drug

Smoking Cessation Products. The MMA includes smoking cessation drugs in the definition of covered Part D drugs. We believe this represents sound policy. To enhance the effectiveness of these drugs, many health plans, like Kaiser Permanente, condition coverage of smoking cessation products on the enrollee's participation in smoking cessation classes. CMS should clarify in its final rule that MA-PD plans may apply Part D drug coverage criteria that include the beneficiary's participation in support and educational programs established by the plan related to smoking cessation. Further, CMS should be aware that most nicotine replacement products are OTC and do not require a prescription. As such, they would be excluded from the standard Part D drug benefit. This exclusion seems to be at odds with the intent of the MMA to insure coverage of smoking cessation products. CMS might consider waivers that would permit MA-PDs and PDPs to better integrate use of these OTC products with their Part D benefits.

Otherwise Excluded Drugs for Covered Purposes. CMS correctly adopts the MMA's list of excluded Part D drugs, but neither the MMA nor the proposed rule addresses the problem posed by otherwise excluded drugs that are sometimes used for covered purposes. A good example is the exclusion of agents when used for the symptomatic relief of cough and colds. Some of these drugs, such as decongestant combination products, are commonly prescribed for cough and cold. However, decongestant combination products can be appropriately prescribed for the treatment of allergic conditions. Until pharmacy and medical systems are better integrated, specifically linking diagnosis to prescription, it will be very difficult to establish when these drugs are prescribed for covered Part D indications and when they are not.

As automated medical record and clinical information systems continue to be adopted over the next several years, diagnosis capture should be more common. For now, however, administering this list of excluded drugs will be very difficult. Fortunately, most of these items are extremely low cost drugs, and their incidental coverage would not be a significant factor in Part D costs. Until systems are able to administer this exclusion, CMS should consider waiving this exclusion under certain circumstances because it has the potential to affect coverage of needed drugs inappropriately.

Manufacturer Required Items and Services. We strongly support CMS' efforts to prevent manufacturers from imposing associated tests and monitoring services that would be exclusively available from the manufacturer. We recommend that this be expanded to prohibit Medicare reimbursement for any drugs where the manufacturer imposes restricted or exclusive distribution systems. These programs unnecessarily increase costs and present an administrative burden, because claims and beneficiary out-of-pocket costs must be repatriated into plan systems accumulating TrOOP.

Preventing Coverage Gaps between Parts B and D. CMS has requested comments on how to avoid coverage gaps between Part B drugs and Part D drugs. This will be a difficult problem to resolve because Part B drug coverage varies by geographic region and MA-PD plans will be left to interpret coverage based on their experience within different CMS regions. We believe that regional coverage determinations should become obsolete with the transition to a Part D drug benefit, and that CMS should develop ways to rationalize a national Part B drug benefit. We recognize that this may require statutory changes.

b. Dispensing Fees (§423.100) (p. 46647)

CMS correctly notes that the term "dispensing fee" is not defined by the MMA, and suggests several alternative definitions. Dispensing fees in the private market today typically do not cover most of the allocated costs incurred by a pharmacy in dispensing a drug. Instead, pharmacies recover these costs through the difference between their pharmacy's acquisition cost of the drug and the ingredient cost portion of their reimbursement for the drug. Accordingly, to the extent that CMS believes it necessary to further define "dispensing fee," the best definition is the one that ties the fee most directly to the actual cost of the transfer of the drug. Other costs will be captured in the overall negotiated price.

For administrative simplicity, CMS should permit Part D providers to have a single dispensing fee, and provide separately for appropriate payments to SNF providers and others when appropriate. To the extent that beneficiaries will pay these additional costs during periods of noncoverage, we believe that it is reasonable that such costs should be counted toward TrOOP.

2. Requirements Related to Qualified Prescription Drug Coverage (§423.104) (P.46649)

a. Standard Prescription Drug Coverage

Definition of Generic Drug. The MMA specifically provides for limited copayments above the catastrophic threshold for "generic" and "preferred multiple source" drugs. While "multiple source drugs" are defined in the Medicaid statute, and that definition is adopted by the MMA, there is no definition of "generic" drugs in the MMA or the proposed rule.

Health plans generally distinguish "generic" from "brand" drugs based on how commercial pricing services (such as the Red Book) identify a particular drug. Drugs that have been approved by the FDA under the abbreviated new drug approval process but are available from only one manufacturer (because the original manufacturer has vacated the market) are typically considered by these pricing services to be brand name drugs. This is appropriate because these drugs have no direct generic competition. CMS should allow Part D providers the flexibility to adopt this approach.

Counting Out-of-Network Spending Toward TrOOP. CMS' willingness to count (against TrOOP) cost-sharing for drugs purchased at out-of-network pharmacies except when absolutely necessary could significantly discourage in-network utilization – an important factor in constraining Part D costs. This problem relates to the expansive out-of-network coverage

provision that exceeds what is necessary and appropriate to provide for urgent drug needs. (See discussion below).

Counting Charitable Reimbursements Toward TrOOP. We believe that CMS has taken an overly expansive reading of MMA § 1860D-2(b)(4)(C)(ii), which states that drugs "reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs." While the underlying policy is sound – Medicare should generally not credit non-Medicare insurance-type drug coverage toward incurred costs – CMS' regulatory provision is unnecessarily restrictive. Currently, organizations like Kaiser Permanente have member financial assistance programs for beneficiaries who have difficulty paying premiums and cost-sharing for their care. CMS proposes to allow other charities to pay for beneficiaries' drug costs and have such payments counted as incurred costs but would exclude legitimate financial assistance programs like those of Kaiser Foundation Health Plan, Inc.

The only reason why an organization like Kaiser Foundation Health Plan, Inc. should be treated differently from third-party charities is CMS' appropriate concern that an MA-PD plan could seek to fill in gaps in plan coverage, thereby increasing Medicare costs in a way not anticipated by the statute. We urge CMS to work with MA organizations to allow them to continue to provide financial assistance to their members in a way that would be consonant with CMS' policy concerns. We hope that for the sake of beneficiaries enrolled in MA-PD plans, in the presence of appropriate protections, this prohibition could be waived.

c. Negotiated Prices (P.46654)

Clarification of "Best Price" Exemption. CMS appropriately makes reference to the law exempting prices negotiated with manufacturers on behalf of Part D plans or qualified retiree drug plans from the Medicaid "Best Price" rebate program. The purpose of this exemption is to avoid the now well-acknowledged anti-competitive impact of the "Best Price" formula, which in essence imposes a price floor on the private drug purchasing market. It will be difficult for MA-PD plans and PDP sponsors to use this exemption to the benefit of Medicare and Medicare beneficiaries unless CMS makes clear that Part D providers may negotiate lower prices than they are currently negotiating or have already negotiated for their commercial business. Part D providers should be able to negotiate simultaneously for commercial prices (which would count for "Best Price" purposes) and Medicare/qualified retiree prices (which would not).

Without very clear guidance from CMS, we expect drug manufacturers to hesitate to negotiate aggressively on price for fear of enforcement action claiming that they are improperly offering deeper Medicare rebates to support higher commercial prices. Manufacturers will be concerned about the threat of reopening Medicaid rebate calculations, with some questioning whether a portion of Medicare discounts and rebates should be allocated to "Best Price" calculations.

We encourage CMS to undertake dialogue with Part D providers, drug manufacturers and the Office of the Inspector General as soon as possible to provide clear guidance in this important and complicated area. Further, CMS should consider alternatives to the existing "Best

Price" rebate formula to recommend to Congress. A flat rebate formula, for example, could generate the same savings for state Medicaid programs, while eliminating the negative impact of the "Best Price" formula on the prescription drug market generally.

Negotiated Prices for MA-PDs Operating Their Own Pharmacies. The MMA requires Part D providers to provide access to "negotiated prices" to their enrollees. Negotiated prices "should take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remuneration, for covered part D drugs, and include any dispensing fees for such drugs" (Section 1860D-2(d)(1)(B)). Negotiated prices are used under the MMA to establish benefit levels and prices charged to beneficiaries during periods of non-coverage. These provisions, however, appear to envision network model plans contracting with provider pharmacies – negotiated prices in this context are appropriately addressed in the regulation. Network model plans negotiate reimbursement rates with contract retail pharmacies. These rates are composed of "ingredient cost" reimbursement (typically based on a discount off a "list" price like average wholesale price) and a dispensing fee. The dispensing fee is generally not enough to cover the actual dispensing costs, and thus the "ingredient cost" reimbursement actually covers some of the pharmacy's costs, including overhead and revenue requirements. The "ingredient cost" reimbursement is based on, but does not actually represent, the cost of the drug itself.

Because MA organizations that own and operate their own pharmacies do not negotiate a reimbursement rate with contract pharmacies, these organizations must establish prices to be used in calculating benefit levels and cost sharing in their MA-PD plans. These MA organizations today acquire drugs directly from manufacturers or wholesalers, and pay for those drugs – the organizations are not reimbursing contract pharmacies. The prices the MA organization's pharmacies set must include additional amounts to cover overhead costs of operating facilities, pharmacy operations systems, and capital and margin requirements allocated to the pharmacy program. These are the same costs that are borne by contract pharmacies in the network model.

CMS should define negotiated prices with respect to MA organizations and cost HMOs that own and operate their own pharmacies as the prescription charge established by the MA organization or cost HMO that includes the acquisition cost of the drug, dispensing, operational, capital, overhead and margin costs. CMS should require those organizations to demonstrate how they take into account price concessions from manufacturers, as the MMA requires, in establishing their negotiated prices. CMS has several options in determining whether an MA organization's negotiated prices meet the standard of § 1860D-2(d)(1)(B). One is to compare the organization's negotiated prices to negotiated prices of network model plans in the same market. Another is to require the MA organization to demonstrate how it takes price discounts it receives from manufacturers into account in its pricing methodology or pricing formula. Under either method, CMS should seek to treat these MA organizations in as parallel a manner possible as other pharmacy providers serving in Part D plan networks.

Clarification of Formulary Drugs for which 100 Percent Cost-Sharing is Required. CMS may wish to clarify its language relating to the description of "or other cost sharing" as referring to "plan designs that may include, as a part of their formulary design, access to negotiated prices

on certain drugs but at a tier within their formulary in which the plan would pay no benefits and the beneficiary would be responsible for 100 percent cost sharing." It may be appropriate for Part D providers, as part of their benefit designs, to impose prior authorization or step therapy requirements on formulary drugs. However, we are concerned that Part D providers not take this language as a signal that it is appropriate to include drugs on a formulary that would, under usual circumstances, not be covered. Drugs that are ordinarily not covered should be considered nonformulary drugs. Beneficiaries will be confused if the concept of "on formulary" is so counter-intuitive.

4. Access to Covered Part D Drugs – Pharmacy Network (§423.120) (P. 46655)

a. Pharmacy Access Standards

Access Standards for MA-Owned and Operated Pharmacies. The proposed rule appropriately adopts language addressing waiver of access standards for MA-PD plans that provide access to Part D drugs through pharmacies owned and operated by the MA organization. CMS would require these plans to show compliance with standards "comparable" to the access standard for other Part D provider networks.

In assessing "comparability" of access (under §423.120(a)(1)), CMS should consider the inherent convenience of having pharmacies co-located in facilities where medical services are provided. The access standards cited in §423.120(a)(1) generally do not take this factor into account. MA organizations that own and operate their own pharmacies should be credited in terms of maximizing convenience for beneficiaries by having on-site pharmacies. In addition, to meet the comparability requirement, these MA organizations may sometimes include in their networks very limited numbers of contract retail pharmacies in geographic areas where the organizations do not yet have their own owned and operated pharmacies. (Typically this happens in a transitional period of expansion of the MA-PD plan's service area). CMS should include consideration of these contract pharmacies in determining whether the MA-PD plan's pharmacy access is "comparable to" the standards set forth in §423.120(a)(1).

Any Willing Pharmacy Requirement. The extent to which the "any willing pharmacy" requirement is applied to MA organizations owning and operating their own pharmacies is unclear in the MMA. To assure that the access requirements as a whole are most appropriately applied to MA organizations that own and operate their pharmacies, we believe that the "any willing pharmacy" requirement should be applied to them in two ways: First, the requirement should permit these MA organizations to maintain a limited network of contract pharmacies for purposes of meeting the access standards in those geographic areas where this is necessary for appropriate beneficiary access. This will permit the MA organization to continue to provide its MA-PD members in these areas with favorable negotiated prices. Second, the requirement should be applied to these MA organizations in as narrowly targeted a manner as possible, such as by five digit zip code on the basis of areas in which the MA organization has contracted with a retail pharmacy to provide appropriate access. These MA organizations should be able to use tools similar to those described in §423.120(a)(5) to distinguish the limited network of contract pharmacies. We believe that this approach will help to maximize both choice and affordability for beneficiaries.

Application of "Level Playing Field" Rule for MA Organizations with their Own Pharmacies. MA organizations that own and operate their own pharmacies usually have internalized systems for providing prescription services by mail that are fully integrated with the overall pharmacy operation. For example, most Kaiser Permanente regions use centers with automated dispensing technology to carry out both refills for in-facility pickup and mail delivery of refills. As a result, the "level playing field" provisions (§423.120(a)(4)) are generally inappropriate to be applied in this context. Because of this integrated cost structure, and the fact that the negotiated price itself does not differ between mailed drugs and those picked up at the local facility pharmacy, it is difficult to provide an incentive to beneficiaries to use the mail service, which is, in fact, less costly. To promote efficiency, CMS should permit these organizations to establish differential benefit levels for mail delivery as opposed to in-facility pickup.

b. Formulary requirements (P. 46659)

P&T Committee Role. CMS requests additional information on whether or not the requirement that formularies be "developed and reviewed" by a pharmaceutical and therapeutic (P&T) committee should mean that the committee's decisions regarding the plan's formulary should be binding on the Part D provider. We agree with CMS that this is the proper interpretation of the MMA. However, we would note, that MA organizations may be required to have ultimate responsibility over their P&T committees under the organization's accreditation requirements. Thus, there may be theoretical circumstances under which an MA organization may be required to intervene in a P&T committee action. We believe this would be a rare circumstance, but CMS should include language to the effect that MA organizations may continue to meet any accreditation requirements that would otherwise conflict with Part D requirements.

In addition, CMS states that it is "our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of benefit drugs (e.g., prior authorization, step therapy, generics programs)." We agree. CMS should take care, however, not to require that P&T committees be engaged in more specific benefit design issues – such as the level of copayments. Certainly P&T committee decision-making should be informed by benefit design, but ultimately benefit design is the province of the Part D provider.

P&T Committee Membership. MMA requires PDP sponsor and MA organization P&T committees to include certain members who are "independent and free of conflict with respect to the sponsor and plan." Section 1860D-4(b)(3)(A)(ii). CMS is further describing this to mean that these P&T committee members must have "no stake, financial or otherwise, in formulary determinations." We support a strict interpretation of this requirement. However, the interpretation of the term "independent" creates something of a conflict for highly integrated MA organizations, in that their P&T committees are composed entirely of providers treating enrollees in the MA organization, although those providers are not directly employed by the MA organization. CMS should consider a physician or pharmacist who treats patients enrolled in a

plan as "independent and free of conflict with the sponsor or plan" so long as the physician's relationship to the MA organization is limited to that of a physician treating enrollees, and not as the recipient of remuneration from the MA organization unrelated to his/her clinical responsibilities to care for enrollees of the organization.

In addition, Section 1860D-4(b)(3)(A) requires that a majority of members of the committee be practicing physicians and/or pharmacists. We also support CMS' urging that P&T committee members represent various clinical specialties relevant to the Medicare population.

Inclusion of a Range of Doses and Strengths. CMS should clarify that it is acceptable for Part D providers to favor some dosages over others on their formularies. To the extent feasible, formularies should provide a range of strengths and doses. However, sometimes good clinical pharmacy practice will focus on particular doses of formulary drugs. In addition, Part D providers can sometimes negotiate favorable prices only on some strengths or dosages of drugs. For example, based on the vagaries of pharmaceutical pricing, it is sometimes less expensive to use two 10 mg tablets in lieu of one 20 mg tablet. Clarity in the final rule would prevent manufacturers from trying to avoid Part D sponsors' efforts to manage which doses are used by clinicians, and prevent manufacturers from refusing to negotiate lower prices on some dosage forms of drugs, under the misapprehension that contracting only for certain doses of a drug is not valid under the MMA.

Formulary Classes and Categories. We appreciate CMS' discussion of the drug classes and categories that the U.S. Pharmacopeia (USP) is currently developing under contract with CMS. Overall, we believe that USP is doing a good job at a difficult task – balancing appropriate access to drugs with assuring that Part D providers will have the ability to use formularies to stimulate competition among similar drugs. The context of a multiple drug requirement makes this task much more difficult. We agree with CMS' position that while it cannot challenge a Part D provider's classification scheme *itself* for being discriminatory if it complies with the USP model, such a formulary could still be discriminatory in its composition, and therefore subject to oversight by CMS. For example, if a formulary that complied with the USP classification scheme included only two older tricyclic anti-depressants (and no newer selective serotonin reuptake inhibitors) that were in the broader class of re-uptake inhibitors under the USP draft model, or if no statin were included among the choices of cholesterol lowering drugs, CMS would be well within its authority to challenge the formulary composition itself as discriminatory.

We believe the criticism of USP on this point by the pharmaceutical industry has been extremely misleading, suggesting that a broad "safe harbor" exists for formularies complying with the USP model. To the extent a safe harbor exists, it should be limited to the Part D provider's adoption of USP's model for classes and categories of drugs. USP's scheme of "recommended subdivisions" provides helpful guidance to P&T committees developing formularies, and is an important signal to CMS that formularies not including representation of the subdivisions should be examined carefully for discriminatory design. CMS should require Part D providers not including drugs on USP's recommended subdivision list – which we believe can happen with legitimate cause in a few circumstances – to submit information justifying these

formulary exclusions and demonstrating that the Part D provider will insure appropriate access to those drugs when medically necessary.

Other Factors for Judging Formularies. It is appropriate that CMS consider additional factors in determining whether a formulary adequately meets the needs of beneficiaries enrolled in the Part D plan. One factor that CMS should consider is whether a formulary is generally used for commercial populations, including management of employer retiree prescription drug benefits. Many providers offering Part D drug coverage are likely to use very similar, if not exactly the same, formularies that they have already developed for the remainder of their business. Similarly, there are managed care organizations, like Kaiser Permanente, whose providers in each Kaiser region use a single formulary exclusively. These formularies are developed and managed by the same physicians who are treating plan enrollees, and they are used broadly to manage clinical practice, not just to manage the prescription drug benefit. Overall, it is in the interest of Medicare to permit such organizations to continue using these formularies as long as they meet the needs of beneficiaries. CMS should consider applying waivers for such formularies.

Notification of Formulary Changes to Affected Enrollees. In general, CMS' interpretation of §1860D-4(b)(3)(E) in §423.120(b)(5) is appropriate. However, we believe that CMS should modify its definition in the preamble of "affected enrollee" by adding to "a plan enrollee who is currently taking a covered Part D drug that is either being removed from the formulary, or whose preferred or tiered cost sharing status is changing" another clause stating "and whose coverage is being affected by such a formulary removal or change in status." Formularies may change, but many Part D providers are likely to continue providing the same degree of coverage for beneficiaries already taking those drugs. For such beneficiaries, a notice that the formulary status of their drug is changing would be extremely confusing, and could lead beneficiaries to seek to change Part D providers despite the fact that their existing Part D provider is not modifying its coverage of the drug the beneficiary is taking.

In addition, we believe that notice should not be required when the enrollee's cost-sharing is being reduced, or when generic competitors have dropped out of the market leaving only one supplier and the generic drug as a result becomes effectively treated as a single-source "brand name" drug. (See discussion above relating to definition of generic drugs.)

Clarification of Website Posting of Formularies. The requirement that a Part D provider post its formulary on its website should be clarified to require only that the list of drugs on an MA-PD or PDP formulary be posted on a public website, as opposed to the full range of clinical information that may be associated with any particular drug or class of drug on a formulary.

5. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§423.124) (P. 46662)

The MMA requires adequate emergency access to covered Part D drugs. CMS states that the term "emergency medical condition" is too narrow for the context of prescription drug needs. We agree. However, in rejecting the "prudent layperson standard" without substituting another standard of prudent behavior, and applying the emergency access requirement to such a broad set

of circumstances, the proposed rule has the potential to undermine effective network management and significantly increase Medicare costs. For example, by permitting out-of-network access whenever there is no network pharmacy within reasonable driving distance that is open 24 hours/7 days a week – whether or not the drug is urgently needed, or whether the patient should have been able to foresee the need to obtain a refill in a timely manner – is excessive. Similarly, if a patient should have foreseen that he or she would run out of drugs while traveling and failed to obtain an in-network refill prior to traveling, the Part D provider should not be required to provide for out-of-network coverage of the drug. The circumstances under which out-of-network pharmacies can be used should be more narrowly circumscribed. We also recommend that CMS take steps to assure that out-of-network pharmacies not be able to exploit this exception through marketing. CMS should not permit out-of-network pharmacies to advertise their services to Medicare beneficiaries as Medicare-covered services, for example.

6. Dissemination of Plan Information (§423.128) (p. 46663)

d. Claims Information

CMS should reconsider the requirement that a monthly Explanation of Benefits (EOB) be provided to beneficiaries. This is currently not a common practice and it will needlessly raise administrative costs for MA-PDs and PDPs when more reasonable alternatives to provide the same information are available. (For a plan like Kaiser Permanente, this requirement would mean sending out more than 500,000 EOB letters per month with associated processing, production and postage costs). For example, Part D providers could provide much of the same information – particularly the most important information about the beneficiary's current accrued annual spending – at the point-of-dispensing the drug. At a minimum, CMS should allow for MA-PDs and PDPs to provide this information as part of the prescription information provided to beneficiaries when they obtain their prescriptions. This would be consistent with CMS' intention that the information be provided in months when prescription drug benefits are being provided.

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§423.132) (P. 46665)

Under the waiver provisions of subsection §423.132(c), CMS should include a waiver of this requirement for MA providers owning and operating their own pharmacies. Without a waiver, we are unsure of how we would advise Kaiser Permanente's pharmacists to implement this requirement. Typically, Kaiser Permanente pharmacies carry only one version of any particular generic drug at any one time, except when transitioning from one manufacturer's product to another's. During such a transition, for a short period of time, there may be more than one drug – with potentially different underlying prices – in the Kaiser Permanente pharmacies. Establishing systems to notify beneficiaries of the price of equivalent drugs during these rare periods would be onerous. As part of a prepaid, integrated delivery system, Kaiser Permanente pharmacies have no incentive to persuade a beneficiary to obtain a higher cost generic drug that might be available. Given the very high generic utilization in Kaiser Permanente pharmacies, this requirement would be confusing to pharmacists and difficult to administer.

8. Privacy, Confidentiality, and Accuracy of Enrollee Records (§423.136) (P. 46666)

In addition to enrollee records, CMS should consider whether prescription data or prescriber practice pattern data will be shared with vendors who can then supply this information to the pharmaceutical industry for marketing purposes. Some MA organizations are concerned that providing data to drug manufacturers will have the negative effect of assisting manufacturers in targeting their marketing of unnecessary, expensive drugs in a more effective manner. At a minimum, CMS should permit MA organizations and PDP sponsors to prevent pharmacies in their networks and out-of-network pharmacies (as a condition of reimbursement), from releasing prescriber data to third parties.

II. Provisions of the Proposed Rule

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

1. Overview (§423.150)(P.46666)

a. Cost Effective Drug Utilization Management

CMS has requested comments on whether the Medicaid drug utilization review standards are considered "industry standards" and whether and how they should be incorporated into Part D. A provision of §1927(g)(2)(A)(i), requiring screening for drug-disease contraindications, although desirable, is probably not able to be implemented in an effective enough manner as to be considered a meaningful industry standard at this time. This specification would be more appropriately incorporated with implementation of the final Electronic Prescribing Program portion of the regulation to assure the necessary clinical information is available upon which drug-disease contraindication screening can occur.

b. Quality Assurance

Much policy work has recently been done on the issue of patient safety. Most policy makers have come to recognize that the primary problem with public reporting of medical errors is that it induces underreporting. As a result, the best approach to quality improvement is a program that holds disclosed information in strict confidence, where information collected can be systematically analyzed for root causes and a feedback loop can be established to providers in order prevent future errors.

CMS should recognize that public reporting and comparison of medication errors rates will likely have a chilling effect on the self-reporting of medication errors by physicians, pharmacists and others. Kaiser Permanente has long had systems to track and trend medication errors and develop solutions to reduce errors. Other pharmacy providers may have similar systems. Insuring that medication error reporting systems remain robust will require CMS to keep medication error reports in confidence.

CMS also invited comments on the definition of "medication error." We believe CMS' adopted definition is appropriate, but because of the diversity of types and causes of events covered by this broad definition, CMS should establish a variety of sub-classifications that would provide more meaningful analysis.

In general, different requirements in different jurisdictions for public or internal reporting of medication errors affect the levels of reporting and the severity of events that are reported. As a result, risk-adjustment of error types across jurisdictions with different regulatory requirements is problematic. CMS should be very cautious in implementing any kind of comparative reporting scheme. Part D providers with good internal reporting systems as a part of comprehensive quality management efforts could be badly disadvantaged compared to Part D providers with less well-advanced reporting systems. In addition, Part D providers filling prescriptions in states with more effective reporting requirements may look artificially more

error-prone than those filling prescriptions in other states. Before mandating any quality assurance requirements regarding medication error reporting, CMS should assess whether such a system would even be capable of fairly comparing different providers.

Because of the breadth of the FDA definition of medication error, any reporting and collection system should divide errors into at least two categories, based upon attribution of cause. The first group includes errors caused by acts (of commission or omission) that occurred while the medication was in the control of provider personnel or personnel affiliated with, and acting on behalf, of the provider. The second group includes errors caused by acts of the patient or the patient's caregiver (e.g. family member), and while the medication was in control of the patient or the patient's caregiver. This group of errors is intended to incorporate those events which are/were *not* attributable to providers, systems, or communications.

A second level of stratification should separate "near misses" from "actual" errors caused by providers. In the first instance, an error was committed while the medication was still in the possession of the health care professional, but was caught before the medication was released to the patient. "Actual" errors include only those instances where the medication had left the control of the provider(s). We believe that the only segment of "medication errors" that are appropriate for comparative analysis are those where the medication actually reached the patient, and which were the result of acts of the provider(s).

There are multiple measures other than medication errors that are appropriate for incorporation into a robust quality assurance program for pharmaceutical service\ providers. However, because of the diversity of organizational and structural design of various delivery models, we believe that it will be extremely difficult for CMS to specify a fixed grouping of quality assurance measures that are applicable across all MA-PDs and PDPs. What quality assurance measures Kaiser Permanente has developed as appropriate for our integrated system model may not be reasonable, appropriate, or even achievable for other organizations. The enumeration and description of the many possible components of a first-rate pharmacy quality assurance program are beyond the scope of this comment. For that reason, Kaiser Permanente hopes that CMS will invite further direct discussions with the Part D provider community on the entire quality assurance section of the proposed rule.

3. Consumer Satisfaction Surveys (§423.156) (P. 46670)

Fully integrated MA organizations, unlike other MA organizations and PDP sponsors, own and operate their own pharmacies. As a result, survey instruments may be confusing to beneficiaries enrolled in these organizations if the instrument is designed only for network model plans. In addition, to the extent that survey instruments do not reflect satisfaction ratings with retail pharmacies under contract to network model plans, comparisons between network plans and integrated organizations will be unlikely to result in apples-to-apples comparisons. In addition, consumer satisfaction ratings in health care are notoriously suspect to regional variation (i.e., ratings are often higher across the board for all providers in Hawaii and lower in some other regions of the country). In reporting satisfaction levels, CMS should attempt to adjust for these variations.

5. Quality Improvement Organization (QIO) Activities (§423.162) (P.46672)

MA organizations delivering benefits through their owned and operated pharmacies are likely to rely on specialized pharmacy information systems that differ from the systems designed for PDP sponsors to communicate with their contract network pharmacies. As a result, it is possible that pharmacy data may be misinterpreted by a QIO. If QIOs will be using data from integrated MA organizations to assess quality, it will be important to work closely with the organizations to understand the data, or to develop more efficient methods to achieve the same result – an appropriate assessment of quality performance.

II. Provisions of the Proposed Rule

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

2. Requirements for Submission of Bids and Related Information (P.46674)

We appreciate CMS' allowing plans to provide pricing data as late in the bidding cycle as possible; capturing price trend data accurately is important. However, this must be weighed against the need for MA organizations to quote Part D and "wrap-around" drug premiums to employer groups early in the bidding cycle. For organizations with significant numbers of members enrolled as retirees in employer groups, the lateness of the final approval of Part D (and Part A/B) bids presents a difficult problem. Providing organizations with as much detail as early as possible can mitigate this problem. For instance, the risk adjustment model and "average individual" data will not be provided until February 18, 2005; providing that dataset even six weeks earlier would help organizations develop retiree group premiums in a timely manner. In addition, the early provision of "data sources, methodologies, assumptions,…, data elements" will help organizations significantly in developing their proposals most efficiently and in supporting a fair and efficient review by CMS.

3. General CMS Guidelines for Actuarial Valuation of Prescription Drug Coverage (P.46675)

We request that the details of data sources, methodologies, assumptions, and other techniques used in evaluating actuarial equivalence be outlined for public review in a future Notice of Proposed Rulemaking.

4. Determining Actuarial Equivalency for Variants of Standard Coverage and for Alternative Coverage (P.46676)

In general, we support the approach of actuarial equivalence, as long as CMS provides thorough review of Part D providers' estimates of reinsurance to ensure a "level playing field." We are concerned that even when meeting the tests of actuarial equivalence, it would be possible for a Part D provider to establish a benefit design that could be significantly more attractive to beneficiaries with relatively low drug costs than those with higher drug costs. For example, an actuarially equivalent benefit providing 100% coverage at the low end and 100% cost sharing at the high end of what would have been the initial coverage interval under the standard Part D design would likely be much more attractive to a beneficiary with $1000 in total drug costs, even if the benefit would provide the same amount of total coverage to a beneficiary with greater drug needs. CMS should clarify that benefit designs seemingly targeted to attract healthier beneficiaries would not be permitted, rather than simply limiting its concern to discrimination against beneficiaries with specific illnesses based on the drug costs associated with those illnesses.

At the same time, it is important the CMS provide MA-PDs and PDPs with enough flexibility to provide appropriate options for benefit designs whose cost-sharing will be simpler for beneficiaries to understand. We believe that having the ability to establish flat copayments

rather than the 25% coinsurance of the standard design is important. CMS should permit Part D providers to round flat copayments to the nearest $5 dollar level, as these are the benefit designs commonly offered in the market place. CMS should also allow for reasonable flexibility in brand and generic differentials in flat copayments.

b. Test for Alternative Coverage

2. Test for Assuring Equivalent Unsubsidized Value of Coverage (P.46677)

We agree with the proposed method for this test for equivalent unsubsidized value between alternative coverage and standard coverage. We, too, have found that in all cases the reinsurance subsidy is equal to or less than for any alternative coverage that is actuarially equivalent or better than standard Part D. Therefore, it is not possible for any alternative coverage plan that is actuarially equivalent or better to have a lower unsubsidized value.

5. Information Included with the Bid (P.46678)

a. Bid Format

We ask that CMS clarify the components of the standardized bid, including whether the plan's reinsurance estimate will be standardized, and how that will flow through the calculations.

Administrative costs should be viewed as those costs incurred by an MA-PD or PDP in managing the insurance and claims processing functions of providing a drug benefit, as distinguished from costs related to delivering covered services such as operating pharmacies. This will permit a more level playing field between network model MA organizations and PDP sponsors and more integrated MA organizations that own and operate their own pharmacies.

6. Review and Negotiation of Bid and Approval of Plans (P.46679)

e. Private Sector Price Negotiation and Formulary Design

We plan to submit copies of our formulary for CMS' review at the time of our bid, but we note that our bid will depend in substantial part on whether we can use our existing formulary. To the extent that CMS determines that any particular drug or group of drugs must be added to our formulary, our bid may be significantly affected. CMS should expedite its review of formularies – particularly when an MA-PD or PDP submits the same formulary it uses in management of the drug benefits for large numbers of retirees, and when the MA-PD or PDP provides hassle-free access to nonformulary drugs when medically necessary.

CMS notes in the preamble that "we expect that the private negotiations between PDP sponsors and drugs manufacturers would achieve comparable or better savings than direct negotiation between the government and manufacturers . . . ." This observation is more likely to prove accurate if CMS does not interfere excessively with Part D providers' management of their formularies.

a. Authority to Review Bids (p. 46679)

We support CMS' efforts in these areas to help create a more level playing field. CMS has stated that it would have the authority to "determine whether the bids are in keeping with premiums charged in other insurance contexts" (P.46679), but also says that there is no "comparable concept" to SSSGs (P.46679). CMS should clarify how its intended oversight would differ from the SSSG requirements in the FEHBP, and what data CMS will ask of Part D providers in administering this provision for both Parts D and A/B. Also, we point out that there is currently no coverage in the market comparable to Part D, either in benefit design or formulary administration. These differences make "other insurance contexts" very difficult to compare with Part D. We suggest that CMS carefully review Part D providers' benefit designs for fairness and equity, and let market competition resolve the premium comparability issue.

d. Rebate Reallocation for MA-PD Plans (P.46680):

We support CMS' proposal to allow plans to reallocate the Part C rebate credit and resubmit modified benefit structures to account for differences between the projected and final national average monthly bid amounts. However, greater flexibility is needed regarding changes for employer groups whose benefit structures and premiums will likely have been finalized prior to final national average bid determinations. To provide stability for beneficiaries enrolled as retirees of employer groups, we encourage CMS to consider giving plans and CMS the option to waive or postpone small to moderate amounts of benefit change.

f. Bid Level Negotiation (P.46682)

We encourage CMS to:

- use electronic methods of recording and transferring documentation,

- obtain sufficient data to ensure a thorough review, thus increasing the likelihood of a "level playing field",

- minimize documentation requirements for data which would have little likelihood of being used in negotiation, and

- specify data requirements as early as possible in the bid cycle.

We also ask CMS to clarify which information can be protected from disclosure under the Freedom of Information Act. We feel strongly that all bid information, including prices and actuarial assumptions, should be kept confidential for competitive reasons.

7. National Average Bid Amount (P.46683)

To calculate the average bid, we suggest that all MA-PD plans be counted in the weighting scheme because virtually all MA-PD plans will offer Part D. In subsequent years, we support the proposal for giving new local MA-PDs' bids no weight.

In adjusting for geographic differences among MA-PD plans, we support a method that reflects true differences in drug costs, and that carefully controls for differential use of generics and utilization management by drug plans.

8. Rules Regarding Premiums (P.46685)

As proposed, the late enrollment penalty does not seem to compensate Part D providers for the administrative costs of tracking each enrollee's length of late enrollment and premium effects. In effect, this cost is borne by all enrollees in the plan's administrative costs. Consideration should be given to including the administrative costs of late enrollment tracking in the late enrollment penalty.

We support a clear and strong penalty to encourage early enrollment in Part D. The 1% per month penalty seems to achieve this. However, we have no utilization data on which to evaluate the proposed 1% loading for actuarial accuracy.

II. Provisions of the Proposed Rule

G. Payments to PDP Sponsors and MA Organizations offering MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

4. Requirement for Disclosure of Information (§423.322) (P.46686)

a. Data Submission

Claims submission and reconciliation have proven to be expensive, even for the simplified encounter data now used in M+C risk adjustment. Several million dollars have been added to Kaiser Permanente's M+C expenses simply to accomplish this objective. Claims creation and submission for the pharmacy claims as proposed would probably be even more expensive, given the volume of data and the number of data elements. We encourage CMS to be parsimonious in collecting data, with the understanding that plans would retain full data for audits.

c. Coverage Year

We assume the intent is to apply late rebates to the following year's costs and prices rather than make a retroactive adjustment to the previous year. We ask that CMS clarify this point.

5. Determination of Payment (§423.329) (P.46688)

a. Direct Subsidies

CMS correctly incorporates the MMA's provisions for calculating the direct subsidy (§1860D-15(a)(1)) into §423.329. However, in the preamble, CMS incorrectly asserts that there cannot be a "negative premium."

Without statutory support and inconsistent with the plain text of the statutory formula for setting the direct subsidy, CMS states in the preamble that "[w]e do not believe that the statute envisions plan payments in excess of negotiated costs, since this would violate the revenue requirements provisions discussed in the Subpart F of this preamble." This interpretation of the MMA would eliminate the possibility of a "negative premium," would unnecessarily discourage MA-PD plans from becoming more efficient, would provide an effective subsidy to higher cost plans, and would discourage beneficiaries from enrolling in the most efficient plans. This could increase Medicare costs, because fewer beneficiaries would enroll in lower cost plans, selecting higher cost plans instead.

The direct subsidy and the beneficiary premium are established by formula under the statute. The MMA anticipates that Part D providers may bid below the national average weighted bid. The Part D provider's premium is the difference between its bid and the national average bid. The benefit of the low cost bid is thus directly passed on to beneficiaries in the form of

reduced premiums. It is conceivable that a PDP or MA-PD standardized bid could be far enough below the national average that the difference between the Part D provider's bid and the national average bid would be greater than the statutorily-defined beneficiary premium. (This would result from highly efficient utilization patterns, high levels of generic dispensing and clinically appropriate cost-management practices. It would not result from favorable selection, which would be addressed substantially though risk adjustment of payments.) Thus, through mathematical operation, the statutory formula necessarily could produce a negative premium. Applying this to the direct subsidy formula, subtracting a negative premium from the Part D provider's bid results in an increased direct subsidy. The plain text of the statute mandates this result.

We agree with CMS that one of its primary goals should be to implement the statute in a manner providing the greatest possible benefit to beneficiaries consistent with Congressional intent. The interpretation in the preamble that seemingly prohibits a "negative premium" is incorrect both textually and as a matter of legislative intent. It is also counterproductive because it would eliminate the opportunity for beneficiaries to receive the value provided by a very low cost Part D provider. It would be a greater benefit to beneficiaries if CMS were to require a Part D provider with such a low bid as to result in a negative premium to return the value of the savings to the beneficiary in the form of an enhanced benefit that would be covered by the enhanced direct subsidy. The value of any lost reinsurance should be factored into payment for the enhanced benefit.

Such an interpretation would be consistent with other areas of Medicare policy requiring savings to accrue primarily to the advantage of beneficiaries. Providing an incentive for more beneficiaries to enroll in low cost MA-PD and PDPs could save Medicare money overall. Allowing very efficient Part D providers to enhance the Part D benefit without charging a premium maximizes market competition, program cost control and beneficiary interests.

b. Risk Adjustment

We recommend CMS examine use of a low-income subside (LIS) flag in future development of the risk adjustment model, just as it has used Medicaid as a special status for additional payment.

d. Reinsurance Subsidies

ii. Payment of Reinsurance Subsidy

We support predictability of payment, especially in starting years for this new benefit. Therefore, we support the "1/12" method of payment, with appropriate interest and discount calculations and a retrospective settlement after the close of the year.

iv. Adjustments for the Insurance Effect of Supplemental Coverage

Although we are reluctant to add actuarial adjustments where there is so little experience and data, we do support CMS' effort to put all Part D providers on a level and equitable playing field with regard to payment for the base Part D benefit.

The impact of induced utilization will vary among Part D providers based on the extent to which their utilization reflects physician prescribing patterns. In well-managed plans, we predict the effect to be small. In view of the range of possible effects, we recommend that Part D providers forecast their own supplemental effects and that these forecasts be stringently reviewed by CMS.

We strongly suggest that CMS provide clarification that Part D providers will then be allowed to include the revenue requirement of "foregone" reinsurance revenue into the supplemental premium. We would also suggest that this represents another area where a capitated reinsurance demonstration program would be useful.

6. Low-Income Cost-Sharing Subsidy Interim Payments (P.46690)

Again, we support predictability of payment and we support the "1/12" methods of payment, with appropriate interest and discount calculations and a retrospective settlement after the close of the year.

II. Provisions of the Proposed Rule

I. Organization Compliance with State Law and Preemption by Federal Law

3. Preemption of State Laws and Prohibition of Premium Taxes (P.46696)

On P. 46696, CMS notes that the MMA extended general preemption of State laws (except for licensure and solvency laws) to PDP sponsors. CMS implements this general preemption by applying it in §423.440 to "prescription drug plans offered by PDP sponsors and MA-PD plans offered by MA organizations". However, we believe that it was an oversight for CMS not to extend the same general preemption of State laws to cost HMOs, at least with respect to their qualifying Part D offerings. Section 1860D-21(e) applies Part D (and related provisions of Part C) to the qualifying Part D coverage offered by cost HMOs "in the same manner as such provisions apply to the provision of such [Part D] coverage under an MA-PD local plan…and coverage under such a [HMO cost] contract…shall be deemed to be an MA-PD local plan." CMS echoes this statutory provision and confirms it on P. 46753 where it says that "Part D rules will generally apply to…HMOs and CMPs…that contract under §1876 and that offer qualified prescription drug coverage…in the same manner as such rules apply to local MA-PD plans." When cost HMOs act as local MA-PD plans and are "treated" as local MA-PD plans, Congress intended that they should have the benefit of the general preemption of State laws, just as do MA-PD plans offered by MA organizations.

II. Provisions of the Proposed Rule

J. Coordination of Part D Plans with other Prescription Drug Coverage.

2. Application of Part D Rules to MA-PD Plans on and After January 1, 2006 (§423.458) (P.46697)

In this section, CMS notes that it will waive the pharmacy network access requirements as described in §423.120(a)(3) of the proposed rule "in the case of an MA-PD plan that provides access…to qualified prescription drug coverage through pharmacies owned and operated by the MA organization," if CMS determines that the MA-PD plan's pharmacy network is sufficient to provide comparable access. We assume, but are not certain, that this waiver will also be made available to cost HMOs that offer qualifying Part D coverage and provide access to qualified prescription drug coverage through pharmacies these cost HMOs own and operate. In this same section, CMS states that "Part D rules generally apply to §1876 Cost HMOs…in the same or in a similar manner as the rules apply to MA-PD local plans." Therefore, we believe that the same waiver of pharmacy network access requirements should be available to cost HMOs offering qualifying Part D coverage and providing access to negotiated prices through their owned and operated pharmacies. CMS should confirm this in its final rule.

4. Application to Employer Groups

a. Employer Group Waivers (P. 46698)

In this section CMS notes that the proposed rule (§423.458(c)) extends to PDP sponsors the same opportunity as MA organizations already have to seek waivers that would facilitate the provision of prescription drug benefits to employer group enrollees in the most effective and efficient manner. However, §423.458 is silent as to the availability of employer group waivers for cost HMOs providing qualifying Part D coverage. While the MMA (§1860D-22(b)) specifically extends employer group waivers to PDP sponsors, it is silent as to cost HMOs. However, the MMA (§1860D-21(e)) also provides for regulatory parity between MA organizations offering MA-PD plans and cost HMOs offering qualifying Part D coverage. We believe this expression of Congressional intent is clearly intended to facilitate the offering of qualifying Part D coverage by cost HMOs. As such, it is more than adequate basis for the final rule that we request, i.e., that qualifying Part D coverage offered by a cost HMO be considered an MA-PD plan for purposes of enabling the cost HMO to obtain the same employer group waivers as MA organizations can obtain for their MA-PD plans.

5. Medicare Secondary Payer Procedures (P.46699)

In its discussion of the Medicare Secondary Payer (MSP) procedures applicable to Part D, CMS notes that the MMA extended the same MSP rules governing MA organizations to PDP sponsors, and thus both PDP sponsors and MA organizations are permitted to recover from liable third-parties when Medicare is secondary, irrespective of State law. CMS goes on to say that in accord with §1860D-12(g) of the MMA that extends preemption from State law to PDP sponsors, "States would be prohibited from exercising authority over prescription drug plans in

any area governed by Medicare Part D (including our regulations under Chapter 423) other than State licensing laws and State laws related to plan solvency." We believe that this is an accurate statement with respect to PDP sponsors. However, we also think it is and should be an accurate statement (and should be included in the final rule) with respect to cost HMOs offering qualifying Part D coverage. Part D is a federal program and should be implemented by all Part D providers in accord with the same federal rules and without regard to any State laws except those governing licensure and solvency. CMS needs to make it very clear in every pertinent part of the final rule that when cost HMOs offer qualifying Part D coverage, that coverage is to be considered as an MA-PD plan for all purposes including access to waivers and general preemption from State law.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage

c. Coordination of Benefits (P.46702)

CMS notes occasions when Medicare pays secondary to other insurance, including when Medicare beneficiaries are classified as "working aged" and have primary prescription drug coverage through an employer group. This coverage will be primary to Medicare. These Medicare secondary beneficiaries are permitted to enroll in MA plans, and many do. They are also entitled to enroll in Part D and many will enroll in their current MA organization's MA-PD plan. In fact, many of these Medicare secondary beneficiaries will be automatically enrolled in their MA organization's MA-PD plan as of January 1, 2006, pursuant to §422.66. However, it is not clear how CMS expects MA organizations to compare primary employer group drug coverage with secondary Part D coverage to determine which coverage should pay first for any prescription for a Part D-covered drug. For example, a primary employer group drug coverage could have a $500 deductible and unlimited coverage thereafter with a $10 copayment for generic drugs and a $25 copayment for brand name drugs. The structure of such employer group drug coverage is very different from the structure of the Part D drug benefit. It is not clear how CMS expects MA organizations to compare the two structures to determine which one is primary for any given prescription. We agree that the number of Medicare beneficiaries for whom Medicare will be secondary payer for Part D will be relatively small, but MA organizations need much clearer direction in making primary and secondary determinations, or need to have CMS make these determinations itself.

d. Collection of Data on Third Party Coverage (P.46704)

CMS discusses Coordination of Benefits (COB) among all entities likely to reimburse beneficiaries for Part D costs. CMS says that the MMA authorizes it to establish procedures for determining if out-of-pocket costs for Part D enrollees are being reimbursed by other payers and for alerting Part D plans about such arrangements. CMS says this authority could mean (1) it only has to determine the presence of alternative coverage and alert Part D plans of such, or (2) it must determine "if specific claim costs have been reimbursed by alternative coverage". We strongly prefer the second option. We believe CMS should maintain and administer COB records with which it could inform Part D providers about drug cost reimbursements by third parties. Without such a unitary national approach to tracking and maintaining reimbursement

records, the Part D benefit would be seriously at risk for incomplete, inconsistent and inequitable application of COB by the various Part D providers.

e. Tracking True Out-of-Pocket (TrOOP) Costs (P. 46705)

CMS says that it is considering two basic options for "operationalizing the data exchange related to the Part D COB system and TrOOP accounting [tracking]". Those basic options are (1) that PDPs and MA-PDs would be solely responsible for tracking TrOOP costs, or (2) CMS would hire a "TrOOP Facilitation Contractor to establish a single point of contact between payers, primary or secondary". We believe that a "TrOOP facilitation contractor" functioning as a single point of contact between primary and secondary payers would be the most cost-efficient means for providing accurate, consistently interpreted, and timely information to all parties involved in operationalizing Part D. Otherwise, inconsistent interpretation and application of information by the various Part D providers would inevitably produce inequities in the provision of the Part D benefit and confusion for beneficiaries.

II. Provisions of the Proposed Rule

M. Grievances, Coverage Reconsiderations and Appeals. (P. 46717)

This Subpart refers consistently and only to "PDP sponsors", leading the reader reasonably to conclude that none of it applies to MA organizations offering MA-PD plans or §1876 cost HMOs offering qualifying Part D coverage. If CMS intends for any provisions of this Subpart to apply to MA organizations or cost HMOs, CMS must specify those provisions and the nature of their application. However, it would be a mistake for CMS to revise this Subpart by merely adding references to MA organizations and cost HMOs, because those entities are already governed by the Section 422 and Section 417 appeals procedures, respectively, and there are differences between those appeal procedures and the procedures set out in Subpart M. For example, an MA organization that upholds an adverse organization decision in whole or part must immediately forward the file to the IRE. Under §423.600 an individual dissatisfied with a redetermination must file a written request for reconsideration. Instead of making Subpart M globally applicable to MA organizations and cost HMOs, CMS should revise Section 422 and Section 417, respectively, by incorporating in them the specific provisions of Subpart M that will be applicable to these entities' MA-PD plans. In that way, CMS would provide for these entities an integrated set of appeals procedures that will govern the provision of Parts A, B and D benefits. This approach would also facilitate greater consistency in the appeals procedures governing Part B drugs and Part D drugs, which consistency is not a concern for PDP sponsors and is not addressed in Subpart M.

One substantive issue deserves comment. On P. 46720, CMS discusses its rules for non-formulary exceptions. Although it is not required by the MMA, a Part D provider may establish an exceptions process that delegates the determination of whether a nonformulary drug is medically necessary – and therefore covered – to the treating physician. In such cases, CMS should not require the Part D provider to develop an elaborate administrative exceptions process at this level because the beneficiary already can easily and straightforwardly ask his/her treating physician for such a determination. If the physician's determination is not to approve the beneficiary's request for a formulary exception, the beneficiary should have the right to request the Part D provider to make a redetermination in the regular appeals process.

II. Provisions of the Proposed Rule

P. Premiums and Cost-Sharing for Low-Income Individuals.

3. Premium Subsidy (§423.780) and Cost-Sharing Subsidy (§423.782)

b. Other Low-Income Subsidy Eligible Individuals (P. 46729)

We understand that there are basically two categories of low-income individuals eligible for Part D subsidies: (a) full subsidy eligible individuals (including full-benefit dual eligibles and QMBs, SLMBs, and QI-1s) and (b) other low-income subsidy eligible individuals. The former (a) beneficiaries will pay no Part D premiums. The latter (b) beneficiaries will receive a Part D premium subsidy which will be set on a sliding scale – a subsidy of 100% of the premium for beneficiaries below 135% of FPL to no subsidy for beneficiaries at or above 150% of the FPL. CMS asks for comments concerning how it should establish the sliding scale premium subsidy. It suggests that it might set the scale in a "stepped" fashion, i.e., a "set decrease in the subsidy amount for every 5% increase in income level". We believe that for true ease of administration, there should be as few steps as possible in this sliding scale.

To put it another way, there should be as few as possible different reduced premiums for low-income beneficiaries between 135% and 150% of FPL. The administrative burden of tracking and implementing a multitude of different premiums for these other low-income beneficiaries would vastly outweigh any perceived equity achieved by setting the premium in many steps carefully calibrated to relate directly to the individual's income level. The administration of the Part D benefit for low-income individuals will already be a very complex endeavor, requiring ongoing communications between State Medicaid agencies, the Social Security Administration, CMS and Part D providers. Adding a multi-stepped sliding scale for premium reduction would only make administration more complex. Information about low-income individuals should be as straightforward and as consistently conveyed as possible, and when there are differences in treatment to be accorded to these individuals that are not set by statute, CMS should use its regulatory authority to have as few differences as possible. Therefore, we recommend that the sliding scale for premiums for these low-income members between 135% and 150% of FPL have as few "steps" as possible.

CMS states that with the exception of Special Needs plans, an MA-PD plan may not reduce or eliminate the copayments the MMA establishes for dual-eligible individuals, because doing so would violate the MA "uniformity of benefits" principle set forth in §423.265(c). This position is misguided. At the specific direction of the MMA, these low-income individuals will already pay lower premiums and lower cost-sharing than any of the other individuals enrolled in the same MA-PD plan. At this point the "uniformity of benefits" principle has already been redefined by virtue of Congress' desire to make sure that Part D benefits are within the financial grasp of these low-income members. Moreover, certain MA organizations have, in the past, obtained OIG Advisory Opinions that expressly permit them to waive premiums and cost-sharing for low-income members enrolled in their Medicare+Choice (now MA) plans. Therefore, such waivers already reduce the premiums and cost-sharing paid by low-income MA plan members for Parts A and B benefits. We believe that CMS should permit the same approach with respect

to Part D benefits. That is, MA organizations should be able to seek OIG Advisory Opinions that expressly permit them to reduce the Part D cost-sharing and premiums to be paid by low income members. Such waivers would enhance the Part D benefit for these low-income members and would ease the administrative burden on MA-PD plans, especially with respect to copayments of $1 or $2. Often these small copayments are more expensive to collect than the revenue or program savings that they represent.

4. Administration of Subsidy Program (§423.800) (P.46732)

CMS notes that it will be establishing a "process to notify the PDP sponsor or MA organization that an individual is both eligible for the subsidy and the amount of the subsidy." We are most concerned about retroactive determinations of low-income status, and any duty upon an MA organization to refund premium and cost-sharing amounts paid by a low-income MA-PD plan member before either the member or the MA organization were informed of the member's low-income status. We strongly believe that CMS should limit the period of retroactivity of low income status determination to no more than three months. Any longer period of retroactivity (with the consequent responsibility to refund or repay previously paid premiums and cost-sharing) would be excessively burdensome to Part D providers. Any process that CMS establishes will require the cooperation of the State Medicaid agencies, the Social Security Administration, CMS and other Part D providers. Even if each "handoff" works perfectly, there will inevitably be some confusion and some delays among these entities. It is entirely possible that by the time an MA organization is notified of a MA-PD plan member's low-income status, three months will have passed from the time the member first applied for that status. During this time the member will have paid the regular Part D premium and cost-sharing under the MA-PD plan. Will it be the responsibility of CMS to pay the MA-PD plan for the premium and cost-sharing subsidies applicable to the previous three months, and the MA-PD plan's responsibility to make comparable refunds to the low-income individual? It would be far easier for MA-PD plans to administer this process if any refunds due the low-income member (for regular Part D premiums and cost-sharing paid before low-income status was confirmed) were either (1) made by CMS and deducted from any future subsidies CMS owed the MA-PD plan for that low-income individual, or (2) applied by the MA-PD plan to future premiums and cost-sharing payable by the individual.

CMS also asks for suggestions about how and when a Part D provider should notify CMS that the organization has implemented the reduction in premium and/or cost-sharing ordered by CMS for a low-income individual and how CMS will reimburse Part D providers for these reductions. Presumably CMS will inform the Part D provider of the member's low-income status determination at the same time it notifies the low-income member. At that point, CMS should give the Part D provider up to 60 days to inform CMS that the reduction in premium and cost-sharing has been implemented. Implementation should be effective no later than the first day of the second month following the month in which the low-income determination was sent by CMS to the Part D provider. There should not be any special or separate notice that the Part D provider must send to CMS to indicate that the reduction in premium and/or cost-sharing has been implemented. Presumably this notification will be part of the monthly membership transaction file that the Part D provider sends to CMS.

CMS says that it may compute reimbursements for low-income premium and cost-sharing subsidies on a capitated basis (based on the actuarial value of the subsidies). However, these subsidies count toward TrOOP, and Part D providers must track their accumulation. It is not clear how a Part D provider that is reimbursed for low-income subsidies on an aggregated (all low-income individuals) capitated basis can track the accumulation of the subsidies on an individual member, dollar amount basis. We would welcome the opportunity to work with CMS to develop a different approach to this issue.

II. Provisions of the Proposed Rule

T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE and Medigap Requirements

2. Cost-Based HMOs and CMPs offering Part D coverage (§ 417.440 and § 417.534) (P.46753).

CMS acknowledges that the MMA "provides that Part D rules will generally apply to reasonable cost...HMOs that contract under Section 1876 of the Act and that offer qualified prescription drug coverage to Part D eligible enrollees in the same manner as such rules apply to local MA-PD plans." Accordingly, CMS says, the Section 1876 cost regulations "must be revised to reflect the treatment of an HMO or CMP as a local MA-PD plan." However, the two changes to the Part 417 regulations that CMS proposes do not accomplish this goal. The proposed changes only (a) permit cost HMOs to offer Part D coverage, and (b) state that Part D costs cannot be included in a cost HMO's cost report. CMS has not proposed a Part 417 regulation stating that the Part 423 and Part 422 rules that apply to local MA-PD plans also apply to the qualifying Part D coverage of cost HMOs, unless specifically noted to the contrary. There should be such a provision in the final rule.

In addition, the Part 423 and Part 422 rules that carry over to cost HMOs with respect to their qualifying Part D coverage should specifically include access to employer group waivers and general preemption from State laws. Regulatory recognition of this cost HMO "carry over" would implement the clear Congressional intent to apply MA-PD rules to cost HMOs offering qualifying Part D coverage. Moreover, CMS has already seen fit to extend a comparable waiver to cost HMOs without specific statutory authority. On P. 46697, and in Section 423.458(d) on P. 45822, CMS says it will extend to cost HMOs with qualifying Part D coverage a waiver from Part D rules if such rules conflict with or duplicate Section 1876 rules. There is no explicit statutory authority for <u>this</u> waiver for cost HMOs, so the lack of explicit statutory authority for providing cost HMOs with access to employer group waivers and general preemption of State laws should not be a bar either.

CMS-4068-P-1138

Submitter : Laura Hanen **Date & Time:** 10/04/2004 07:10:41

Organization : HIVMMWG

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

CMS-4068-P-1138-Attach-1.doc

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

We the undersigned organizations are national and community-based AIDS organizations that represent people living with HIV/AIDS, medical providers, advocates and program administrators that deliver HIV-related health care and support services. 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. 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. Separately, many individual HIV/AIDS organizations are providing more detailed comments, and many others are also signing onto comments developed through other coalitions. 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.

We 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 7 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 collective 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

DUAL 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, many of our 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 weigh-in 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 dually eligible. 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. However, 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 REGARD 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 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

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[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.

[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.

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 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

[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.

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.

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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.

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.

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 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

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

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 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 includes 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 us through Laura Hanen, Director of Government Relations, National Alliance of State and Territorial HIV/AIDS Directors, at (202) 434-8090 or Christine Lubinski, Executive Director, HIV Medicine Association, at (703) 299-1215.

Sincerely,
AIDS Action
AIDS Action Baltimore
AIDS Action Committee of Massachusetts
AIDS Alliance for Children, Youth and Families
AIDS Foundation of Chicago
AIDS/HIV Health Alternatives
AIDS Housing Association of Tacoma
AIDS Legal Council of Chicago
AIDS Legal Services of the Law Foundation of Silicon Valley
AIDS Medicare Coalition Project
AIDS Project Los Angeles
AIDS Survival Project
AIDS Treatment Activists Coalition (ATAC)
AIDS Treatment Data Network
American Academy of HIV Medicine
Asian & Pacific Islander American Health Forum
Being Alive: People with HIV/AIDS Coalition of Los Angeles
CAEAR: Communities Advocating Emergency AIDS Relief
CareBearers
Cascade AIDS Network
Catholic Charities CYO
Community HIV/AIDS Mobilization Project (CHAMP)
Continuum
Families USA
FOUND, INC.
Gay City Health Project
Gay Men’s Health Crisis

Georgia ADAP Task Force
HIV Alliance
HIV Medicine Association
Housing Works, Inc.
Howard Area Community Center
Human Rights Campaign
Hyacinth AIDS Foundation
International AIDS Empowerment
Kansas City Free Health Clinic
Lambda Legal
Lifelong AIDS Alliance
Michigan Advocates Exchange
Nashville CARES
National Association of People with AIDS
National Alliance of State and Territorial AIDS Directors
National Health Law Program
North Idaho AIDS Coalition
Pierce County AIDS Foundation
Project Inform
San Francisco AIDS Foundation
Seattle HIV/AIDS Planning Council
Sierra Foothills AIDS Foundation
Southwest C.A.R.E. Center
Spokane AIDS Network
The Advocacy Project of Texas
The AIDS Foundation of Saint Louis
The AIDS Institute
The Night Ministry
Title II Community AIDS National Network
Treatment Access Expansion Project
Treatment Action Group
United Communities AIDS Network
Western Pacific

CMS-4068-P-1139

Submitter : Dr. Margaret Giannini **Date & Time:** 10/04/2004 07:10:22

Organization : Office on Disability

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached from the Office on Disability

CMS-4068-P-1139-Attach-1.doc

Office on Disability
Department of Health and Human Services
Constituent Comments Regarding the Draft Regulations
Medicare Modernization Act (MMA).
October 4th, 2004

On behalf of its constituents The Office on Disability would like to thank you for providing us the opportunity to submit comments on the implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. (MMA). The following provides a compilation of the issues collected from the Constituent Input Expert Meeting on the MMA with an emphasis on dual eligibles that was hosted by the Office on Disability with the CMS Center for Medicaid and State Operations on September 14, 2004. Also included in this document are additional issues and comments submitted by constituent groups to the Office on Disability which each organization individually submitted to CMS in response to the August 4th Federal Register.

Constituent Groups represented in this document include:
American Association on Mental Retardation (AAMR)
Association of University Centers on Disabilities (AUCD)
Consortium for Citizens for Disabilities (CCD) with comments endorsed by the following organizations; American Academy of Physical Medicine and Rehabilitation American Association on Mental Retardation, American Association of People with Disabilities, American Medical Rehabilitation Providers Association, American Therapeutic Recreation Association, Association of Academic Physiatrists, Association of University Centers on Disabilities ,Bazelon Center for Mental Health Law Center on Disability Issues and the Health Professions, Easter Seals, Epilepsy Foundation Family Voices, National Alliance for the Mentally Ill, National Association of County Behavioral Health Directors, National Association for the Advancement of Orthotics and Prosthetics, National Association of Protection and Advocacy Systems, National Association of Social Workers, National Mental Health Association, National Multiple Sclerosis Society, Paralyzed Veterans of America, The Arc of the United States, Title II Community AIDS National Network, United Cerebral Palsy, United Spinal Association Volunteers of America ,World Institute on Disability.
California Health Advocates (CHA) endorsed by the World Institute of Disability
Voices of the Retarded (VOR)
National Alliance for the Mentally Ill (NAMI)
Individual Constituent – Julie Beckett

Issue and Comments

USP Guidelines and the Formularies

ISSUE 1. (AAMR)
For people with mental retardation who have 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 or being institutionalized.

They often need access to the newest medications, which have fewer side effects than the older less expensive drugs. Many individuals with multiple disabilities and health conditions have problems with drug interactions. Frequently, extended release versions of medications are needed to effectively manage their serious and complex medical conditions. Access to an alternative, formulary is essential.

One of the particular AAMR concerns pertains to people with mental retardation who are less able to articulate problems with medication side effects. In these situations the doctor has to experiment in order to find the best medication for the individual. That process often takes time since many people with significant disabilities must try multiple medications before the most effective one is found.

COMMENT (AAMR)

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. 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. At the very least, this treatment should apply to:

- People who are dually eligible for Medicare and Medicaid
- People who live in nursing homes, ICF-MR's 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.

ISSUE 2. (AUCD)

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.

COMMENT (AUCD)

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**.**

ISSUE 3. (CCD)
The broad classification scheme in the formularies will lead to far fewer choices of medications for a number of disorders and illnesses than what is commonly seen in the private sector or other federal and state formularies.

COMMENT (CCD)
CCD Health Task Force encourages the USP to recommend that the Model Guidelines for Medicare drug plans include an open formulary for certain targeted beneficiaries with disabilities. To ensure that these special populations have adequate, appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must further be protected from tiered cost sharing that could create insurmountable access barriers.

ISSUE 4. (CCD)
The draft classification in several areas appears biased toward older, less effective medications. The creation of a second-class drug benefit for Medicare beneficiaries that relies on older less effective medications was not the intent of Congress in passing the Medicare Prescription Drug, Improvement and Modernization Act of 2003. Inexpensive drugs may be effective but if the individual cannot tolerate it or take it safely the drug becomes useless.

COMMENT (CCD)
CCD Health Task Force urges the USP to revise the Model Guidelines. It is recommended that the subdivisions in the draft model guidelines become redefined as classes, with the addition of new classes. Though the USP has argued that the Model Guidelines are disease-based approach guidelines do not clarify that there are pharmacologic classes for the therapies used to treat multiple sclerosis, attention deficit hyperactivity disorder, anxiety, and others.

In addition the lack of coverage for the multiple sclerosis immunomodulating therapies in the USP Model Guidelines must be addressed. Specifically, no category appears to cover the current FDA-approved disease-modifying agents for multiple sclerosis --Avonex, Betaseron, Rebif, and Copaxone. The USP draft guidelines do not reflect the current medical practice and treatment for multiple sclerosis.

COMMENT (CCD)
As the multiple sclerosis therapies currently have no approved indications other than for the treatment of multiple sclerosis and for the reasons above, the we recommend that the USP adopt the following classes under the therapeutic category of Immunological Agents that would be mandatory in all Medicare prescription drug plans: Immunomodulators – beta interferon 1-b; Immunomodulators – beta interferon 1-a and Immunomodulators – copolymers. In the case of the anti-convulsants, even if the recommended subdivisions are made into pharmacologic classes, the listing would not be comprehensive and would still favor the older medications. Nearly all of the first line treatments for

seizures and all of the drugs approved after 1978 would fall under "other anticonvulsants."

At a minimum USP must create additional classes based on mechanisms of action for the anti-convulsants. Anti-convulsants are not interchangeable and physicians must have access to the broad array of medications in order to choose what medication will work best for the individual.

ISSUE 5. (CCD)

CCD is concerned that the classes for drugs used to treat mental illness are too broad or non-existent and if adopted will likely cause harmful disruptions in care for individuals eligible for both Medicare and Medicaid and inadequate coverage for other beneficiaries. For example in the category of anti-depressants, the Model Guidelines inappropriately group the newer more effective reuptake inhibitors including the Selective Serotonin Reuptake Inhibitors with the tricyclics, which have more dangerous side effects. Moreover, reuptake inhibitors themselves have different mechanisms of actions and should not all be grouped into one class. They affect brain chemistry in distinct ways; have singular side effects, and some evidence shows that their effectiveness varies depending on the type of depression.

COMMENT (CCD)

It is suggested to use the list of drug classes for anti-depressants developed for the Medicare discount card, which establishes seven separate classes.

ISSUE 6. (CCD)

Within the proposed class of atypicals, anti-psychotics are even less interchangeable than SSRIs. Research shows that different antipsychotic medications (including atypicals) affect separate portions of the brain and affect the brain in very different ways. As a result, they have varied clinical outcomes and side effects.

The USP proposed guidelines include one broad category for "Bipolar Agents" which we presume is meant to cover treatments for bipolar disorder, but no classes are included to ensure coverage of the many different treatments for this complex disease. Individuals with bipolar disorder typically take a variety of medications including anti-convulsants, anti-depressants, and anti-anxiety medications. This is a devastating disease that requires individualized and comprehensive treatment.

COMMENT (CCD)

These broad categories without further specification of the types of medications that must be covered will likely cause confusion among health plans offering the Medicare drug benefit.

- USP needs to include assurances in the Model Guidelines that doctors will be able to prescribe medications regardless of diagnosis.

- The Model Guidelines should also clarify that plans cannot block access to clinically appropriate combination drug therapies and clinically appropriate off-label uses of drugs.

- USP should add a description of how the classes and categories will be updated as new drugs become available that do not currently fall into the proposed classification system. A process should be in place to assure ready access to new drugs as the FDA approves them. This is a particularly urgent issue for people with life-threatening illnesses, those individuals who live with debilitating side effects from their current medications and for people with conditions where there are no effective treatments.

- It is also recommended that USP provide assurances that medications needed for lower-incidence disabilities or disorders that fall into larger pharmalogic categories will be accessible. In some instances it may be critical to require coverage for more than two drugs

- Anti-HIV drugs are not interchangeable in terms of efficacy or side effects and vary significantly for an individual in terms of resistance, tolerance and drug interactions. For people with disabilities, upfront access to medically necessary medications is preferable to relying on cumbersome appeals or exception processes.

ISSUE 7. (NAMI)

NAMI is extremely concerned that the NPRM appears to allow substantial discretion for Medicare prescription drug plans to use restrictive utilization management techniques, including prior authorization, tiered co-payments, "fail first" requirements and step therapy. Given the overwhelming evidence demonstrating the dangers associated with such practices to individuals with mental illnesses, we believe protections are needed. NAMI is grateful for the recognition of these challenges in the NPRM and the need for special exemptions from these techniques for certain beneficiaries, including those with mental illness.

In NAMI's view, restrictive practices such as prior authorization, fail first, and step therapy are both inappropriate and unnecessary for people with mental illnesses. Medications to treat mental illness are not generally interchangeable, including those with the same mechanism of action, and differ in how they affect brain chemistry. It must be recognized that these illnesses themselves are highly variable in terms of symptoms and their impact on individual patients, and physicians must carefully tailor drug therapies to each individual to take into account the patients' current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide.

COMMENT (NAMI)

NAMI proposes a requirement for Medicare prescription drug plans to incorporate an alternative, flexible formulary for enrollees with mental illness into their benefit designs. This formulary would provide access to the full array of medications to treat mental illness (without use of "fail first" requirements, prior authorization, step therapy, therapeutic substitution, or any similar restrictive

policies). Eligibility for this alternative, flexible formulary would be restricted to enrollees diagnosed with a mental illness (including dual eligibles).
This alternative, flexible formulary would instead focus utilization management on practices designed to improve (or at least maintain) the clinical status of individual plan enrollees. Among the advantages and opportunities associated with this recommended alternative, flexible formulary are:

- Integration of provider peer education initiatives designed to improve clinical practice,
- Closer scrutiny and retrospective review of individual clinicians to address instances of "polypharmacy" or other inappropriate prescribing,
- Enhanced data review to identify fraud, deviation from clinical best practice, outlier prescribers, and inappropriate dosing levels, and
- Cost containment through techniques such as targeted case management of chronic illness to improve coordination of care and outcome measurement.

NAMI strongly recommends that the Final Rules ensure that Medicare beneficiaries with mental illnesses have access to the newer medications that are generally more effective and have fewer side effects. Such a protection is consistent with the finding of President Bush's New Freedom Commission on Mental Health. In their Final Report from 2003, they noted, "efforts to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services."
Finally, in a recent report circulated to State Medicaid Agencies entitled "Psychiatric Medications: Addressing Costs without Restricting Access", CMS encourages state Medicaid directors to implement these same types of innovative alternatives instead of restrictive formularies and prior authorizations that increase the risk of the use of multiple prescriptions, reduced compliance, and poor outcomes. NAMI urges CMS to follow the example set forth in this report and integrate the same strategies in the Medicare prescription drug benefit.

ISSUE (8). (BECKETT)
Lack of clarity if draft regulation is saying that as of January 1,2006 and a person who has dual eligibility will put these individuals' medication payments in jeopardy and be used as "guinea pigs" for new drugs on the market simply because physicians have tried everything else.

COMMENT (BECKETT)
Persons with dual eligibility cannot be used as "guinea pigs."

Pharmacy and Therapeutic Committees

ISSUE (9). (NAMI)
In the preamble to the NPRM, CMS states that it interprets the MMA as requiring that a P&T committee's decisions regarding the plan's formularies be binding on the plan. However, these provisions are not included in actual regulations but only discussed in the preamble.

COMMENT (NAMI)
NAMI supports a requirement for advance notice of P&T Committee meetings to ensure adherence to requirements in the MMA that coverage decisions be based "on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature."[1] Such a process should also ensure that beneficiary protections for coverage decisions under the new drug benefit parallel those protections provided by the public comment process in the traditional Medicare program for developing national and local coverage policies. P&T Committees should also be required to document and explain the reasons for their formulary decisions and make these determinations public. This would ensure that the P&T Committee follows the intent of Congress and makes clinical, rather than financial, judgments when developing a formulary.

Therapeutic Substitution

Issue 10. (NAMI)
Preserving the physician's role in the prescribing process is an important beneficiary protection, particularly for vulnerable Medicare populations who may be on multiple medications and living with many co-morbidities. We believe that the patient-physician relationship in these situations is sacrosanct and should not be undermined by any implication that therapeutic substitution can be executed without explicit physician consent.

COMMENT (NAMI)
NAMI strongly recommends that the Final Rules include a requirement for drug plans to put in place an alternative, flexible formulary for beneficiaries with mental illnesses that prevents therapeutic substitution. In addition to including such a requirement in this alternative, flexible formulary, NAMI would also urge that the Final Rules incorporate the same as a basic patient protection for all beneficiaries, including a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician. The preamble to the Proposed Rule indicates support for such a requirement.[2] Alternatively, CMS should also consider a requirement for plans to defer to state laws on therapeutic substitution.

Consumer Protection Provisions

ISSUE 11. (AAMR)
The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries access to needed medications. For many individuals with mental retardation and mental illness, treatment interruptions can lead to serious problems.

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[1] See 42 U.S.C. § 1394w-104(b)(3)(B).

[2] 69 Fed. Reg. at 46,667 ("Therapeutic substitution would always require explicit prescriber notification and approval.").

COMMENT (AAMR)
The final rule must allow for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Appeals Process

ISSUE 12. (AUCD)
The appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. 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.

COMMENT (AUCD)
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.

ISSUE 13. (AUCD)
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. However, as structured in the proposed rule, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

COMMENT (AUCD)
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.

ISSUE 14. (AUCD)
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.

COMMENT (AUCD)

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.

ISSUE 15. (CCD)

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.

COMMENT (CCD)

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.

ISSUE 16. (CCD)

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.

COMMENT (CCD)

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.

ISSUE 17. (NAMI)

Under the Proposed Rule, it is unclear when a decision is considered to be a coverage determination that requires a specific written notice with appeal rights and, in particular, whether a denial of a drug as a non-formulary drug at the pharmacy counter would constitute such a coverage determination. Without a written notice of appeal rights, the beneficiary may never realize that an additional step is required to trigger the appeals process. Consequently, CMS needs to clarify the Final Rule to require that a notice of coverage determination be issued at the time the prescription is denied at the pharmacy and that such notice include an explanation of the beneficiary's appeal rights.

COMMENT (NAMI)

To ensure that beneficiaries' rights are protected, the final regulations should provide meaningful grievance and appeal procedures for denials of coverage and improper conduct by prescription drug plans. NAMI has a number of concerns with regard to these appeal procedures, not the least of which is their complete lack of clarity in establishing different processes and procedures for challenging different kinds of plan decisions.

Next, CMS should clarify that beneficiaries have the right to de novo review of denials of coverage and exception requests before an independent review entity

(IRE). Specifically, the NPRM appears to treat IRE reconsiderations arising from formulary exception requests differently from those arising from other coverage determinations.

ISSUE 18. (NAMI)
Under the MMA and the NPRM, to obtain a non-preferred drug on the same cost-sharing terms as a preferred drug, the prescribing physician must demonstrate that the preferred drug "either would not be as effective . . . or would have adverse effects." Similarly, to receive coverage for a non-formulary drug, the prescribing physician must demonstrate that "all covered Part D drugs on any tier of the formulary . . . would not be as effective for the individual as the non-formulary drug [or] would have adverse effects for the individual."

COMMENT (NAMI)
This second showing necessarily encompasses the determination that the preferred formulary drug is not as effective as the non-formulary drug or would have adverse effects on the individual. Therefore, it would not make sense to grant preferred cost- sharing status to a second or third tier drug for which the beneficiary had demonstrated medical necessity, but not grant similar treatment to a non-formulary drug for which the beneficiary had made a similar showing. Patients should be able to obtain both coverage and preferred status in one appeal.

COMMENT (NAMI)
Beneficiaries with chronic, mental, and other debilitating illnesses must be able to obtain rapid responses to their appeals and not have to navigate multiple procedures.

ISSUE 19. (AAMR)
AAMR is 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 easy access and rapid results for beneficiaries and their doctors. It must include an expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal appeal before there is an independent review by an Administrative Law Judge, while the timeframes for plan decisions are unreasonably long.

COMMENT (AAMR)
We support revamping the exceptions process to: establish clear standards by which prescription drug plans must evaluate all requests for exception; 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.

Dual Eligibles

ISSUE 20. (AUCD, AAMR)
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. There is concern that there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the 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),

COMMENT (AUCD)
It is recommended that transfer of drug coverage from Medicaid to Medicare for dual eligibles are delayed by at least six months. This is critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. This may require a legislative change; hopefully CMS will actively support such legislation in the current session of Congress.

COMMENT (AUCD)
AUCD is 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:

COMMENT (AUCD)
AUCD recommends delaying transfer of drug coverage from Medicaid to Medicare for dual eligibles by at least six months. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population.

COMMENT (AAMR)
AAMR recommend that it be delayed at least six months. It is absolutely essential that the health and safety of the sickest and most vulnerable Medicare beneficiaries be protected. AAMR will support the necessary legislative change and hope that CMS will actively support such legislation in the current session of Congress.

ISSUE 21. (NAMI, CHA)
NAMI feels strongly that the final regulations should address the unique problems faced by beneficiaries who qualify for both Medicare and Medicaid (so-called “dual eligibles”). These individuals are particularly vulnerable because of their low incomes. Significantly,

a large percentage of dual eligibles (by some estimates as many as 25%) are living with severe mental illnesses.

Medications to treat mental illnesses are not generally interchangeable. It is imperative that the Final Rules recognize that mental illnesses themselves are highly variable in terms of symptoms and their impact on individual beneficiaries, and the treatment currently being provided to many dual eligibles has been carefully tailored with specific drug therapies. Such treatment typically takes into account the individual's current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide.

COMMENT (NAMI)

"Continuity of care" requirement is the most effective means for achieving the goals of ensuring a smooth transition to the Part D drug benefit for dual eligibles and maintaining access to effective treatments that ensure clinical stability. At a minimum, dual eligibles with mental illnesses should be allowed to continue on the medications they are currently taking and not be required to switch to another drug.

COMMENT (CHA)

After extensive review of the proposed rule, most reviewers we work with have found it impossible to understand how dual eligibles will access seamless drug coverage. We are particularly concerned for those Social Security SSDI beneficiaries who are in a return to work stage of their lives, and how these new MMA rules will integrate with existing Social Security work rules. Delaying the rule for duals until these issues are clarified would support the President's New Freedom Initiative that encourages these beneficiaries to seek employment. CMS faces a daunting challenge just finding and enrolling all duals, regardless of their work status, before their drug benefits under Medicaid end December 31, 2004. Once reached, duals will need extensive, comprehensive one-on-one help understanding the transfer of their benefits from Medicaid to Medicare and how these benefits affect their work status.

Duals and low-income beneficiaries are an especially difficult population to reach. They are much less likely to use the Internet, and some cannot even be reached by phone. Many duals, particularly those with cognitive impairment or mental illness, are therefore likely to have a break in benefits when either Medicare or Medicaid will not cover them.

COMMENT (CHA)

We urge CMS to delay termination of Medicaid prescription drug benefits for dual eligible beneficiaries for at least one year.

We urge CMS to delay the transition from Medicaid prescription drug benefits to Medicare for dual eligible beneficiaries.

ISSUE 22. (CHA)
Congress and the Administration have promised that the dual eligible Medicare beneficiaries will be better off under the Part D prescription drug benefit than they are under Medicaid's drug coverage. If CMS is to keep that promise, duals and others with serious medical conditions or mental illness must be able to get their medications and maintain their continuity of care. Drug plans must not be able to force duals to switch medications to stay within the formulary of a particular plan or tier. The exception process and appeals and grievance process described in the proposed regulation will be very difficult for duals and others with mental illness or cognitive impairment to navigate without substantial and individual assistance. Duals and others could be denied medications for weeks during the appeals process with no requirement that the plan provide an emergency supply. Duals and others who are unable to negotiate these systems may go without essential medications.

COMMENT (CHA)
We urge CMS to ensure that continuity of care will be maintained for all Medicare beneficiaries enrolling in a drug plan.

Education and Outreach Issues Regarding Enrollment

ISSUE 23. (AUCD, AAMR, NAMI)
Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. Outreach to Medicare beneficiaries with disabilities will be extremely important in the enrollment process

COMMENT (AUCD)
AUCD urges 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. 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 facilitate the flow of information between CMS and people with disabilities. 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 could be used to help CMS in its efforts to develop materials, provide technical assistance and assist with 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.

COMMENT (AAMR)
AAMR strongly urges CMS to develop specific regional plans for facilitating beneficiary enrollment that incorporates collaborative partnerships with state and local disability agencies and advocacy organizations.

COMMENT (NAMI)
NAMI urges that provisions in the NPRM on collaboration with state and local agencies and community-based organizations on outreach and enrollment for beneficiaries with disabilities need to be expanded. This is especially the case with respect to outreach and engagement needed to reach vulnerable beneficiaries living with severe mental illness.
In order to ensure enrollment and comprehensive coverage for beneficiaries with mental illness, CMS should take every step necessary to partner with community-based organizations with experience in reaching out to and engaging Medicare beneficiaries with mental illness and state and local agencies that coordinate benefits for these individuals. Beneficiaries with mental illness will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available through these agencies will help inform beneficiaries with mental illness about the new benefit. In order to address the many difficult, detailed, and time-consuming questions that beneficiaries are certain to 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 should also develop a specific plan for facilitating enrollment of with mental disabilities, especially severe mental illnesses, in each region that incorporates collaborative partnerships with and additional funding for state and local public and non-profit agencies and organizations with relevant experience in reaching out to people with mental impairments. NAMI would also suggest that CMS require drug plans to include in their bids, specific plans for encouraging enrollment of often hard-to-reach, vulnerable beneficiaries such as individuals with mental disabilities.

ISSUE 24. (CHA)
Materials used to communicate with Medicare beneficiaries must be accurate, timely and available in different languages and alternative formats from both CMS and from the plans. Medicare beneficiaries must be able to clearly understand the range of new choices, decisions they must make, and the consequences of those decisions. Requirements and standards for materials the plans use should not be in guidance to the plans, but in the final regulation where they will be enforceable. Simply adding more information to the price comparison website is inadequate for the vast majority of Medicare beneficiaries. Written information needs to be widely available with referral to trusted sources for individualized assistance. At a minimum, beneficiaries will need to understand their choices, the cost of each choice including premiums and out of pocket costs, providers who will supply covered services, be able to determine which choices best meet their needs, and know the rights they have and how to exercise them. Without

clear, accurate, and detailed information beneficiaries will be unable to make choices that meet their needs.

COMMENT (CHA)
We urge CMS to require clear, accurate, and timely disclosure of all pertinent information about benefits, costs, and providers, initially and with each change that occurs.

Access To Medications

ISSUE 25. (AUCD, NAMI)
It is extremely important that individuals with disabilities receive access to the medication that they require.

COMMENT (AUCD)
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.

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.

COMMENT (NAMI)
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.

ISSUE 26. (CHA)
We are particularly concerned with the standards for involuntary disenrollment in the proposed regulation. Allowing involuntary disenrollment for disruptive, unruly, abusive, uncooperative, or threatening behavior is a lower threshold than in the Medicare + Choice standards and could lead to discrimination against duals and others with mental illness or cognitive impairments.

COMMENT (CHA)
CMS must develop specific procedures and protections plans are required to follow that meet the special needs of this population to ensure that they are not subject to discriminatory practices by the plans.
We urge CMS to provide at a minimum the same protections in the M+C program regulations.

Eligibility and Enrollment

ISSUE 27. (CHA)
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. Many may not understand the changes to their Medigap policies and what is meant by "creditable coverage." Six months may be insufficient time to understand the Part D program, understand how Part D coordinates with other drug coverage they may have, and to then choose the drug plan that is right for them or to retain their Medigap policies H, I, and J with drug coverage. Experience with the Medicare-endorsed prescription drug discount card shows that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 credit available to them. Our clients find the program too complex and confusing.

COMMENT (CHA)
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. We further ask CMS to create a special enrollment period, with no late penalty imposed, if a Medigap issuer or other entity providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage. Beneficiaries should not be penalized and have to pay more when they delay enrollment because they were given inadequate, incomplete, incorrect or no information.

ISSUE 28. (CHA)
Section 423.58 Procedures to determine and document creditable coverage
The discussion in the Preamble to the Regulation references the difficulty of determining creditable coverage and the inability to 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 Medigap policies they have issued in single states, multiple states, nationally, or to affinity groups. In addition we expect confusion by both companies and our clients because CMS has expanded the definition of a Medicare Supplement (Medigap) policy to include riders and freestanding benefits for prescription drugs. Medicare beneficiaries may lose the right to replace their supplemental benefits as a result of mistakes on the part of issuers, when a retiree plan no longer provides creditable coverage, or when Dual Eligibles lose their eligibility for Medicaid.

COMMENT (CHA)
We urge CMS to add guaranteed issue rights for Medicare beneficiaries who lose creditable coverage. They should be entitled to the same choices they would have had if their coverage had not been creditable.

Involuntary Disenrollment for Disruptive Behavior

ISSUE 29. (NAMI)
NAMI is concerned about provisions in the NPRM that will allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening". This provision creates vast opportunity for discrimination against individuals with mental illness by prescription drug plans and Medicare Advantage plans. Individual beneficiaries subject to disenrollment 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 that would increase their premiums indefinitely

COMMENT (NAMI)
Plans should be required to develop mechanisms for accommodating the special needs of these individuals, and CMS should provide additional safeguards to ensure that they do not lose access to drug coverage.

ISSUE 30. (NAMI)
It is further troubling that CMS is proposing an expedited disenrollment process that appears to undermine the minimal standards and protections included in the NPRM

COMMENT (NAMI)
This expedited process proposal should be excluded from the Final Rule. In addition, CMS needs to provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and with a prohibition on late enrollment penalties for beneficiaries that seek an enrollment in a new plan.

NAMI recommends that drug plans should not be allowed to disenroll a beneficiary because of the refusal or inability of a beneficiary to adhere to a treatment plan developed by the plan or any health care professionals associated

with the plan. Treatment adherence is already an enormous challenge for many beneficiaries living with mental illness under normal circumstances. Involuntary disenrollment as part of the Medicare drug benefit is certain to result in additional tragic and unnecessary setbacks for these individuals.

NAMI further recommends that plans seeking to disenroll an individual beneficiary be required to document efforts to provide a reasonable accommodation for a beneficiary with a mental disability in accordance with the Americans with Disabilities Act. Such documentation should be provided to beneficiaries and their family, with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment from CMS.

Long Term Care Facilities

ISSUE 31. (VOR)
Long-term care facilities receive special mention in the new law. Although certain dual eligibles will be subject to Medicare premiums and cost sharing, full dual eligibles, including dual eligibles in "long term care facilities," are exempt from co-payments. According to the proposed regulations, the definition of "long term care facility" is in question:

COMMENT (VOR)
According to the proposed regulations, the definition of "long term care facility" is in question:

> "We request comments regarding our definition of the term long-term care facility in §422.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in §440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs." [69 Fed. Reg. 46648-49 (Tuesday, August 3, 2004)].
> VOR strongly agrees.

ISSUE 32. (VOR)
With regard to accessing medications, most ICFs/MR contract with long term care pharmacies and it is critical that individuals continue to access prescription medications through these established vendors. For any population, continuity of medication benefits is critical.

COMMENT (VOR)
Due to ongoing, wholesale efforts to serve almost all of the ICF/MR-eligible population in less restrictive waiver settings, it seems misguided and even dangerous to transfer or divert these individuals from ICF/MR supports and then also restrict their prescription medication options simply because of where they are now living. As established, the severity of cognitive disabilities and related medical conditions in community waiver settings will mirror the conditions of ICF/MR residents. Furthermore, as individuals age, or the severity of a medical condition worsens, some waiver participants will be (re)admitted to ICFs/MR. Continuity of benefits would be enhanced if the definition of "institutionalized" includes our waiver population.

For all of the above reasons, eligible individuals on waiting lists for ICFs/MR and HCBS services should also be included.

CMS-4068-P-1140

Submitter : Mr. Michael Weinberger **Date & Time:** 10/04/2004 07:10:21

Organization : Johnson & Johnson Health Care Systems

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Comments from Johnson & Johnson Health Care Systems are attached.

Issues 1-10

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

Comments from Johnson & Johnson Health Care Systems are attached.
Issue: Proposed Rule - Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (Electronic Prescribing)

CMS-4068-P-1140-Attach-1.doc

CMS-4068-P-1140-Attach-2.pdf

CMS-4068-P-1140-Attach-2.pdf

CMS-4068-P-1140-Attach-1.doc

Johnson & Johnson
HEALTH CARE SYSTEMS INC.

1125 Trenton-Harbourton Road
Mail-Stop K1-07
Titusville, NJ 08560

600-730-3739 / 267-200-0070 Fax
e-mail: mweinbe1@scaus.jnj.com

Michael Weinberger
Executive Director, Prescribing Alliances
Managed Markets Division

October 4, 2004

Filed Electronically

The Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–4068-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4068-P; Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (Electronic Prescribing)

Dear Dr. McClellan:

On behalf of Johnson & Johnson Health Care Systems, I am writing to comment on the e-prescribing section of the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Medicare Prescription Drug Benefit," 69 Fed. Reg. 46,632 (Aug. 3, 2004). Johnson & Johnson Health Care Systems appreciates this opportunity to comment on these important provisions of the proposed rule, and looks forward to working with CMS to ensure that these provisions are implemented in a manner that maintains clinical standards of care and optimizes patient outcomes.

I. BACKGROUND

Johnson & Johnson Health Care Systems is a strong proponent of electronic prescribing. While proper studies are needed, we have every reason to believe that e-prescribing will result in fewer medication errors, improved process and cost efficiency, and better patient therapeutic compliance. We have also noted the observations made by many in the healthcare technology field that e-prescribing is a first step toward the broader adoption of electronic medical records and the electronic interchange of pertinent information between interoperable provider healthcare systems. While we support the principle of electronic prescribing, we do want to ensure that, in moving quickly to realize its unique benefits, we do not inadvertently compromise a physician's ability to exercise his or her best clinical judgment in the interest of maximizing patient health outcomes. As with any innovation, we need to find the right balance between aggressively driving adoption of e- prescribing and carefully monitoring its development and implementation to avoid unintended consequences.

In order to ensure that electronic prescribing rules adequately reflect real-world experience with the national implementation of e-prescribing, including any unintended consequences, we feel strongly that the pilots recommended by the MMA should be completed prior to finalization of e-prescribing regulations. While the Secretary is permitted under the statute to pre-empt these pilots if sufficient real-world experience is deemed to exist, it is our assessment that this is not the case. A further explanation of our position on the need to carry out national pilots is included within this comment letter.

II. THE PROPOSED RULE

We believe that electronic prescribing technology presents an unprecedented

opportunity to influence physician decision making at the "point of prescription." Unlike the traditional world of paper prescribing, stakeholders can now insert themselves into the prescribing process before the prescription ever leaves the "electronic pad." While there is certainly an appropriate utilization of this new opportunity to insert additional logic into the prescribing process, our concern lies with the potential for misuse of this technological opportunity that could occur without the patient's best interests in mind. We believe that it is important that the regulations include the appropriate safeguards to ensure that inappropriate messaging aimed at influencing the prescriber is prevented.

To this end we comment below on a number of issues related to the provision of information to the prescriber including neutral presentation, messaging and electronic prior authorization. As indicated above, we also comment on the strong need to carry out the e-prescribing pilots as described in the MMA, as well as the need to develop standards through a separate rulemaking process.

A. Development of Rules to Implement E-Prescribing

J&J strongly recommends that CMS conduct the pilot studies envisioned by the MMA and conduct a separate rulemaking process to develop e-prescribing standards following completion of the pilot studies.

The statute calls for the establishment of pilot programs beginning in 2006 to test the emerging electronic prescribing standards. We strongly support this requirement. We recognize that the statute does permit the Secretary to dispense with the pilot if, at his/her discretion, the standard that is adopted has already been sufficiently tested in the marketplace. If that were to happen the standards for e-prescribing would become final and binding immediately. We wish to sound a note of caution that, in our rush to do something beneficial for patients, we don't inadvertently introduce new problems.

While we support the adoption of e-prescribing, we are concerned with the possible ramifications of accelerating an artificially evolved set of solutions. In point of fact, though a small number of vendors have implemented true end-to-end e-prescribing during the past several years, none have successfully done so on a national basis. Further, the large networks that will be used to transmit information between physicians and payors and then between physicians and pharmacies are still in their infancy, having become fully operational during the past eighteen to twenty-four months.

Though the intentions of those that wish to accelerate the safety benefits of e-prescribing are good, rushing to a mandatory national set of standards in an immature marketplace with a limited number of players and a newly formed infrastructure could have serious unintended consequences. As with any private marketplace, time and experience tend to weed out inferior solutions from superior solutions. Private vendors are forced to improve the viability of their offerings through customer demands and competition. By pushing too hard on today's less-developed e-prescribing marketplace and infrastructure, we are artificially limiting this natural process of product improvement.

Physicians are also concerned about moving too far ahead before e-prescribing standards and systems can be adequately tested on a national basis. In part because they will cover much of the costs not only for the early systems, but for those that follow if real-world implementation of untested solutions requires reworking of the infrastructure. But more so because in the rush to improve healthcare for their patients, they, and in fact most interested parties, want to be

certain that e-prescribing solutions do in fact achieve their goal—and that unintended consequences are avoided.

The best way to ensure this outcome is to go forward with the pilots as described in the statute while concurrently permitting and encouraging the e-prescribing private marketplace to evolve. It is reasonable to try to accelerate adoption, but not through pre-emption of pilots or at the cost of the natural quality improvement that occurs when a full complement of players have been able to enter and compete in the private marketplace.

B. Need For CMS To Address Operational Standards In Addition To Technical Standards

In developing recommendations to CMS, the National Committee on Vital and Health Statistics (NCVHS) heard testimony about the need not only for technical standards but also operational standards that would govern how e-prescribing systems actually function and the types of physician and patient protections contemplated by the statute. Ultimately, the NCVHS determined that their scope should be limited to technical communication standards. However, in recognizing that Congress intended there to be protections with respect to how e-prescribing systems present information and interact with prescribers and patients, NCVHS expressly recommended to the Secretary of Health and Human Services that the agency adopt regulations "requir[ing] that e-prescribing messages received through e-prescribing applications be free from commercial bias."

We recommend that CMS engage in subsequent rulemaking to define appropriate parameters around electronic prescribing that are needed to protect patients from inappropriate messaging and other possible abuses of this new technology.

C. Information Must be Presented in a Neutral Manner

The MMA requires that the prescriber have access to "neutral and unbiased information on the full range of covered outpatient drugs."

We believe that "neutral and unbiased" presentation means that, when a physician prescribes a drug, he or she should be presented with all pertinent information at the beginning of the prescribing process, including a single, consolidated list of the drugs normally used to treat a particular condition. This list should indicate which drugs are on-formulary preferred, on-formulary but not preferred, and entirely off-formulary. Ideally, the listed information should be provided on a single (and if necessary scrollable) screen without the need for excessive "clicking" or burdensome navigation. Doing otherwise might constitute an attempt to unduly influence the physician's selection before he or she has been fully informed of the complete range of choices and may make it less likely that the physician will see the names of drugs that are not as incentive- and rebate-friendly but which offer better efficacy and tolerability for the patient. We strongly believe that under the best standard of care, a physician and patient should be given full exposure to all clinical and financial information related to a prescription prior to a therapeutic decision being made.

D. Commercial Messaging is Not Limited to Product Advertising; E-prescribing Systems Vendors Should Not Be Permitted to Receive Incentive Payments from Plans for Switching a Patient's Therapy Based Entirely on Non-clinical Factors

We recommend that CMS prohibit commercial messaging, especially that which is aimed at influencing a physician who has already indicated his or her preferred therapy after having been presented with all patient-specific clinical and financial considerations. We would further suggest that commercial messaging be understood to include not only manufacturer advertising but any financially-motivated messaging from stakeholders including plans, PBMs, or e-prescribing vendors. .

Thus, plans or PBMs should not be permitted to pay electronic prescribing vendors for each prescription they successfully switch from the physician's intended selection to a more rebate-friendly or otherwise purely cost-driven choice, without specific consideration of the best care for a particular patient. While in some instances, the preferred formulary drug may achieve the best balance of clinical and financial value for the patient, in some cases there may be other drugs that are on-formulary but not preferred, or are off-formulary, which better serve the patient's needs. In these instances, the physician should not be subjected to interruptive pop-up messages attempting to persuade him or her to select a certain drug because it is financially more appealing to certain stakeholders (due to higher rebates or incentive payments).

E. E-prescribing Standards should Facilitate Real-time Prior Authorization

Recognizing that an important benefit from e-prescribing is increased efficiency in health information exchange, the MMA clearly indicates a preference for the use of "real-time" information delivery with regard to this technology, specifically requiring that, "[t]o the extent feasible, the information exchanged [via e-prescribing] shall be on an interactive, real-time basis. Additionally, "prescribing health care professionals [are] to have ready access" to prescribing information.

We strongly advocate that just as formulary and benefits information should be available real-time, the function of gaining prior authorization should have the advantages of being real-time. In fact, in the electronic environment, not making prior authorization available on a real-time basis could be a tactic used by e-prescribing stakeholders to restrict a physician's prescribing practices. Informing a physician electronically that prior authorization is required, but then forcing him/her to use non-electronic means to seek such authorization (e.g., telephones and faxes) could impose a significant burden on the physician relative to simply selecting a therapy for which the technology throws out no roadblocks. So, ideally, the physician should be able to prescribe a drug, fulfill any prior authorization requirements, and receive the authorization needed to send the script on to the pharmacy in a simple, efficient electronic manner.

III. CONCLUSION

We appreciate the opportunity to comment on these important electronic prescribing issues raised by the proposed rule. We would be happy to provide additional information to you or your staff on the topics we have addressed in this letter.

Sincerely,

Michael Weinberger

Johnson & Johnson
HEALTH CARE SYSTEMS INC.

1125 Trenton-Harbourton Road
Mail-Stop K1-07
Titusville, NJ 08560

600-730-3739 / 267-200-0070 Fax
e-mail: mweinbe1@scaus.jnj.com

Michael Weinberger
Executive Director, Prescribing Alliances
Managed Markets Division

October 4, 2004

Filed Electronically

The Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–4068-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4068-P; Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule – Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (Electronic Prescribing)

Dear Dr. McClellan:

On behalf of Johnson & Johnson Health Care Systems, I am writing to comment on the e-prescribing section of the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Medicare Prescription Drug Benefit," 69 Fed. Reg. 46,632 (Aug. 3, 2004). Johnson & Johnson Health Care Systems appreciates this opportunity to comment on these important provisions of the proposed rule, and looks forward to working with CMS to ensure that these provisions are implemented in a manner that maintains clinical standards of care and optimizes patient outcomes.

I. BACKGROUND

Johnson & Johnson Health Care Systems is a strong proponent of electronic prescribing. While proper studies are needed, we have every reason to believe that e-prescribing will result in fewer medication errors, improved process and cost efficiency, and better patient therapeutic compliance. We have also noted the observations made by many in the healthcare technology field that e-prescribing is a first step toward the broader adoption of electronic medical records and the electronic interchange of pertinent information between interoperable provider healthcare systems. While we support the principle of electronic prescribing, we do want to ensure that, in moving quickly to realize its unique benefits, we do not inadvertently compromise a physician's ability to exercise his or her best clinical judgment in the interest of maximizing patient health outcomes. As with any innovation, we need to find the right balance between aggressively driving adoption of e- prescribing and carefully monitoring its development and implementation to avoid unintended consequences.

In order to ensure that electronic prescribing rules adequately reflect real-world experience with the national implementation of e-prescribing, including any unintended consequences, we feel strongly that the pilots recommended by the MMA should be completed prior to finalization of e-prescribing regulations. While the Secretary is permitted under the statute to pre-empt these pilots if sufficient real-world experience is deemed to exist, it is our assessment that this is not the case. A further explanation of our position on the need to carry out national pilots is included within this comment letter.

II. THE PROPOSED RULE

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opportunity to influence physician decision making at the "point of prescription." Unlike the traditional world of paper prescribing, stakeholders can now insert themselves into the prescribing process before the prescription ever leaves the "electronic pad." While there is certainly an appropriate utilization of this new opportunity to insert additional logic into the prescribing process, our concern lies with the potential for misuse of this technological opportunity that could occur without the patient's best interests in mind. We believe that it is important that the regulations include the appropriate safeguards to ensure that inappropriate messaging aimed at influencing the prescriber is prevented.

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III. CONCLUSION

We appreciate the opportunity to comment on these important electronic prescribing issues raised by the proposed rule. We would be happy to provide additional information to you or your staff on the topics we have addressed in this letter.

Sincerely,

Michael Weinberger

CMS-4068-P-1141

Submitter : Dr. Don Hawley **Date & Time:** 10/04/2004 07:10:40

Organization : Utah Dept. of Health, DHCF

Category : State Government

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

We understand SSA will be inquiring about transfer of assets. We are unaware that such a transfer would result in ineligibility for an otherwise eligible SSI applicant. Determining the amount and intentions behind such transfers is also difficult and time-consuming. Therefore, we question the need to pursue transfer of assets.

CMS-4068-P-1142

Submitter : **Barbara Jolly** **Date & Time:** **10/04/2004 07:10:37**

Organization : **Integrity Healthcare Services, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments

CMS-4068-P-1142-Attach-1.doc

Date: October 4, 2004
To: To Whom it May Concern
From: Integrity Healthcare Services Inc.
Subject: MMA comments

Integrity Healthcare Services, 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.

Integrity Healthcare Services Inc is a regional provider of home infusion services. Founded in 1993, Integrity has grown steadily and now provides services to over 4500 patients in 19 states. We have developed expertise in nutritional support, oncology care, cardiac therapy, pain management and enteral therapy, all of which are currently covered by Medicare in the home setting. We have developed expertise in this field and have developed systems of data collection that have allowed us to effectively gather the data needed to med Medicare criteria for these challenging therapies. Integrity Healthcare Services Inc. also provides intravenous antibiotics, hydration, neurology therapies and most other infusion therapies seen in home care today.

All of our offices are accredited by the Joint Commission on Accreditation of Healthcare Organizations. Our clinical outcomes are excellent. Many of the services we provide require a great deal of clinical management and strong clinical expertise. Our ability to manage patients well keeps them out of hospitals and keeps the total cost of healthcare manageable.

Integrity Healthcare Services Inc. has measured patient satisfaction and is proud of it record of pleasing greater than 99% of our patients, based on the perception of care surveys provided to all of our patients.

Many elderly and/or disabled patients find it difficult to travel to outpatient ambulatory infusion clinics, hospitals, or physicians' offices. The availability of home infusion services is not only convenient for them, but saves the cost of ambulance transport for them to obtain services in a hospital or clinic-based setting.

Integrity Healthcare Services Inc. is pleased that Medicare Modernization is underway and that Medicare patients will soon be able to obtain their infusion services in a more cost-effective and less problematic setting.

Integrity Healthcare Services, 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,

Barbara Jolly, RPh, MPA
Director, Clinical Support Services
Integrity Healthcare Services Inc.

Submitter : Dr. Mary Ann Kliethermes Pharm D **Date & Time:** 10/04/2004 07:10:11

Organization : UICMC - MTMS Clinic

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document for comments.

CMS-4068-P-1143-Attach-1.doc

Comments to file code: CMS – 4068 – P

Commenting on Section C:

Voluntary Prescription Drug Benefit and Beneficiary Protections

Subsections a; b; and c

(We will comment on the subsections in reverse)

Comments on Section C, subsection c:

At the University of Illinois at Chicago (UIC) we currently run a pharmacy based Multiple Medication Therapy Management Service (MTMS) Clinic. After review of the section of the Proposed Rules published in the August 3, 2004 Federal Register, we believe the best way to address the very comprehensive issues and questions raised would be to describe our clinic. We have learned much the past three years developing our clinic and do not wish to be presumptive in suggesting that our processes and policies are how the MTMP program should be modeled. We do believe, however that our experiences will be beneficial in development of CMS rules and regulations. We will briefly describe our institution, provide a brief history of our clinic, our structure, the evolution and type of services provided, preliminary data on our clinic and services; as well as the pitfalls, barriers and opportunities of such a program. By doing so, we hope to adequately address the questions asked by CMS in the proposed rules.

<u>The Organization</u>

The University of Illinois at Chicago (UIC) Medical Center is a state supported public facility with a 300 bed licensed hospital and ambulatory clinics. UIC Medical Center provides a wide range of ambulatory care services including primary and specialty care, diagnostic testing services and ancillary patient support services. The majority of the patients seen at UIC are African American and Hispanic descent. A significant number of the patients are indigent or working poor, and currently have little to no medication coverage, or qualify for Illinois Medicaid or other indigent programs. Many of our patients have been employed but do not have retirement insurance that provides health care benefits. The majority of our patients are solely dependent on social security checks. Many do have current Medicare services and would be eligible for the new Part D benefit. Patients seen at UIC are challenging due to their multiple disease states, poor adherence to medication regimens, significant social and financial needs.

At UIC, ambulatory clinical pharmacists provide patient care services in pharmacist-managed clinics such as Medication Therapy Management, Smoking Cessation, Amiodarone and Antithrombosis. These clinical pharmacists provide patient care in collaboration with other referring health care providers

(physicians, nurse clinicians, etc.). Clinical pharmacy services are also provided in the following clinics: Internal Medicine, Family Medicine, Dialysis, Renal Transplant, Cardiology, Neurology, HIV, Oncology, Psychiatry, Surgery, Wellness Center and Women's Health. We will only be addressing the services provided in our MTMS program.

MTMS Clinic History

The MTMS clinic was initially formed to handle workflow issues that developed when one or more patients presented simultaneously with 10 or greater prescriptions to the outpatient pharmacy. To avoid long wait times this situation created, the program was formed to plan for these patients by scheduling them with appointments for their refills. It was called the "Refill 10 Program". It became clear that these patients had increased needs for assistance in other areas such as education, access and adherence issues and clinical monitoring. Due to staff turnover and staff responsibilities unrelated to MTMS, the program stalled at various stages of development.

Three years ago, dedicated pharmacists were hired for the program, which created needed stability. Over the past three years the program has nearly tripled in patient load (Approximately 60 patients to the current active number of 175) without any concerted effort at marketing. Referrals have come primarily from word of mouth within the health center. Thus far over 225 patients have participated in the program the past three years. Loss of patients from the program is due primarily to moving out of service area, death and nursing home placement. Rarely has a patient left the program due to perceived lack of benefit or dissatisfaction with service. The staff has grown from 2.3 full time equivalent employees (two part time pharmacists and a full time pharmacy technician) to the current number of six (two full time pharmacists, four part time pharmacists, one full time pharmacy technician and one part time technician). The program not only provides clinical patient care services but also dispensing services that will be further described below.

Currently the program is supported by margins made on dispensing of MTMS patient medications and by integration with a complex formula of college teaching responsibilities and the overall functioning of the outpatient pharmacy. From a business standpoint, MTMS patients are consistent and reliable monthly business therefor a consistent stream of revenue. There are two problems from our point of view with this method. Margins continue to decrease and are intended to pay only for dispensing costs. This makes it hard to provide the high quality MTMS services in this model. The MTMP section of the new Medicare Drug Law is anticipated to rectify this. In addition, incentives are conflicting. With this method, increased revenue relates to increased medications dispensed to a patient. This is a negative incentive to reduce medications. In particular, if one drug due to contracting gives us a larger margin there is an even greater negative incentive to get that patient off that drug when there is no indication.

This is a situation we currently face for example with our contracted proton pump inhibitor. We hope that we perform the right and ethical services for the patient, but that negative incentive places pressures on the program when staffing is tight and you cannot adequately provide services for your patients

Facility Description

The MTMS clinic is located in the outpatient pharmacy (Pharmaceutical Care Center, PCC). The MTMS work area includes 4 pharmacist cubicles each with a computer. Patients are seen by appointment in two consultation rooms, which contains a desk, a computer, and two chairs. We share this patient visit space with the Medication Assistance Program (program for patients without any insurance or coverage for medications). This configuration is currently insufficient with our number of staff and patients. The addition of one to two more pharmacist workstations and one more patient visit room would be optimal. A mobile sphygmomanometer and blood pressure cuff is shared between the two consultation rooms. A scale is available in one of the counseling rooms. Point-of-care laboratory technology, such as a blood glucose monitor, is being considered for institution approval and purchase to improve patient monitoring.

Unfortunately the outpatient pharmacy is not located in the UIC ambulatory clinic building but ½ block down the street in another UIC building that is primarily offices. Due to this outpatient pharmacy does not have patient transport services of any kind. Many of our patients have difficulty with ambulating and therefor we must see them wherever we can in the clinic building where both internal and external transportation services exist. Some clinics (ie. Cardiology, Geriatrics, Wellness) have been very supportive lending us space when it is available. Sometimes we must see our patients in waiting areas and lobbies within the clinic.

An area of the PCC is devoted to filling prescriptions for the service, which includes a counter (approximately 10 feet by 3 feet) and a computer. We currently fill approximately 100 prescriptions per day for our patients. The technicians have access to the pharmacy's automatic filling devices. A separate area in the pharmacy is needed to store medication boxes and filled prescription bottles, since the MTMS pharmacists hold on to all the medication used for patients needing medication boxes. Medication boxes are purchased by the pharmacy in bulk for approximately $5 each. Patients who require them are given medication boxes free of charge at present as a service because the cost of the medication boxes would be prohibitive for the majority of our patients. We use a medication box exchange program with each refill. This increases our efficiencies in utilizing technicians to fill the medication boxes when ever possible and makes the patient visit length more manageable.

Commentary

We have provided some of our numbers and facility descriptions to help CMS optimally work with the PDP or MA to determine rules in establishing fees for MTMP. Facility fixed costs do not appear to be large contributors to overall program costs. These include office space, patient visit rooms, utilities, computers and monitoring tools such as blood pressure cuffs, weight scale, etc. Ongoing supply costs include office supplies (paper, charts, etc.), also are not major contributors. However not having clinic space makes providing this service a challenge and creates some difficulties with patient confidentiality issues. We would like to suggest that adequate patient visit space for patient confidentiality be a rule for participation. As you will note in the services provided section below we spend significant time in monitoring, educating and solving problems for patients. This type of work needs appropriate space for confidentiality.

Employee costs and workload in our opinion will be the major driver in determining adequate fees to run such a program. We have discovered that number of medications and diagnosis has a minor impact in determining workload. The major drivers of workload are a combination of cognitive level of the patient, amount of social support (family and financial) for the patient, number of health care providers, type of diagnosis, number of diagnosis and number of medications in descending order of contribution. We are working to develop an acuity scale to help us determine appropriate staffing. Without good models of determining workload, It has been a struggled to obtain administrative approval of staffing to meet our vision of best practices and care of our patients. Our concern is that very little available to guide fees for MTMS. This program will struggle, as we have, to provide optimal service to achieve the best outcomes unless this issue of how to determine appropriate staffing needs is answered. Beginning to work on a financial model to determine cost and adequate reimbursement for the level of services we provide. We are struggling to do this for two reasons, insufficient staff to take the time from patient care for data collection and the ability to obtain the financial information of our clinic due to our current administrative and financial structure.

As a separate item, we would like to see adherence aids such as medication boxes included in reimbursement as a supply cost per patient. In our experience use of the medication boxes have had dramatic improvement in adherence and patient outcomes.

Program Description

The following are the vision, mission statements and patient goals for our MTMS program.

Mission Statement

The MTP Program's mission is to assist patients, whom have multiple chronic medications due to multiple chronic conditions, with the management of their drug therapy in order to improve or maintain their health and prevent or minimize drug therapy-related.

Vision

Our vision is that by being medication-use specialists and patient care providers, our patients will have improved health status as measured by their clinical, economic, and humanitarian outcomes.

Patient Related Goals

- Improve and sustain an acceptable patient adherence to their drug regimen
- Assist as needed with difficulties in access to medications
- Incorporate patient participation in self-care and self-management of medications when able
- Streamline pharmacy visits and the refill process
- Assure there is no time lapse or missed doses between refills
- Prevent duplication of drug therapy, and avoidable drug interactions
- Identify, monitor for, and prevent or minimize adverse drug events or medication related complications
- Assist other care providers in monitoring patients drug therapy and medical conditions, particularly their response to therapy in-between provider visits
- Provide patient/caregiver education on the purpose of the drug therapy, the particulars in taking their medications, expected side effects and important adverse reactions that need to be reported
- Improve healthcare utilization and minimize the individual's healthcare cost
- Assist in continuity and coordination of care with other healthcare providers as it relates to the patient's drug therapy and overall health
- Recommend to the patient and other healthcare providers when necessary preventative measure such as immunizations and routine labs that are established by evidence based medical guidelines
- Improve patient satisfaction with their healthcare as it relates to their drug therapy

Commentary

Based on the comments outlined in the proposed rule our mission and vision are in line with the goals intended by the legislation for a MTMP service. As stated under the proposed rules, the MTMP is to provide services that will optimize therapeutic outcomes for target beneficiaries and to improve understanding of medications, adherence to medications and detection of adverse drug events

and patterns of overuse and under use of medications. We will address in more detail how we have attempted to work on these very issues the past 3 years.

Criteria for enrollment:

Our criteria for enrollment into our clinic is as follows:

> A UIC patient may enter the MTP program by referral from any UIC healthcare professional who recognizes a patient whom meets any of the following five conditions:
> 1. The patient has multiple medications, disease states, or health care providers resulting in diminished coordination of care
> 2. Has difficulty in self management of medications
> 3. Has difficulty in adherence to chronic medications
> 4. Significant lack of understanding or knowledge of chronic drug therapy
> 5. The patient agrees to having prescriptions filled at UIC pharmacy

Preliminary data on UIC MTMS patients show that they receive a range of 4 to 32 medications with an average of 15.3 medications. The average number of daily doses of routine medications (not "prn" or as needed) for our patients is 20 with a range of 8 to 36. The range of diagnosis for MTMS patients is 4 to 15 with an average of 9.6 conditions. The average age of our patients is 64 with a range of 35 to 93. The average monthly revenue for prescriptions from the current MTMS patients' (n =175) is between $800 and $900. The range of charges for these same patients is $164 to $3175. We do not have data on the number of healthcare providers our patients see but are currently collecting that data as part of our information gathering in determining acuity.

Commentary

Throughout the Proposed Rules the request is made to help define disease, drug and cost issues to use for identification of targeted beneficiaries for MTMP services. We find this a difficult question to answer. Our data suggests the ranges for these parameters are quite large for patients that need this service. We have had difficulty defining a particular number of medications because as already alluded to, it does not appear to be the most important driving force of patient need for our clinic. For example our patient on only 4 medications is an elderly patient over 80 years old who has severe dementia and indigent. Her middle age son is her primary care giver and refuses any nursing home placement. He unfortunately is alcoholic. She is on warfarin for atrial fibrillation. Despite the social situation the son does take adequate care of the patient as assessed by social services and we would concur. Managing and understanding her medications, especially the warfarin, was difficult for him. With medication boxes, education and support we have been able to stabilize fluctuations in her INR and reduce the frequency of clinic visits for INR testing from weekly to monthly.

The adverse drug event literature provides some guidance in the area of number of medications. Review of the studies suggests a number around 6 or greater medications result in an exponential increased risk for an adverse drug event. Another issue with identifying potential beneficiaries using number of medications is defining what medications should be included in that number. Do you include over the counter medications such as multivitamins, acetaminophen and "as needed" medications? Acetaminophen is used in higher doses for osteoarthritis certainly has potential for serious adverse events such as renal toxicity, warfarin interaction, etc. Narcotic type medications, i.e. codiene, hydrocodone are often used on an "as need basis", yet are a drug class often implicated in adverse drug events. Including all these types of medications will greatly increase the number of target beneficiaries. Based on our experience the criteria of identifying those patients having difficulty in management, adherence and understanding are better definers of the need for MTMP services. Usually if a patient is having one of these problems they are on multiple medications with multiple conditions.

Enrollment of patient to MTMS Clinic

Each new patient is assigned to a primary MTMS pharmacist. Efforts are made to match the needs of the patient with the interest, specialty and skills of the MTMS pharmacist. For example if Diabetes issues are a major problem of the patient, we attempt to assign the MTMS pharmacist with interest and skills in that area. Phase one of the intake procedure involves information gathering. The pharmacist assigned to the patient will speak with the referring health care professional to ascertain the needs/expectations they have for the patients' involvement in the program. The pharmacist will do a review of the patient's electronic medical record for medical history, diagnosis list, number of providers, demographic data, laboratory data and medication lists from each health provider. This is an essential step in the process because it provides for the pharmacist a clearer picture of the multiple issues and problems that may be associated with the patient. The more information that can be gleaned the better the identification of the patient's medication problems and the better the formulation of the plan of care to address the patient's specific problems.

The next phase in the intake procedure involves the initial interview with the patient. The program is explained to the patient and the patient is admitted to the program on a voluntary basis. If the patient agrees to participate further information gathering from the patient is done. The pharmacist continues to identify medication-related problems and formulate a plan of care. We are currently in the process of developing patients' rights and responsibilities and informed consent procedures for the MTMS program. A medication regimen reconciliation is conducted with/for the patient. If the intake interview is being conducted by phone the patient will be scheduled to be seen as soon as possible and asked to bring all/any of their various medication bottles with them at that time. If the intake interview is being conducted in person the pharmacist will determine whether the patients' recollection will suffice or if a return appointment

(with bottles in tow) is required. We have found medication reconciliation a major issue for the majority of our patients. We often find discrepancies among the medication lists identified by the multiple providers and often they differ with what the patient believes or the medications the patient has in their possession. The pharmacist will contact other UIC health care professionals and/or outside pharmacies to reconcile any differing medication lists, and provides the patient with a definitive medication regimen. The pharmacist will then identify and find initial solutions to the following problems or concerns: those of the patient, those of the referring health care professional and any identified by the pharmacist during the interview. These may include initiation of an adherence aid, initiation of various educational needs, initiation of a monitoring plan and management of medication refills to coincide with scheduled patient visits, etc. The patient will be scheduled for their first routine MTMS clinic visit. Visits will be based on multiple factors: the need for refills, medication changes or administration of narrow therapeutic index medications, the patients' mental and/or physical capacity, the patients' clinical stability, all at the pharmacist's discretion.

The patient's prescriptions are transferred to the UIC outpatient pharmacy and the patient will be entered into the pharmacy dispensing system by the MTMS technician and tagged as a MTMS patient along with the appropriate pharmacist name.

A pharmacy paper chart will be created for the patient. The paper chart serves several purposes. First it serves as a back up to the electronic chart for down time. Second, since the system wide electronic chart is so massive, it is often difficult to look at needed data succinctly, the paper chart allows the MTMS staff to pull off the electronic chart information that is critical to our needs in care of the patient. The paper chart is a 4-section chart that includes an initial assessment sheet of demographic and clinical data, current lab values, current medication list and MTMS progress notes as well as pertinent progress notes from other health care providers. Third we may not always have access to the electronic chart when seeing a patient and therefore the paper chart allows us to follow the plan of care and take notes during patient visits. Finally it helps us maintain continuity of care within our department if another pharmacist needs to see someone else's patient. Review of the paper chart is quicker and easier than review of the full electronic chart. From the initial intake process the pharmacist will generate the initial assessment form for the paper chart, create an accurate medication list in the electronic chart and document the initial visit in the electronic chart and print copies for the paper chart. The medication list must tie all medications to a condition or diagnosis and be evaluated for appropriateness. If problems are found those medications will be investigated for possible adjustment of discontinuation. Start and stop dates will be listed for each medication when possible. Allergies, intolerances and current creatinine clearances are documented. A "copy and paste" list will also be included to assist other health care professionals in maintaining and accurate list for their patient visit documentation. The initial visit documentation will contain date and reason for

referral and the referring party, brief description of the interview, identification and assessment of patient problems, a plan of care, intended follow-up activities as well as the return to clinic date. The initial visit may be forwarded to the referring health care provider for review and signature if needed.

Routine Visits

A routine visit is scheduled on monthly bases, however it may be scheduled more frequently based on needs of the patients. For example patients referred from psychiatry are usually seen on a weekly basis due to the need to closely monitor their adherence. As these patients improve they may be rewarded with less frequent visits. Another example is patients taking warfarin. If these patients require medication boxes, we see them every INR visit to adjust the warfarin dose appropriately and make changes in their medication box.

The process for each routine visit includes three components, preparation for the visit, the visit itself, and the follow up and documentation post visit. Prior to each visit the pharmacist will review the electronic medical record for any clinic visits and lab results since their last appointment to identify any medication changes or other changes in the plan of care. The pharmacist will determine what medications need to be refilled and institute any changes for the patient this month and pass that information to the MTMS pharmacy technician. The MTMS technician will fill the medications in advance of the visit so that medications are filled in a timely manner, any needed refills can be obtained prior to the visit, medication boxes can be filled and any other problems can be addressed prior to the patients' appointment. The medications are filled by the MTMS technician and checked by a designated pharmacist. Technicians, students and residents and MTMS pharmacists fill the medication boxes, which are double-checked by another one of these persons for accuracy. The pharmacist will also use the electronic scheduling system to be informed and educate/counsel the patient about other upcoming health provider visits. We also use other scheduled visits to schedule the next MTMS visit, as transportation issues are a major problem for our patients. This not only eases their transportation burden but also improves their compliance in making clinic visits.

During the visit process the MTMS pharmacist reviews the status of the patient, addressing any ongoing problems and identifying any new problems. The MTMS pharmacists assesses the patients current condition, their adherence, monitors their response to all the drug therapy, monitors for any drug related problems. The MTMS pharmacist incorporates evidence based monitoring and guidelines as best they can (i.e blood pressures done each visit, assuring there is appropriate ADA follow up with diabetic patients, etc.) when indicated. The pharmacist will review the medications in the patients pill bottles or medication boxes for any change in medications and as needed for new medications. If there is an issue that needs to be addressed during the visit the pharmacist will direct the patient to take the appropriate steps and assist them as needed or contact

the patients' appropriate health care provider. This may range from sending patients to the emergency room for suspected DVT's, severe orthostatic changes, or pneumonia to helping a patient replace their cane or walker, to assisting with set up of social services such as meals on wheels, to setting up follow up medical appointments. For emergent situations we contact the appropriate physician when ever possible. Any education needs are continued or new needs are addressed. This may range from discussions on what value morning blood sugars should be to discussions on salt in diet and how to manage those issues. Of note, when a patient does not make the scheduled visit, we follow up the next day with a phone call to check status and reschedule visit. We also use phone visits when necessary due to transportation issues and arrange to see these patients when they are able to come to the medical center. In this situation we mail out their medications and do our clinical assessment that cannot be performed over the phone at a non-dispensing visit.

The final phase of routine care is performing any follow up that due to time or seriousness can be done after the patient visit and documentation of the visit. After each visit a note is placed in the patient's chart containing documentation of the visit, monitoring parameter results, updating the medication list as needed, social issues as needed, allergies, medication adherence and action/plan for each medical condition addressed. This note is forwarded to the appropriate physician or health care provider as necessary.

Summary of Services Provided

As relationships develop with our MTMS patients, we have found that our patients begin to rely on us extensively for navigation through the health care system. This is most likely a result of two forces. The first is we see these patients more than any other health care provider and the trust that develops with that frequent of relationship results in more demands for services from our program. In addition we often spend significant time with them educationally explaining their disease states, the tests that are to be performed and the medications they are on. The MTMS staff are all skilled in the ability of taking the complex and explaining the information in simple terms.

When we looked at all the services we have provided for patients it can be best be described as what ever needs to be done to make sure the patient has the right drug and the right dose to take at the right time. With that tenant in mind we can justify much of what we end up providing for the patient. Our jobs would be easier if other support staff were not so lean within the health system such as nursing and social services. Unfortunately, the increasing costs and decreasing reimbursement of the health care industry has pushed UIC as well as many other institutions into this predicament.

A summary of all the types of services we provide are listed below in no particular order:

1. maintaining accurate medication profile with indications
2. management of drug therapy and refills
3. processing and dispensing of medication
4. monitoring drug therapy
5. recommendations and modification of drug therapy as needed
6. minimum of monthly review of patient records and orders on electronic chart
7. recommend or initiate changes based on MD notes
8. physical assessment at visits,
9. assessing current condition at visit.
10. evaluating response to therapy
11. interpretation of lab and other data
12. drug information questions primarily from patients, but also other health care providers
13. identification, documentation and management of ADE's
14. evaluate and manage drug interactions
15. coordinates timely and accurate delivery of medications
16. coordinates or recommends collection of labs.
17. patient education
18. develop trusting patient relationships
19. coordination of care between multiple health care providers and institutions (hospital, nursing home, home agencies)
20. evaluate, manage and encourage adherence
21. evaluate need for drug not receiving, too little or too much of correct drug, drug without indication.
22. documentation of visits and other patient interactions in electronic chart
23. assist with insurance coverage
24. assist with social services and DME issues
25. assist with transportation issues
26. assist in follow up with MD and testing appointments
27. provide and fill pill boxes and other adherence aids
28. providing medication list (future develop patient health passport)
29. education of students, residents and other health care professionals

It would be difficult to signal out any particular service as more frequent than another, because each patients needs can be so different from patient to patient as well from visit to visit. If forced to, however, a large part of our time is involved in coordination of care between the multiple providers. Reduction in this time would allow us to spend more time working on education and monitoring of the patient. Coordination of care so that vital information is passed on from one provider to another is an area our health care industry needs to improve on make much more efficient. Interestingly the list described above is strikingly similar to

a published list from the American College of Clinical Pharmacy titled Practice Guidelines for Pharmacotherapy Specialists from the following reference *Pharmacotherapy* 2000;20:487-490. These services also completely meet the Medication Therapy Management Services – Definition and Program Criteria released by the Pharmacy profession Stakeholders Consensus document released July 7, 2004.

Commentary

In the Proposed Rules MTMP section, information on best practices and essential components of an MTMP program is requested. We find it somewhat difficult to define ourselves as best practice as we see many areas that we need to develop and improve. We however certainly have a model that by our subjective assessment works. We have a number of patients whose hospitalization rate has significantly decreased, and whose health status has dramatically improved since referral to our clinic. We are working on collecting this data in retrospective review so that we can present this information more objectively. Hopefully by outlining our services and procedures this will assist CMS, not only looking at our model but others that may respond, in determining the key elements of an MTMS program. In our view each step and each service we have outlined above is a key element and service for our patients.

Lower Acuity Patient Services

As we have developed the MTMS clinic we have noted that there are certain patients who do not need the level of assistance we have described above. We have recently launched a program to address this type of patients called the Rx Bag and Go Program. These patients have very similar demographic characteristics as the MTMS program outlined above with regard to number of diseases, number of medications and age. These patients however are generally able to self manage their health care with some assistance. For Rx Bag and Go patients we assist in obtaining needed refill orders, coordinate refills and dispensing to one day a month, have routine schedule appointments, maintain an accurate medication list on the electronic chart, provide some monitoring (primarily adherence and adverse events) and education as needed. Visit times and workload is less. This is a new program and we expect, as the patients progress with their disease states, may feed into the MTMS clinic. We also believe this is a group of patients that may be overall healthier and would benefit most from educational programs on medications and disease states. We hope to develop this concept into group visits with dispensing of medication and patient educational programming. Currently there are 33 patients in this program.

Quality Assurance Activities

We are only at the beginning of this activity. We strongly believe the two major measures of quality should be medication adherence rates and adverse drug events. Over the past three years both of these measures have been routinely documented in MTMS patient progress notes. We are beginning the process of retrospectively collecting this data. Subjectively based on our experience, we anticipate our adherence rates to be in the 90% range with a trend towards improvement the longer the patient is in the program. We suspect our adverse drug event rates, once we collect them, will be high because we seek this information and document it, therefore our detection rate will be higher than what may be reported in the literature for ambulatory settings. We also expect to see decreased severity and a lower amount of preventable adverse drug events as we view detecting these and managing them our primary responsibility. Finally we believe evaluation of clinical disease outcome measures should be secondary measures of outcomes and quality. Based on some preliminary data, it appears that by improving adherence and potentially minimizing drug problems, measures such as blood pressures and HgA1c's have significantly improved. We would have been very pleased if we could have provided this data for CMS at this time, however our staffing issues have greatly hindered us in collection of this data. We hope to have more objective information in the next 4 to 6 months.

Commentary

We believe this is an area that needs to be approached with scientific rigor. Our hypothesis is that patients' outcomes do indeed improve. However, to our knowledge the type of service we have described has not been rigorously tested to prove its value over its potential cost. It is our belief that this may need to be done in a case controlled prospective study where patients in the same institution are randomly assigned to MTMS service versus standard services. This may need to be a study with fairly large patient numbers to show the difference and therefore may need to have a multi-center component. CMS may wish to consider such an endeavor.

Final Commentary

We have one additional major concern with the MTMP program that we have not already addressed above. Our concern lies with the administration of the program and in particular with the PDP portion. Based on increased adherence and therefore increased utilization of medications we may very well see and expect medication expenses to rise. The cost savings of the program may be in decreased hospitalizations, and other health care resource utilization. The PDP's will not feel or benefit from these cost savings, as they are not managing it. Our fear is that the PDP's will then force tactics that are in our opinion very

labor intensive, affect access and results in poor care and consequently outcomes such as prior approvals, increasing co-pays, and limitations on prescriptions. It seems to us that the MA –PD plans are a better option for administering this plan unless the PDP's are rewarded for decreased Medicare Part A and Part B costs for their beneficiaries and penalized for increases.

Comments on Section C, subsection b:

We would like to comment on subsection b: Dispensing fees. We agree that dispensing fee should mean that the cost of dispensing the medication. We believe our current predicament is due to the fact that the pharmacy industry kept adding other services to the dispensing fee and thus the $30 aspirin.

The question that needs to be answered is will management services of home care medication be covered under MTMS due to the high cost clause? What about the routine education and monitoring that is done with dispensing in the outpatient setting? With regard to supplies, we think supplies should be their own separate charge and a perdiem charge for home care supplies makes sense. As alluded to above, we would like to see medication boxes also fit into this category. It is our understanding there are now codes in part B to bill for supplies as a per diem. This concept easily be transferred to Part D. CMS states that the legislation did not give them that option. Is that just not nit picking? Certainly we do not believe it was the intent of the legislation to give drug with out the tools to administer the drug.

We do not like adding any pharmacy management services to the definition of dispensing fee or we are back with exposes of $30 aspirins. There needs to be a professional fee added for pharmacist evaluation of prescription and patient education or whatever professional work is needed in follow up that will not be MTMS.

Comments on Section C, subsection a:

We would also like to comment on the Covered Part D Drug sections. We are very concerned and disturbed by the list of drugs that may currently be excluded or otherwise restricted. This list to us does not appear to have medical or scientific merit behind it but rather looks somewhat political. The first group of medications that are of concern are those for weight loss or weight gain. Obesity is a major health care problem that contributes highly to the current common disease states and medication use. We have seen in our own population the decreased need of diabetic therapy with significant weight loss. Although the current medications may not be optimal there certainly will be better agents to come that based on this ruling may be restricted at a huge cost to patients. The second group of agents that concern us are OTC's. In particular is aspirin that

has major morbidity and mortality benefits in cardiovascular diseases and Diabetes and is part of the government Healthy people 2010 goals to increase its use when indicated. Acetaminophen is currently the recommended drug of choice to treat osteoarthritis. When patients cannot afford these medications it will result in more NSAIDS, COX2's , other prescription anti-platelet agent being utilized because they are covered at an increased cost to the system. This can be stated for vitamins, allergy, cough cold products and GERD products as well. We have all seen this happen. We are also concerned about the benzodiazepines. These drugs are also used for seizure disorder, are the drug of choice for post-traumatic syndrome and used in chronic anxiety. To us this policy signals out people with these disorders for no apparently good reason. We are highly critical of this list.

In closing we appreciate the opportunity to comment to CMS on the Medicare part D bill. We offer our assistance to CMS in any future work.

Mary Ann Kliethermes, Pharm.D.
Manager of the MTMS Clinic
Pharmaceutical Care Center (MC 884)
College of Pharmacy
University of Illinois at Chicago
840 South Wood Street
Chicago, Illinois 60612
Phone 312 996-6787
mak30@uic.edu

MTMS Pharmacy Staff

Anne Marie Schullo-Feulner, Pharm.D.
Jessica Tilton, Pharm.D.
Shiyun Kim, Pharm.D.
Jessica Mitchell, Pharm.D.
Christine Godwin, Pharm.D.

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CMS-4068-P-1144

Submitter : Mr. Robert Gassner **Date & Time:** 10/04/2004 07:10:14

Organization : National Psoriasis Foundation

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to present these comments on docket CMS-4068-P.

A recent study estimated that there are more than 800,000 Americans age 65 or older with psoriasis, and nearly 1.5 million 55 or older with the disease. These Americans are part of the present, potential, and future Medicare population who most need a prescription drug benefit.

Psoriasis is a lifelong skin disease that occurs when faulty signals in the immune system cause skin cells to regenerate too quickly. Extra skin cells build up on the skin?s surface, forming red, flaky, scaly lesions that can itch, crack, bleed and be extremely painful. Psoriasis generally appears on the elbows, knees, limbs and scalp but it can appear anywhere on the body, covering some people from head to toe.

The Food and Drug Administration (FDA) reports that psoriasis has two peaks of occurrence, one at 20-30 years of age and one at 50-60 years of age, indicating that while some patients have faced psoriasis for decades by the time they are eligible for Medicare, others are grappling with a relatively new disease at that time.

About one quarter of psoriasis patients have also been diagnosed with psoriatic arthritis, a degenerative disease of the joints and connective tissues associated with psoriasis, and similar to rheumatoid arthritis. A 1999 study found that psoriasis can cause reductions in physical and mental functioning comparable to that seen in diabetes, heart disease, hypertension, and depression.

Treatments for moderate to severe psoriasis present patients with difficult trade-offs. The bottom line for psoriasis patients today is that no treatment works for everyone, some treatments lose effectiveness over time, all treatments carry a unique set of side effects, and newly-approved treatments are also currently the most expensive. This presents a challenging situation for patients and their physicians.

It is essential that Medicare beneficiaries, through Part D and Part B, have access to the full range of psoriasis therapies, so they, in conjunction with their physician, can choose the treatments that are most appropriate for them and meet the medical standard of care.

The Psoriasis Foundation hopes the guidelines being developed by U.S. Pharmacopeia do not discourage access to this range of options. We urge CMS to direct prescription drug plan sponsors and Medicare Advantage organizations to offer psoriasis and psoriatic arthritis patients this full range of treatment options at reasonable prices.

The Psoriasis Foundation also urges CMS to guard against harmful utilization management strategies. Private insurers? prohibitive cost sharing, inappropriate step therapy, and unnecessary prior authorization requirements are hurting psoriasis patients. This should not carry over into Part D.

We also hope Part D formularies will not limit the possibilities for various combination therapies. This is a standard of care that applies to many patients, not just those with psoriasis.

Also, if the formularies limit access to therapies, this will discourage many people, particularly patients with moderate to severe psoriasis and/or psoriatic arthritis, from enrolling in Part D. This may be discriminatory and could hamper implementation of the benefit. For example, only one drug is FDA-approved with an indication for psoriatic arthritis. A formulary that did not offer this drug would be inadequate.

Finally, the Psoriasis Foundation encourages CMS to consider the comments on the Part D proposed rules submitted by the National Health Council. The Foundation fully supports the Council?s recommendations.

Part D will offer older Americans an historic opportunity to improve their health. We look forward to working with CMS to make sure the program fulfills its promise to Medicare beneficiaries with psoriasis and psoriatic arthritis.

CMS-4068-P-1145

Submitter : Mr. William Ilgenfritz **Date & Time:** 10/04/2004 07:10:06

Organization : Keystone Health Plan Central

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-4068-P-1145-Attach-1.doc

October 4, 2004

Centers for Medicare and Medicaid Services

As requested by CMS, Keystone Health Plan Central is submitting comments electronically on the Notice of Proposal Rule Making for Title I of the Medicare Modernization Act. We appreciate this opportunity to respond.

Should you have any questions, please contact Bill Ilgenfritz, Policy and Planning Manager, Government Programs at (717) 541-7590

Thank you.

Keystone Health Plan Central- MMA Regulatory Review Comments

Title	Subpart	Citation	Issue
I	A	423.4	CMS should determine actuarial valuation from the Plan's perspective; not the beneficiary's. This affects plan design. It's a matter of what is desirable (member view) versus what is actuarially equivalent (Plan view).
I	B	423.30(b) 423.34(a)	CMS is allowing automatic disenrollment (back to Original Medicare) for an MA-PD member who enrolls in a PDP. The member should have to make an active choice to disenroll from the MA-PD in this scenario to ensure informed choice and prevent inadvertent lock-out. They should be given proper "warning" by CMS or the PDP prior to the disenrollment taking place. In essence, the member's health care/medical benefit is being dictated by the automatic result of this PDP choice. This will be disruptive to plan and many retro actions will result.
I	B	423.30	Regarding the penalty for late enrollment in part D, CMS is shifting the administrative burden for tracking and collecting the penalty to the Plans. CMS appears to have attempted to lessen Plan administrative burden in Title II - MA, but have increased it for Part D.
I	B	423.48	In suggesting CMS will provide beneficiary info to PDPs and MA-PDs for "educational purposes", we still have some privacy concerns, although CMS seems to declare that those concerns need not be applicable here. CMS needs to be more specific as to how MA-PDs can use this information.
I	B	423.56(a)	Creditable coverage - Will the Plan have to determine whether or not a new the prospective enrollee had creditable coverage? We could we assume creditable coverage is present in every PDP or MA-PD, but we need to know where the prospective is coming from. This would be a potential administrative burden.
I	C	423.100	If a Plan would provide non-covered drugs (not OTCs and not part of an enhanced alternative) would those costs count as out of pocket?
I	C	423.132	The requirement of pharmacies explaining at point of sale the cost differential on dispensed versus lowest priced generic is burdensome.

I	F	423.293 (c) (1)	This relates to collection of Part D Late Fee via Social Security check deduction option. If a beneficiary chooses the S.S. check deduction option for their consolidated premium payment method, under 422.262 (f), it appears the Part D late fee penalty would also be collected via this deduction. How will this be penalty deduction be reported to the Plan? Will it be noted distinctly on MMR? Tracking this will be a burden.
I	J	423.464(c)	We oppose the possible CMS requirement of MA-PDs to pay USER FEES for transmittal of COB information with SPAPs. This seems an undue burden.
I	M	423.578	Although CMS seems to suggest they are the same, Part D Claim payment guidelines <u>are different</u> from those in MA. For MA, only requires 95% of non-contracted clean claims are to be paid in 30 days. The requirement to make all payment determinations in 30 days appears to go beyond this.
I	M	423.578	CMS says exceptions must be approved *indefinitely* (as long as the prescribing provider continues to prescribe the drug and the drug continues to be safe for treating the enrollee's disease or medical condition). This is not standard operating procedure for most Plans and would necessitate changes to procedures and cause drug utilization increases.
I	M	423.578	We think the non-formulary exception process where CMS suggests Plans automatically provide 30 days of drugs is a burden. We suggest having it go to an expedited appeal or the Plan can provide drugs at the time decision is made.
I	General	423	CMS needs to provide “training” to Plans (and others) on various aspects of Part D, as soon as possible.

CMS-4068-P-1146

Submitter : Mr. Samuel Wachsman **Date & Time:** 10/04/2004 07:10:47

Organization : Horizon Healthcare Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4068-P-1146-Attach-1.doc

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Samuel Wachsman, RPh

Director of Pharmacy

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

CMS-4068-P-1147

Submitter : Mr. E. Neil Trautwein **Date & Time:** 10/04/2004 08:10:22

Organization : National Association of Manufacturers

Category : Other Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

Attachment

CMS-4068-P-1147-Attach-1.rtf

E. Neil Trautwein

Assistant Vice President

Human Resources Policy

October 4, 2004

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4068-P
7500 Security Boulevard
Baltimore, MD 21244-8014

Re: Comments on proposed rule regarding Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)

Dear Sirs/Madams:

On behalf of the National Association of Manufacturers (NAM), I am pleased to submit the following comments on the proposed regulations to implement the Medicare Modernization Act (MMA): Proposed Rule Regarding the Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P), published on August 3, 2004. The NAM commends the CMS for issuing a proposed rule that will help encourage employers who offer retiree health coverage to continue to do so. The NAM intends these brief comments to help further improve these regulations. We also join in the comments of our partners in the Employers' Coalition on Medicare (ECOM) and commend the more extensive comments of our other friends and allies in the business community.

Early Issuance of Final Regulations

We urge CMS to issue its final rule by December 31, 2004 (or the earliest possible date thereafter) to allow employers the necessary lead time in 2005 to structure benefit offerings and employee communications. The latter point is critical given requirements that employers provide retirees adequate notice of any benefit plan changes. As many of our coalition allies have indicated, these timing constraints affect employers who accept the subsidy as well as those who prefer to wrap around the new Medicare Part D coverage.

Actuarial Equivalence

One of the most contentious elements of the MMA debate was whether employers who sponsor retiree coverage could "profit" by receiving more in subsidy payments than provided to retirees in benefits or, in the terms of the regulations, to receive a "windfall." The arguments ignored the bitter reality of retiree benefits: retiree health coverage isn't a money-making proposition, and is, in fact, quite the complete opposite. We support efforts to define actuarial equivalence to prevent even the appearance of a potential windfall.

We agree that the two-prong approach of determining whether an employer's plan meets the test of actuarial equivalence is both consistent with statutory language under section 1860D-11(c) as well as the best means of preventing any potential windfall. The first prong compares the gross

1331 Pennsylvania Avenue, NW • Washington, DC 20004-1790 • (202) 637-3127 • Fax (202) 637-3182 • ntrautwein@nam.org • www.nam.org

value of the employer's retiree prescription drug benefit to the value of the Medicare Part D benefit. The second prong compares the net value of the employer's retiree prescription drug benefit less the retiree contribution to the value of the Part D benefit. In more plain terms, an employer cannot receive more subsidy than he or she provides in benefits: the "windfall" is a myth.

We encourage CMS to allow flexibility in determining actuarial equivalence and to avoid using a fixed value test. CMS should allow employers to compare the value of their retiree prescription drug coverage minus retiree contributions and administrative expenses to the value of the Medicare Part D benefit minus the beneficiary premium amount, administrative expenses and the effect of the True-Out-Of-Pocket (TROOP) provisions. As a simpler alternative, particularly in the first year or two of the benefit, would be to allow the employer plan to determine the amount it expects to receive in subsidy payments and use this amount as a correctable proxy for the value of Part D coverage.

Waivers

The MMA extends broad authority to CMS to waive requirements that could discourage continuation of employer or union-sponsored retiree health plans. Such waiver authority is consistent with that exercised by CMS in relation to the Medicare+Choice program. It will be critical to the development of the successor Medicare Advantage (MA) plans and new Prescription Drug Plans (PDP). We urge CMS to exercise its waiver authority liberally in the early years of the MMA and to provide clear and early guidance to employers on all aspects of the waiver process.

Definition of Plan

We urge CMS to recognize that in accepting the Department of Treasury's COBRA definition of "plan" for the purpose of determining actuarial equivalence, employers make distinctions in classes of retirees. Distinctions and factors important to the administration of retiree benefits go beyond those important to COBRA administration. Flexibility in CMS' interpretation again will be critical.

Application Process

We urge CMS to provide greater flexibility in its deadlines. The proposed rule would require employers to apply for the retiree drug subsidy no later than September 30, 2005, quite possibly well before employers are in a position to completely and accurately attest to actuarial equivalence. We urge CMS to give plan sponsors flexibility in the timing and manner in which to file updated attestation information during the year. We also urge CMS to safeguard communications in regard to attestation to protect proprietary information and beneficiary privacy. Finally, we urge CMS to affirm that the MMA does not authorize individuals or their representatives to challenge the attestation of actuarial equivalence.

Compliance Assistance

We urge the CMS to interpret the eventual final regulations with a compliance assistance-first view, an approach adopted with success in other agencies. The waiver process and flexibility in interpreting the MMA, this regulation and guidances will also be important to achieving our shared goal of encouraging as many employers who presently offer retiree health coverage to continue to do so while precluding even the appearance of "windfalls" and also limiting overall federal costs.

Conclusion

Thank you for considering these comments and those of our allies and peers in the employer community. We appreciate the efforts of CMS to work with the NAM and other members of the employer community. We employers believe that these regulations, as modified, will go a long way to shoring up retiree health benefits, thus assuring that retirees have access to generous and flexible health benefits. The NAM welcomes the opportunity to work with CMS as these regulations and subsequent guidances are finalized to help ensure the prompt implementation of the MMA.

Sincerely,

/s/

E. Neil Trautwein
Assistant Vice President
Human Resources Policy

Sent via email attachment to http://www.cms.hhs.gov/regulations/ecomments

CMS-4068-P-1148

Submitter : Mrs. Patricia Carroll-Grant **Date & Time:** 10/04/2004 08:10:28

Organization : Mrs. Patricia Carroll-Grant

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

please accept the attached comments
thank you
pat carroll-grant

CMS-4068-P-1148-Attach-1.doc

Delaware Pharmacists Society
P.O. Box 454, Smyrna, DE 19977

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

Re: CMS-4068-P

Dr. Mark McClellan, Administrator:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. The Delaware Pharmacists Society represents over 300 Delaware pharmacists practicing in all settings including community, hospital, long-term care, and the pharmaceutical industry.

Pharmacy Access Standards

CMS rules should be revised to require plans to meet the TRICARE pharmacy access standards on a local level, not on the plan's overall service level. Requiring plans to meet the standard on the local level will ensure convenient access to local pharmacy services and preserve important pharmacist – patient relationships. In the interest of the beneficiary, CMS should require PDPs to offer a standard contract to all pharmacies. Also, CMS should require oversight of PDP's and MA-PD's to protect Medicare beneficiaries from PDP's and MA-PD's that would circumvent quality measures to provide

Medication Therapy Management

The concept of providing medication therapy management (MTM) is an excellent one and providing services such as beneficiary counseling, formulating prescription drug treatment plans, and evaluating and monitoring patient response are critical elements of providing quality care. However, there is ***No Standard Benefits Defined*** – This means there could be considerable variances between plans even within the same region. The regulation provides that pharmacists may provide these MTM services, however, there is no incentive for PDP's to pay for these services. Savings realized by MTM services are often the result of fewer medical expenses such as hospital or doctor visits or nursing home admissions. PDP's only provide prescription drug coverage. MA-PD's would realize a cost effectiveness because there is an incentive to lower costs on the medical side, however, not requiring PDPs to have standards in place when MTM

services are provided could result in lesser quality MTM and fewer actual health care outcome improvements.

In addition to the specific comments below, we request that CMS adopt the MTMS definition principles outlined in a consensus statement developed by 11 national pharmacy organizations, including organizations representing managed care pharmacy. 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 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): PDP 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 PDP outline quality and other performance benchmarks. PDP should be held financially responsible for not meeting these benchmarks related to MTMP**.**

Standard Benefit Card

We strongly support the proposed requirement to require all plans to use a standard benefit card using the approved NCPDP format.

Prescription drug coverage will help improve the health outcomes and quality of life for many seniors and pharmacists are ready to assist seniors in making smart choices about their health.

Sincerely,
Pat Carroll-Grant, RPh. CDE
Executive Director
Delaware Pharmacists Society

Submitter : Todd Timbrook **Date & Time:** 10/04/2004 08:10:43

Organization : Home Solutions Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter of comment

CMS-4068-P-1149-Attach-1.doc

HOME SOLUTIONS
INFUSION THERAPY ®
www.TPNatHome.com

Reply to:

☐ **Corporate Office:**
215 Shore Road,
Somers Point, NJ 08244
Office: (609) 926-6577
Toll Free: (888) 646-6379
Fax: (609) 926-6588

☐ **Branch Office:**
2 Walnut Grove Drive, Suite 140
Horsham, PA 19044
Office: (215) 549-5500
Toll Free: (800) 447-4879
Fax: (215) 843 2823

Home Solutions 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.

Home Solutions was founded in 1996 to meet the needs of the growing home infusion pharmacy industry. We are now one of the largest independently owned infusion providers in the tri-state area of New Jersey, Pennsylvania and Delaware and employ over 100 individuals. Our success is due in part to our clinical expertise of managing the home infusion patient safely and cost effectively in the home setting. Each year we treat in excess of five thousand (5000) patients per year and have had an overall client satisfaction rate of close to 100%. We have clinical expertise in particular of managing the Congestive Heart Failure and Nutritional Support population to name just a few. Since the development of the Medicare Part C program we have contracted with several managed care organizations to handle infusion cases outside the walls of the hospital and managed care has realized significant cost savings. Home Solutions has waited for the day that CMS would recognize the home infusion benefit and is hopeful that our **clinical services** will now be part of the Medicare Part D benefit.

Home Solutions 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.

HOME SOLUTIONS INFUSION THERAPY ®
www.TPNatHome.com

Reply to:

☐ **Corporate Office:**
215 Shore Road,
Somers Point, NJ 08244
Office: (609) 926-6577
Toll Free: (888) 646-6379
Fax: (609) 926-6588

☐ **Branch Office:**
2 Walnut Grove Drive, Suite 140
Horsham, PA 19044
Office: (215) 549-5500
Toll Free: (800) 447-4879
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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 any willing infusion pharmacy** 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,

Todd D. Timbrook, RPh.
President/CEO

Joint Commission
on Accreditation of Healthcare Organizations

Submitter : Mr. Edward Neumann **Date & Time:** 10/04/2004 08:10:21

Organization : HomeCare I.V. of Bend, Inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

HomeCare I.V. of Bend, 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.

HomeCare I.V. of Bend, Inc., is an accredited, independently owned, freestanding home infusion service serving the mostly rural population of eastern Oregon from a single location in Bend, Oregon. Since 1989, our company has cared for more than five thousand patients providing them with the clinical and cost-saving benefits of home infusion. We work closely with Clear Choice Health Plans Medicare + Choice plan providing their members quality infusion care at significant cost savings compared with equivalent care in physician or hospital settings. Clinical outcomes and patient satisfaction are consistently high; coverage of infusion therapies not enjoyed by traditional Medicare beneficiaries is especially appreciated in this population.

HomeCare I.V. of Bend, 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 provided in a manner that is consistent with established national quality standards.

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$ 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 for your consideration of these important issues.

Edward Neumann
Vice President/CFO

CMS-4068-P-1151

Submitter : Mr. Jason Hodges **Date & Time:** 10/04/2004 08:10:16

Organization : American Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

While I understand and support the intent of the bill, I feel that the bill will, in the long-run, end up "bailing-out" insurance companies and employers. Companies are currently struggling to provide retirement plans for their employers. With the enacting of this bill, the government will assume this role and employers will no longer feel compelled to provide such benefits. I firmly believe that employer provided benefits currently in effect for senior will rapidly diminish with the enacting of this bill, leading to a large increase in overall costs upon the government. I believe that shifting this burden to the government will result in a lesser quality of health care in the future.

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

I am also concerned with the bill's effort to level the playing field. While the plan seems to allow a beneficiary to obtain drugs at either a retail store or a mail order pharmacy, I'm afraid that some of the plan's wording will end up squeezing small business owners out of their jobs. PBM's will be allowed to negotiate deals with big retail chains, and the retail chains will be able to absorb the negative financial impact; however, a small independent pharmacy will be less likely to be able to compete with the larger chains when it comes to dispensing fees. As a general statement, community pharmacy as a whole is going to take a large financial hit with the implementation of this bill. For years, community pharmacy has relied on cash-paying customers to be able to maintain a viable business plan. With the implementation of the new bill, most of the cash paying customers will become beneficiaries, and pharmacies will make less money. In this system, the big chain stores that rely on each other will be more able to withstand the strain better that a small business.

BENEFITS AND BENEFICIARY PROTECTIONS

While the competitive business concepts of formularies may allow for lower costs, the therapeutic outcomes associated with forcing a beneficiary to obtain a formulary drug may be sub-optimal. If a patient has been taking a drug for 15 years and then enrolls in a plan in which that drug is not covered, the patient's health may suffer by being switched to a new med. I also feel that enacting formularies will place a burden on pharmacists that they are not paid for. Patients will bring in prescriptions for drugs that their plan does not cover. It will then be a pharmacist's job to call physicians and to get a drug that is covered. Pharmacists are not currently paid for this action. If formularies are required, I suggest that a change-of-prescription fee be introduced, making PBM's pay pharmacists for this service.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Concerning the definition of dispensing fee, I feel that the dispensing fee should include activities related to the transfer of the possession of the drug from the pharmacy to the beneficiary including charges associated with mixing drugs delivery and overhead. I think the dispensing fee should also include activities related to certain drugs that require an abnormal amount of time. Dispensing fee for a new prescription should be different for that of a refill prescription. I also feel that the manner in which dispensing fees are set should not be left solely to the discretion of PBM's. In the current system, pharmacies have no control over how much they get paid to dispense drugs. Insurance companies and PBM's set prices that pharmacies are virtually forced to accept. I feel that dispensing fees should be uniform across all the PBM's the government approves.

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

One part of the proposed regulations says that pharmacists must provide beneficiaries will any price differential between the drug prescribed and the lowest price generic. I submit that this burden should lie with PBM's. Once again, pharmacists only make one dispensing fee with each prescription. It is not financially sound for a pharmacist to look up the cost of each generic associated with a certain prescription, especially if each plan offers different prices that will change over time.

On the topic of medication therapy management, it seems that the plan language allows PBM's to decide how much service they are willing to pay

for. While this does seem financially sound, I feel that PBM's will set rates too low for such services to be a financially sound business practice for pharmacists. In this case, lesser qualified individuals may end up making sub-optimal interventions. I submit that that the bill authors' reconsider setting some type of minimum reimbursement rate.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

I feel that the "donut hole" is a obstacle that will end up causing many problems. If you look at the $2300 cap prior to being cut off. That allows approximately $200 a month. I submit that this figure is not high enough. A cholesterol med, a PPI, HTN meds, and any relevant diabetic supplies will easily put a person over this limit. I feel that once a person reaches this limit it will be very hard to convince them to continue paying their deductible. I also feel that this unexplained donut hole will place a burden on pharmacists, since it will be the pharmacist's place to explain the plan.

CMS-4068-P-1152

Submitter : Michael Reiner **Date & Time:** 10/04/2004 08:10:16

Organization : Nextron Infusion Services

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document

CMS-4068-P-1152-Attach-1.doc

October 4, 2004

Nextron Infusion Services, Inc. (Nextron) 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.

Nextron has been providing home infusion therapies for the past fourteen years in the New York-New Jersey metropolitan area. We have serviced thousands of patients during this time helping to save the healthcare system a significant amount of money by treating patients in the less costly home care setting. We have had the opportunity to be of service to many Medicare patients through some of the Medicare managed care plans that we participate in. We have been able to teat patients with intravenous antibiotics at home who would have been required to remain in the hospital setting if they had traditional Medicare benefits. The patients were pleased with these services and the hospitals were happy to discharge these patients as their acuity level no longer required hospitalization. In addition. By treating these patients at home, we saved the Medicare program thousand of dollars just with one of these patients. For example a hospitalized patient being treated with intravenous antibiotics in a hospital for 28 days due to an osteomyletis would conservatively cost about $25,000. This same patient can be treated at home for 28 days for less than $4,000. Our company is JCAHO accredited and we have close to a 100% patient satisfaction rate with our services. There have been many other Medicare beneficiaries who could have benefited from our services, but unfortunately under the current benefits were not eligible for home infusion therapy. It is our hope that with the passage and fair implementation of the Part D prescription drug benefit we will also be able to care for these patients in the future.

Nextron 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> http://www.nhianet.org/perdiemfinal.htm .

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

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

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

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

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

Sincerely,

Michael Reiner
General Manager
Nextron Infusion Services, Inc.

CMS-4068-P-1153

Submitter : Ms. Cheryl Ham **Date & Time:** 10/04/2004 08:10:56

Organization : Chicago Consulting Actuaries LLC

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Chicago Consulting Actuaries LLC (CCA) is please to submit the attached comments regarding the Medicare Prescription Drug Benefit (CMS-4068-P).

CMS-4068-P-1153-Attach-1.doc

CHICAGO CONSULTING ACTUARIES
Where numbers become ideas®

October 4, 2004 VIA e-mail

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

RE: Comments on Proposed Rule Regarding Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)

Dear Sir/Madam:

Chicago Consulting Actuaries LLC (CCA) is pleased to submit comments regarding the proposed regulation on the Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P), published in the Federal Register on August 3, 2004.

CCA performs actuarial valuations for the postretirement benefit programs of many publicly traded and privately held companies. We assist employers preparing relevant information for their financial statements. As actuaries, we also assist many companies in their due diligence analysis of employee benefit programs in merger and acquisition situations. We have extensive knowledge of postretirement benefit programs, and thus feel qualified to offer commentary on the proposed regulation.

Subpart G – Payments to PDP Sponsors and MA Organizations Offering MA–PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

5.d. Reinsurance Subsidies (Page 46689)
The calculation of the standardized bid amount with all of the required adjustments can become quite complicated, especially with respect to the expected reinsurance subsidy for a plan offering enhanced alternative coverage. We believe it would be very useful if CMS would include a sample calculation of a standardized bid amount for a PDP offering enhanced alternative coverage, as well as a sample calculation of the actual reinsurance

subsidy for this plan, including how adjustments will be made to reflect the true out-of-pocket threshold (TrOOP) and the insurance effect (utilization differences).

7.b. Allowable Risk Corridor Costs (Page 46691)
While we find table G-1, Illustration of Risk Sharing Arrangements for Hypothetical Plan, very useful, the calculation for a plan offering enhanced alternative coverage could work very differently. We believe it would also be helpful if CMS would include a sample risk sharing calculation for a PDP offering enhanced alternative coverage.

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

4.a. Employer Group Waivers (Page 46698)
Many employers would like to consider a wrap-around approach to Part D. However, one of the administrative issues in providing such a plan is that if retirees are located in multiple regions across the country, the benefit package for one retiree is likely to be different than for a retiree in a different region, making it difficult for the employer to provide a uniform wrap-around design. Allowing waivers that would allow PDPs and MA-PDs to develop cross-regional offerings, where the benefits would be the same across multiple geographic regions, would make the wrap-around design a feasible option for many more employers.

6.e. Tracking True Out-of-Pocket (TrOOP) Costs (Page 46705)
Of the two options proposed by CMS to operationalize the data exchange related to Part D coordination of benefits when an employer or union plan provides wrap-around coverage, we believe that establishing a facilitation coordinator as a single point of contact between primary and secondary payers is the most feasible approach from an employer perspective. This approach would be more cost effective and should result in lower user fees than each PDP and MA-PD plan being solely responsible for developing the infrastructure to track TrOOP costs.

Subpart R – Payments to Sponsors of Retiree Prescription Drug Plan

2. Definitions (Sec. 423.886) (Page 46739)
Section 423.886 defines the employer subsidy payment as 28% of allowable retiree costs attributable to the gross covered prescription drug costs between the cost threshold ($250) and the cost limit ($5,000). In many communications regarding this provision, such as the Discussion Paper for the Employer Open Door Forum held on August 20, 2004, the explanation of subsidy payment is shorthanded as 28% of the retiree's allowable costs that fall between $250 and $5,000. The ultimate subsidy amount is not necessarily the same for each of these explanations. To clear up the confusion surrounding these differences, we believe that it would be very helpful if CMS would include a sample calculation of the employer subsidy, including hypothetical gross and allowable amounts and the resulting subsidy.

3.b.2. Establishing Actuarial Equivalency

Preferred Approach (Pages 46741 and 46742)

The right basis for determining actuarial equivalence for obtaining the employer subsidy payment presents many challenges from a theoretical standpoint. We agree that the "single prong" approach undermines one of the main policy objectives articulated by Congress and could result in windfalls to employers. CCA supports that a version of the "two-prong" test be used to determine actuarial equivalence. Although we believe this definition most accurately reflects Congressional intent, based upon our reading of the language in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), it is not clear that this intent is or is not supported by the statutory language due to the silence on the issue. For the first prong the "gross" test makes sense, as it would confirm that the total value of benefits provided to the beneficiary under the employer plan are at least as generous as what they could receive under Medicare Part D. For the net value determination of the second prong, we believe that the appropriate comparison value is the net value of the standard Medicare Part D benefit. In the general provisions section of the preamble on page 46635, it is stated that "actuarial equivalence refers to a determination that, in the aggregate, the dollar value of drug coverage for a set of beneficiaries under one plan can be shown to be equal to the dollar value for those same beneficiaries under another plan". To use any of the other suggested comparison values in determining actuarial equivalence, such as the per capita subsidy or the after-tax value of the per capita subsidy then would go against the very definition of the term.

We also encourage CMS to maintain flexibility in the approach used to determine actuarial equivalence by not stipulating fixed dollar values for the Medicare Part D or per capita subsidy comparison. Allowing the comparison to reflect employer specific utilization, geography and plan design differences when credible data is available would create the best comparison as to the value of Medicare Part D for a particular employer and their retirees. When credible employer specific data is not available it would be appropriate for CMS to provide guidance as to reasonable sources of data, such as proprietary datasets, normative databases or other sources.

Also, in other areas of the act and regulations, it has been specifically stated that the difference between expected utilization under the standard Part D benefit plan and a more generous benefit plan should be taken into account. We ask that CMS clarify whether this is also allowable under Subpart R for determining actuarial equivalence.

Definition of "Plan" for Determining Actuarial Equivalence (Page 46472)

As CMS has indicated, there is tremendous diversity among employer prescription drug plans, in that for a particular employer several different benefit designs are often offered, or different retiree contribution levels are required based on certain criteria such as bargained status, service at retirement or retiree vs. dependent status. CMS has proposed that all benefits provided by a sponsor are presumed to be under a single plan unless it is clear from the plan documents or operation that there are separate plan arrangements. Further, CMS has proposed that actuarial equivalence be based on the average benefit

across all participants in the plan vs. based on the benefit package received by the individual or each group of individuals. CCA supports the proposed CMS definition of a plan in this context, as well as the intention to base actuarial equivalence on the average benefit across all participants in the plan, as this supports the statutory language of a "group health plan" as defined in the MMA, as well as due to the simplicity of the all or nothing approach versus of having to isolate separate groups of individuals.

3.c. Sponsor Application for Subsidy Payment and Required Information (Page 46743)

CMS has proposed that the deadline for the retiree drug subsidy application be no later than September 30, 2005 and no later than 90 days prior to year-end for future years. For many employers, compiling all of the required information by this deadline for the subsidy application could be challenging, most especially the attestation of actuarial equivalence and the data file of qualifying covered retirees. Typically, annual open enrollment does not take place until late September or early October each year. Therefore plan enrollment is not known by September 30. We suggest that CMS provide greater flexibility such that an employer might be required to submit the actuarial attestation and a preliminary qualifying covered retiree data file by September 30, but allow additional data on qualifying covered retirees and/or other supporting data to be filed at a later date prior to year-end, after annual enrollment elections are finalized. If necessary, payment would be delayed until all of the information is complete.

3.d. Creditable Coverage and Notification (Page 46744)

CCA agrees that the appropriate measure for determining actuarial equivalence with respect to creditable coverage is the "gross value" test. We ask that CMS specifically address whether actuarial equivalence in this context is to be determined on average across all participants in the "plan" as discussed above, or based on the benefit package received by the individual if several design choices are present. Ultimately, it makes sense for actuarial equivalence in this context to be determined on the same basis as concluded for subsidy eligibility. However, if the conclusion for subsidy eligibility is that actuarial equivalence is to be determined on average across all participants in the plan, in the context of creditable coverage that could result in a small number of individuals choosing a design that is not as rich as Medicare Part D but being told that they have creditable coverage. We raise this issue in hope that CMS consider the range of possibilities when addressing this clarification.

We again encourage CMS to maintain flexibility in the approach used to determine actuarial equivalence by not stipulating fixed dollar values for the Medicare Part D. Allowing the comparison to reflect employer specific utilization, geography and plan design differences when credible data is available would create the best comparison as to the value of Medicare Part D for a particular employer and their retirees. When credible employer specific data is not available it would be appropriate for CMS to provide guidance as to reasonable sources of data, such as proprietary datasets, normative databases or other sources.

Also, in other areas of the act and regulations, it has been specifically stated that the difference between expected utilization under the standard Part D benefit plan and a more generous benefit plan should be taken into account. We ask that CMS clarify whether this is also allowable under Subpart R for determining actuarial equivalence.

We recognize that the MMA specifically stipulates that a Special Enrollment Period and protection against a late enrollment penalty is allowed only for involuntary loss of creditable coverage. However, the start of Medicare Part D will likely be a confusing transition for beneficiaries, especially those with multiple options available to them. Therefore, CCA, on behalf of our employer clients, suggests that a transition rule be put into place whereby beneficiaries that voluntarily terminate employer coverage be allowed a Special Enrollment Period. During this transition period, notice of the loss of creditable coverage would be provided in the same manner as for an involuntary loss of coverage.

5.b. Payment Methodology (Page 46746)
CMS has proposed that subsidy payments be made on a monthly basis. While many employers would prefer to receive payment as soon as possible, monthly data submission in order to receive monthly payments may be administratively burdensome as well. Therefore, CCA recommends that CMS adopt a flexible approach regarding subsidy payment where employers could opt to receive monthly, quarterly or annual payment. This would allow employers to balance administrative requirements and related additional costs against timing and cash-flow preferences. This would also relieve some of the pressure from Medicare having to turn around thousands of subsidy payments each and every month.

Finally, we would urge CMS to provide final rules as soon as possible. In the spring of 2005, employers will be developing plan designs for 2006. It will be important for employers to know all of the available options, such as available PDPs and subsidy application requirements as early as possible in order to facilitate these decisions and in order to communicate with retirees on a timely basis. For many employers, open enrollment for 2006 will take place in September/October 2005 so the timing is tight as it is, and compounded because of the need to analyze and communicate a completely new program under Medicare.

Thank you for consideration of our comments. We would be happy to discuss our position with you further, if desired. You can contact me at 312-454-8187 or cham@chicagoconsultingactuaries.com.

Sincerely,

Cheryl A. Ham, F.S.A., M.A.A.A.
Consultant

CMS-4068-P-1154

Submitter : **Date & Time:** **10/04/2004 08:10:11**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-4068-P-1154-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1155

Submitter : **Date & Time:** **10/04/2004 08:10:54**

Organization : **Arthritis Foundation**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

CMS-4068-P-1155-Attach-1.doc

October 4, 2004

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

Re: Comments on CMS-4068-P; Medicare Program; Medicare Prescription Drug Benefit; 69 Fed. Reg. 46632 (August 3, 2004)

Dear Dr. McClellan:

The Arthritis Foundation 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] As the only nationwide, nonprofit health organization helping people take greater control of arthritis by leading efforts to prevent, control and cure arthritis and related diseases -- the nation's number one cause of disability, the Arthritis Foundation is committed to ensuring that all Medicare beneficiaries living with arthritis have meaningful access to prescription drugs and biologic therapies.

There are over 100 forms of arthritis. While there can be a variety of symptoms associated with each form of the disease, severe pain and physical disability is common to all forms of arthritis. According to the Centers for Disease Control and Prevention approximately 70 million Americans have arthritis or chronic joint symptoms, and of this group almost 60 percent are 65 years and older. As the baby boomers age, it is expected that the number of persons with arthritis will increase dramatically. Additionally, different forms of the disease like rheumatoid arthritis can affect people much earlier in life, and many of these persons receive Medicare benefits due to their disability status.

Arthritis is a very complicated disease and persons with arthritis often need access to a variety of interventions to help them reduce pain and prevent disability. Individuals with arthritis require access to comprehensive health care that can include preventive care, self-management programs, surgical interventions, rehabilitation services, and prescription drug, biological and medical device therapies. Timely and appropriate use of

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[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).

these interventions has been demonstrated to reduce both the direct and indirect costs of arthritis. As a result, pharmaceutical and biological therapies are playing an increasingly important role in appropriate care of persons with arthritis.

Recommendations

The Arthritis Foundation 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 Arthritis Foundation'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 Arthritis Foundation 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 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 Arthritis Foundation shares CMS' concern for vulnerable patient populations and urges CMS to recognize patients with arthritis 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 with arthritis.

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[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.

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 beneficiaries with arthritis.

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, beneficiaries 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, the Arthritis Foundation 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 Arthritis Foundation 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 Arthritis Foundation believes that this provision is inappropriate. These provisions create potential opportunities for discrimination against individuals with mental illnesses, physical disabilities, and cognitive impairment. Persons 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.

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.

[5] 69 Fed Reg. at 46642; 42 C.F.R. § 423.44(d)(2)(i).

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, the Arthritis Foundation urges CMS to use its authority and work aggressively to ensure that the full spectrum of necessary medications is available.

The Arthritis Foundation 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 rheumatoid arthritis the Medicare Model Guidelines are biased toward use of older medications in a way that is contrary to 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 persons with arthritis 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, the Arthritis Foundation urges CMS and the USP to expand the list of categories and classes to prevent barriers to beneficiary access caused by overly restrictive formularies. At a minimum, the Arthritis Foundation 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 Arthritis Foundation 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.

For example, the USP Guidelines divide the therapeutic category of Immunological Agents into three classes, one of which is immune suppressants. TNF Inhibitors and Interleukin Inhibitors are not segregated as distinct classes. Therefore, it is possible that plans will only choose to offer two immune suppressants on a formulary, which could severely limit access to important therapies for beneficiaries with rheumatoid arthritis.

The Arthritis Foundation 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, the Arthritis Foundation encourages 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.

- The Arthritis Foundation 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.

- The Arthritis Foundation 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 notice electronically to plan members via a listserve, and/or in writing. The Arthritis Foundation 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 Arthritis Foundation does not believe that the language in the Proposed Rule is sufficient to protect beneficiaries' access to appropriate off-label use of medications.

The Arthritis Foundation 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 Arthritis Foundation believes that 30 days does not provide beneficiaries and their providers sufficient time to respond to a formulary change.

Accordingly, the Arthritis Foundation 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.

The Arthritis Foundation recommends that CMS require plan sponsors to provide immediate notification to patients who attempt to refill an existing prescription or fill a new

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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.

prescription when that 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, the Arthritis Foundation 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, the Arthritis Foundation 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 Arthritis Foundation 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 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 Arthritis Foundation 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 Arthritis Foundation 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 Arthritis Foundation 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 would 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] The Arthritis Foundation 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 Arthritis Foundation 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 problem 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.

The Arthritis Foundation recommends that CMS create a program to educate pharmacists,

[11] 69 Fed. Reg. at 46691.

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. The Arthritis Foundation 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 Arthritis Foundation 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 Arthritis Foundation 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 provided an opportunity to submit comments to be considered by the P&T

[12] SSA 1860D-11(e)(2)(D).
[13] 69 Fed. Reg. at 46660.

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

The Arthritis Foundation 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 202-887-2910 or by e-mail at kbrennan@arthritis.org if we can provide additional information or be of further assistance.

Sincerely,

J. Kevin Brennan
Senior V.P. Public Policy and Advocacy

CMS-4068-P-1156

Submitter : Ms. Patricia Carroll-Grant **Date & Time:** 10/04/2004 08:10:01

Organization : Ms. Patricia Carroll-Grant

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

My comments were submitted under the category physician assistent in error. Please note that I am a pharmacist

CMS-4068-P-1156-Attach-1.doc

Delaware Pharmacists Society
P.O. Box 454, Smyrna, DE 19977

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

Re: CMS-4068-P

Dr. Mark McClellan, Administrator:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. The Delaware Pharmacists Society represents over 300 Delaware pharmacists practicing in all settings including community, hospital, long-term care, and the pharmaceutical industry.

Pharmacy Access Standards

CMS rules should be revised to require plans to meet the TRICARE pharmacy access standards on a local level, not on the plan's overall service level. Requiring plans to meet the standard on the local level will ensure convenient access to local pharmacy services and preserve important pharmacist – patient relationships. In the interest of the beneficiary, CMS should require PDPs to offer a standard contract to all pharmacies. Also, CMS should require oversight of PDP's and MA-PD's to protect Medicare beneficiaries from PDP's and MA-PD's that would circumvent quality measures to provide

Medication Therapy Management

The concept of providing medication therapy management (MTM) is an excellent one and providing services such as beneficiary counseling, formulating prescription drug treatment plans, and evaluating and monitoring patient response are critical elements of providing quality care. However, there is ***No Standard Benefits Defined*** – This means there could be considerable variances between plans even within the same region. The regulation provides that pharmacists may provide these MTM services, however, there is no incentive for PDP's to pay for these services. Savings realized by MTM services are often the result of fewer medical expenses such as hospital or doctor visits or nursing home admissions. PDP's only provide prescription drug coverage. MA-PD's would realize a cost effectiveness because there is an incentive to lower costs on the medical side, however, not requiring PDPs to have standards in place when MTM

services are provided could result in lesser quality MTM and fewer actual health care outcome improvements.

In addition to the specific comments below, we request that CMS adopt the MTMS definition principles outlined in a consensus statement developed by 11 national pharmacy organizations, including organizations representing managed care pharmacy. 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 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): PDP 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 PDP outline quality and other performance benchmarks. PDP should be held financially responsible for not meeting these benchmarks related to MTMP**.**

Standard Benefit Card

We strongly support the proposed requirement to require all plans to use a standard benefit card using the approved NCPDP format.

Prescription drug coverage will help improve the health outcomes and quality of life for many seniors and pharmacists are ready to assist seniors in making smart choices about their health.

Sincerely,
Pat Carroll-Grant, RPh. CDE
Executive Director
Delaware Pharmacists Society

CMS-4068-P-1157

Submitter : **Date & Time:** **10/04/2004 08:10:41**

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Please see comments

CMS-4068-P-1157-Attach-1.doc

CMS-4068-P-1157-Attach-2.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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1. Commenter failed to complete all steps required in order to attach their attachment.

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CMS-4068-P-1158

Submitter : Kristin Bass **Date & Time:** 10/04/2004 08:10:24

Organization : WellPoint

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached Files

CMS-4068-P-1158-Attach-4.doc

CMS-4068-P-1158-Attach-1.doc

CMS-4068-P-1158-Attach-2.doc

CMS-4068-P-1158-Attach-3.doc

WELLPOINT
1455 Pennsylvania Avenue
Suite 575
Washington, DC 20004
Tel (202) 628-7840
Fax (202) 638-1096
Email: Kristin.Bass@wellpoint.com

Kristin A. Bass
Vice President
Federal Affairs

October 4, 2004

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

Re: **CMS–4068–P: Medicare Program; Medicare Prescription Drug Benefit; Notice of Proposed Rulemaking – 42 CFR Parts 403, 411, 417, 423 – Public Comment**

CMS–4069–P: Medicare Program; Establishment of the Medicare Advantage Program; Notice of Proposed Rulemaking – 42 CFR Parts 417 and 422 – Public Comment

Dear Dr. McClellan:

On behalf of WellPoint, thank you for the opportunity to comment on the Medicare Prescription Drug Benefit and Medicare Advantage Proposed Rules published August 3 in the Federal Register (CMS–4068–P; CMS-4069-P). You and your staff are to be commended for drafting these comprehensive rules in such a short period of time. We greatly appreciate your agency's active solicitation of feedback on these rules.

The final rules implementing Titles I and II of MMA and how seniors respond to the new coverage options will be key factors in determining the success of the Medicare Modernization Act of 2003 (MMA). Health plans, pharmacy benefit managers, and other prescription drug plan sponsors want feasible, flexible regulations that will allow them to offer innovative benefit designs that will form the basis of a modern, affordable Part D prescription drug benefit and Medicare Advantage program. Plans must be able to incorporate the cost containment techniques used in commercial products to manage beneficiary costs.

WellPoint submits these comments because our companies are committed to maintaining and expanding consumer choices in Medicare. WellPoint Health Networks provides Medicare Advantage and Medicare Supplemental coverage to more than 400,000 Medicare beneficiaries through Blue Cross of California, Blue Cross Blue Shield of Georgia, Blue Cross Blue Shield of Missouri, Blue Cross Blue Shield of Wisconsin, and UNICARE. In addition, WellPoint Pharmacy Management, a wholly owned subsidiary of WellPoint Health Networks, Inc., and NationsHealth joined together to provide a Medicare-approved prescription drug discount card program—PrecisionDiscounts. More than 200,000 Medicare beneficiaries are currently enrolled in the PrecisionDiscounts card. WellPoint companies serve a total of 15.5 million medical members and 46.2 million specialty members nationwide.

WellPoint has called upon our market experience to provide constructive feedback on various aspects of MMA implementation including in the enclosed detailed comments on the Part D and Medicare Advantage Proposed Rules. Our comments touch on a range of issues in the regulations, but focus on the following key recommendations that are needed for health plan participation and the long-term viability of Part D and Medicare Advantage:

- **Flexible use of cost management techniques**
- **Maintain beneficiary choice of coverage options, including supplemental coverage**
- **Level the playing field for regional and local plans, and for Part D drug plans and Medicare Advantage drug plans**
- **Clarify Part D eligibility and enrollment information sharing between Medicare and plan sponsors**
- **Minimize administrative burdens that provide little to no reciprocal value to Medicare or beneficiaries**

We already have submitted comments on MMA provisions tangential to the Proposed Rules, specifically, Medicare Advantage PPO and Part D regions and the United States Pharmacopeia's draft model Part D drug categories. Copies of those comments are attached for your reference. We also have testified before the National Committee on Vital and Health Statistics as they worked to develop electronic prescribing recommendations. Some of these issues are further discussed in the enclosed detailed comments on the Proposed Rules. However, our comments on the Proposed Rules focus on those recommendations noted above.

Unless otherwise specified in the enclosed comments, WellPoint agrees with the comments submitted by our national trade associations: America's Health Insurance Plans, American Benefits Council, the Blue Cross Blue Shield Association, and Pharmaceutical Care Management Association. I respectfully refer you to their comment letters for additional recommendations regarding the proposed rules.

We look forward to continuing to work with you and your staff on MMA implementation. If you have any questions, please feel free to contact me at (202) 628-7844 or kristin.bass@wellpoint.com.

Sincerely,

Kristin Bass
Vice President
Federal Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1159

Submitter : Miss. Angela Gresham **Date & Time:** 10/04/2004 08:10:25

Organization : Univ of NC Health Care System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Medication Management Therapy Services and reimbursement for such represent a significant advancement in care for seniors. However, reimbursement rates must be sufficient to cover the direct and indirect costs of providing MTMS whether they are provided by pharmacists or other health care practitioners. The starting salary for a clinical pharmacist who has just completed his/her professional training is currently $80,000 + about 22% of this amount for benefits at the Univ of N.C. HCS. If the avg salary + benefit costs for pharmacists performing MTMS services = $100,000 per year ($48 / hour), then reimbursement rates will have to cover this cost in order for institutions to provide MTMS with pharmacists. Our experience in providing MTMServices to diabetic patients suggests that the minimum patient appointment with a pharmacist will require at least 30 minutes of time for a thorough patient interview, review of systems & labs, physical & medication assessment, optimization of medication therapy + in-depth education of the patient (to include documentation of findings, care plan, education provided, and orders). I suggest that the starting reimbursement rate be at least $24 per 30 minute interval with appropriate increases over time as warranted by inflation, etc. Please do not undermine this important legislation with insufficient reimbursement for MTMS.

CMS-4068-P-1160

Submitter : Mrs. Lisa Stonesifer **Date & Time:** 10/04/2004 08:10:22

Organization : Delaware Pharmacists Society

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please accept comments on behalf of the Delaware Pharmacists Society

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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Submitter : Mr. Patrick Duke **Date & Time:** 10/04/2004 08:10:35

Organization : Mr. Patrick Duke

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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.

I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from the pharmacy provider of their choice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan.s network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in service costs, not the cost of the drug product.
Under Medicare Part D, all rebates, discounts or other price concessions should be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements should be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

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 health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.
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.?

CMS-4068-P-1162

Submitter : Ms. Deborah Groeber **Date & Time:** 10/04/2004 08:10:22

Organization : Private Citizen

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

RE:FUTURE PRESCRIPTION DRUG COSTS OF BRUCE F. GROEBER, JR.,
AN INDIVIDUAL WHO IS DUAL MEDICARE-MEDICAID ELIGIBLE

To Whom It May Concern:

I would appreciate it if you would kindly consider the attached comments in making your decision. Please telephone me at 215-517-7444 with any questions, concerns or issues accessing the attached. Thank you for your consideration in this important matter.

Deborah G. Groeber

CMS-4068-P-1162-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1163

Submitter : Ms. Kerry Korpi **Date & Time:** 10/04/2004 08:10:03

Organization : AFSCME

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

see attached file

CMS-4068-P-1163-Attach-1.doc

CMS-4068-P-1164

Submitter : Miss. Heather Olson **Date & Time:** 10/04/2004 08:10:38

Organization : Iowa Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find IHA's comments on the Medicare proposed rule to implement the Prescription Drug Benefit.

Heather

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1165

Submitter : Mr. Stephen Schmahl **Date & Time:** 10/04/2004 08:10:08

Organization : Coram Healthcare

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see my comments in the attached MS Word document

CMS-4068-P-1165-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1166

Submitter : Dr. Agnes Lo **Date & Time:** 10/04/2004 08:10:46

Organization : Dr. Agnes Lo

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Please see attached document.

CMS-4068-P-1166-Attach-1.pdf

CMS-4068-P-1167

Submitter : **Date & Time:** **10/04/2004 08:10:31**

Organization : **Center on Budget and Policy Priorities**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Please find attached our comments to the proposed regulations for the Medicare Prescription Drug Benefit (CMS-4068-P).

Sincerely,

Center on Budget and Policy Priorities
820 First Street, N.E. Suite 510
Washington, DC 20002
(202) 408-1080

CMS-4068-P-1167-Attach-1.doc

CENTER ON BUDGET AND POLICY PRIORITIES

820 First Street, NE, Suite 510, Washington, DC 20002
Tel: 202-408-1080 Fax: 202-408-1056 center@cbpp.org www.cbpp.org

October 4, 2004

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

Subject: Comments on Medicare Prescription Drug Benefit Proposed Rule
(*69 Fed. Reg. 46632-46863,* August 3, 2004)

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulations that implement the new Medicare Prescription Drug Benefit enacted in last year's Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Center on Budget and Policy Priorities is a non-profit policy organization that works at the federal and state levels on fiscal policy and public programs that affect low- and moderate-income families and individuals. Our comments here focus on the new Part D benefit as it will apply to low-income Medicare beneficiaries including those who are dually eligible for both Medicare and Medicaid.

One key issue that we believe has not received appropriate attention in the proposed regulations is the historic opportunity the new drug benefit offers in improving enrollment in various public programs such as food stamps for which many low-income elderly and disabled beneficiaries are eligible. We believe that it is important that the regulation ensures that eligible beneficiaries are connected to other benefits for which they are likely to be eligible. We recognize that one agency, the Centers for Medicare & Medicaid Services (CMS) is promulgating this regulation and that the regulation relates to programs under its purview. But, in addition to Medicare, full Medicaid, and the Medicare Savings Programs for which CMS is responsible, other programs like food stamps, SSI and Social Security are the linchpins of federal support for the members of our society who are aging or experience a disability. This low-income Medicare population cannot be expected to navigate overly complicated enrollment procedures. To the extent that the government as a whole fails to coordinate these benefits, it is failing a very vulnerable population.

In addition, as noted by numerous other groups concerned with the dual eligibles and low-income Medicare beneficiaries, we find that the regulation falls short in many other areas especially in transitioning the dual eligibles from Medicaid drug coverage to the new Medicare drug benefit, ensuring that dual eligibles have access to the drugs they need, and in the processes that are envisioned for enrolling low-income beneficiaries in the low-income subsidies.

Please find below our general comments to the proposed regulations on these issues. Please note that we have also submitted more comprehensive comments along with other groups. These comments were submitted by Families USA.

Sincerely,

Robert Greenstein Executive Director	Edwin Park Senior Health Policy Analyst	Dorothy Rosenbaum Senior Policy Analyst

cc: Eric M. Bost, Under Secretary for Food, Nutrition, and Consumer Services, U.S. Department of Agriculture

Jo Anne B. Barnhart, Commissioner, Social Security Administration

I. General Comments on Improved Coordination with Other Programs Like Food Stamps

A. Background

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Medicare Part D benefit will also be eligible for food stamps. The MMA and the proposed rule provide that applications for the Part D low-income subsidy may be filed with either a State's Medicaid program or with the Social Security Administration (SSA). The proposed rule has very little detail, however, about how the application process is likely to work. Because so many people who are eligible for but not participating in food stamps are likely to apply for the Part D subsidy, this application process presents an historic opportunity to connect eligible seniors and people with disabilities to the Food Stamp Program.

Many Medicare Beneficiaries Who Are Eligible for Part D Subsidies Also Are Eligible for Food Stamps

Many of the low-income Medicare beneficiaries who will be eligible for — and apply for — the new low-income drug subsidies that the prescription drug law provides are eligible for food stamps but not enrolled. A Medicare beneficiary will be eligible for some additional subsidy under Part D if his or her income, together with the income of any spouse who is present, is below 135 percent of the federal poverty level. The asset limit for the Part D low-income subsidy will be $6,000 for single beneficiaries and $9,000 for married couples. (Those with incomes below 150 percent of the poverty line with assets below $10,000 for individuals and $20,000 for couples receive a smaller low-income subsidy).

Food stamp eligibility rules are very similar — the universe of food stamp-eligible Medicare beneficiaries is a subset of the Part D-eligible population. Specifically, to be eligible for food stamps a household must have *net* income, after all available deductions are taken into account, below the federal poverty level and assets, not including a primary residence, personal items, and an automobile in most states, must be below $3,000.

Deductions play an important role in food stamp eligibility and benefit levels by taking into account certain household expenses in determining the amount of income that is available to purchase food. In practice, this means that a Medicare beneficiary could have gross income somewhat above the poverty level and still be eligible for food stamps. For the elderly and people with disabilities, the most important deductions are: a *medical expense deduction* for out-of-pocket medical expenses greater than $35 a month; a *dependent care deduction*, for expenses of up to $175 a month for adults who need care; and a *shelter deduction*, for households that have high shelter costs (including mortgage, rent, taxes, insurance, and utility expenses) in relation to their income.

The primary difference between the Part D subsidy eligibility and food stamp eligibility is the definition of who is considered in the family unit. For the Part D subsidy, only the Medicare beneficiary and his or her spouse, if present, will be considered unless there are related dependents who rely on the individual or his or her spouse for at least one-half of their financial support. For food stamps a household consists of individuals who live together and who purchase and prepare meals together. So in some instances where Medicare beneficiaries live

with others, the food stamp unit will include more people than the Part D family unit. USDA finds, however, that about half of elderly people who are eligible for food stamps but do not participate live alone, so in many cases there will be no difference.

Seniors and People With Disabilities Have Low Food Stamp Participation Rates, Despite Being Eligible for Sizable Benefits

Very low-income elderly and individuals with disabilities — those with annual incomes below about 75 percent of the poverty line (which is $6,788 for an individual and $8,554 for a couple) — are fairly well connected to the safety net; they are generally eligible for cash assistance under the Supplemental Security Income (SSI) Program and health coverage under Medicaid. The majority of these very low-income individuals do participate in food stamps.

But low-income elderly and individuals with disabilities with incomes above this level — including many such people who live below the poverty line — generally do not qualify for SSI or Medicaid, and although they are eligible for food stamps, they often are not enrolled. Overall, the program serves only about a quarter of eligible elderly people and just under half of the population of eligible adults with disabilities. In total, USDA estimates that there are over 6 million seniors and adults with disabilities who are eligible for food stamps but do not receive them.[1] Of course, Medicare beneficiaries who are not receiving SSI or Medicaid are the people who will be applying for the Part D benefit through SSA or state or local offices.

For many low-income Medicare beneficiaries, Social Security benefits bring them close to or modestly above the poverty line. For such households who do not have high expenses — for example, because they live in public housing and have no out-of-pocket medical costs — the food stamp benefit for which they qualify can be relatively low, perhaps only $10 a month. If, however, such a household has high shelter expenses, out-of-pocket medical expenses, or dependent care expenses, its monthly food stamp benefit will be significantly higher. The average Social Security recipient who has medical expenses and receives food stamps qualifies for about $50 a month in benefits. A typical household with members who are elderly or disabled and very high deductions can receive close to $90 a month or more in food stamps. Outreach messages that SSA or states use may be more useful if they explain that households with high expenses will qualify for more food stamps.

Current Responsibilities of SSA and States Make Them Appropriate to Play a Role in Enrolling Medicare Beneficiaries in Food Stamps

The states and SSA each currently have responsibilities related to the Food Stamp Program. Although food stamp benefits are 100 percent federally-funded and many of the program's eligibility and benefit rules are set by federal rules, the states have primary responsibility for virtually all aspects of the administration of the program (as they do with Medicaid), including outreach, certification and enrollment, issuance, and on-going case management. States receive a 50 percent federal match for administrative costs related to food

[1] For the Food Stamp Program an individual is considered to be elderly upon turning 60. So this figure somewhat overstates the number who would also be Medicare beneficiaries.

stamps. With only a handful of exceptions, the same local agency or local office that processes Medicaid applications also determines food stamp eligibility.

The Food Stamp Act envisions that SSA will play an important role in informing seniors and people with disabilities about food stamps. Under section 11(j)(1) of the Food Stamp Act, Social Security and SSI applicants and recipients are to be "informed of the availability of a simple application to participate in [the food stamp] program at the social security office." Section 11(j)(2) of the Food Stamp Act further requires SSA to "forward immediately" to state agencies food stamp applications from households where all members are applicants for or receive SSI. Finally, section 11(j)(2)(C) provides that the Secretary of Agriculture will reimburse the Commissioner of Social Security for any costs associated with these activities. To be clear, this means that food stamps, an entitlement with open-ended funding, can fully reimburse SSA for these food stamp-related activities without Congress needing to appropriate additional funds. (See 7 U.S.C. § 2020(j) — attached.)

Unfortunately, to our knowledge, SSA and USDA are largely out of compliance with Section 11(j)(2) of the Food Stamp Act. There is no uniform simple application currently available at social security offices for applicants or recipients to use to apply for food stamps. Not many social security offices make much effort to inform Social Security or SSI applicants about the availability of food stamps. Nationwide, the total amount that SSA received from USDA for these activities was less than $10 million in fiscal year 2003.

One promising exception is the "Combined Application Projects," or CAPs, that have been implemented in four states (Mississippi, New York, South Carolina, and Washington) in the past decade. In the CAP states, for SSI applicants who live alone, SSA provides a shortened food stamp application form with just a couple of additional questions to what the SSI application gathers. Data from the SSA application and interview are transferred to the food stamp agency, and food stamp benefits are determined without the applicant having to take any further action. (See http://www.fns.usda.gov/fsp/government/caps.pdf.) SSA has agreed to allow three additional states (Florida, Massachusetts, and Pennsylvania) to adopt this model but has declined to make the option available nationwide.

B. Comments on Subpart P Section 423.774 and Subpart S Section 423.904

The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to food stamps and other assistance programs that might help them make ends meet. We urge you in the final regulation, and through other implementation decisions, to set up an eligibility process for the Part D low-income subsidy that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other state- or SSA-administered benefits for which they may qualify. This will require CMS to work collaboratively with SSA, USDA, and state agencies. Below are some specific opportunities that we see.

- **Provide information about food stamps and other major benefits for which applicants may be eligible in any outreach materials that CMS, SSA, and state Medicaid programs design and distribute.** CMS and SSA are planning

large-scale information and outreach efforts in the lead-up to the Medicare drug benefit going into effect. Mailings, on-line resources, and other materials that are made available to low-income Medicare beneficiaries and to groups that work with such beneficiaries could easily include information about the availability of food stamps and how to apply. USDA has developed an on-line prescreening tool at http://209.48.219.49/fns/.

- **Design procedures that allow applications that are filed and other information that applicants provide to be shared between SSA, state agencies, and CMS so that it is available to all agencies.** Such data sharing would allow states to target follow-up outreach to applicants who appear to be eligible for other programs, such as food stamps. For example, states could use the information that applicants provide to them or SSA for the drug benefit to automatically fill out significant sections of a food stamp application. The state could then mail the application to the elderly individual asking him or her simply to fill in the remaining questions and mail the application back, without having to come to the food stamp office.

- **Collaborate with other federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs.** The three agencies should seek to simplify federal program rules so that low-income Medicare beneficiaries can readily access all programs for which they qualify. A model may be the SSA Combined Application Projects that now operate in a handful of states, where SSI applicants are asked only a couple of additional questions and are certified automatically for food stamps based on their SSI applications. The standardized federal rules under these projects have allowed SSI applicants who live alone to apply for food stamps with significantly less burden than would otherwise be required.

- **Develop coordinated redetermination processes that are as simple as possible for Medicare beneficiaries.** Under the regulation, CMS seems to envision that once the Part D benefit is underway, Medicare beneficiaries will have their eligibility redetermined annually. It appears that a beneficiary who receives a Part D subsidy, is a QMB, and also receives food stamps would have to reapply separately for these three benefits at different times and would potentially have to provide virtually all of the same information to three different entities. This is an unreasonable burden for a poor senior or individual with a disability who may find it difficult and confusing to navigate three separate processes. In addition, this population tends to have relatively stable income and other circumstances. One option would be for SSA and state agencies to renew Part D eligibility based on information the beneficiary has provided for other programs, such as food stamps, if it is current. Many states have successfully used this type of “passive renewal” procedure in their Medicaid and State Children’s Health Insurance Programs (SCHIP).

- **USDA can reimburse SSA for the food stamp program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.** This could include, for example, outreach mailings to Medicare beneficiaries or costs associated with making computerized information available to states.

II. General Comments on Other Proposed Regulations

A. Comments on Subpart B — Eligibility and Enrollment

Enrollment of Dual Eligibles in Medicare Part D Plans

The proposed regulations fail to address adequately how responsibility for providing drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the full dual eligibles) will be appropriately transferred from Medicaid to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of instituting the enrollment process. The proposed regulations do not adequately address these issues in a way that would ensure that these 6.4 million dually eligible beneficiaries avoid a potential loss of drug benefits or a gap in drug coverage, either of which could have unfortunate health consequences for these individuals.

According to the preamble, automatic enrollment of dual eligibles as required under section 423.34(d) will not begin until the end of the initial enrollment period on May 15, 2006. However, the Medicaid drug benefit for dual eligibles will no longer be available on January 1, 2006. (Federal Medicaid matching funds will no longer be available for providing outpatient drug coverage to the dual eligibles after January 1, 2006.) Given the difficulty of appropriately educating this population about Part D plan choices, it is a near certainty that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and the scheduled automatic enrollment. This likely scenario would directly contravene Members of Congress' and the Administration's commitment that dual eligibles will be better off under Medicare Part D (or at least not be made worse off). The most appropriate solution would be to delay the cut-off of federal Medicaid matching funds to allow more adequate time to ensure an effective transition of the dual eligibles from Medicaid to the new Medicare Part D benefit. However, that would likely require statutory changes to the MMA. At the very least, CMS needs to encourage large-scale education efforts targeted to the dual eligibles by states and other organizations and allow for an earlier auto-enrollment deadline prior to January 1, 2006 to avoid gaps in coverage for the dual eligibles.

In the preamble, CMS requests comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials are familiar with the needs of their dual eligible populations and have more data readily available on the dual eligibles in their state. They also will already be involved in the enrollment process because they are required to perform low-income subsidy enrollment; therefore, we recommend that states have the option of performing automatic enrollment. (We are concerned that under section 1860D-1(b)(1)(C) of the MMA and section 423.34(d)((2) of the proposed regulations, the auto enrollment must be conducted on a random basis, which may limit the ability of states that are conducting this auto

enrollment from moving dual eligibles to the plan that provides the greatest access to drugs. This too may require further statutory changes)

We are also extremely concerned with ensuring continuity of care for dual eligibles who have substantial drug needs. As discussed below in our comments on the need for special open formularies for the dual eligible population, for example, a disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications.

As outlined in the proposed regulations, dual eligibles would be forced to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because, under the low-income subsidy, they will receive only a premium subsidy up to the cost of the premium for these plans. They will not receive additional premium subsidies for plans with premiums higher than the premium cost of a benchmark plan. The formularies for these plans, however, may not be as comprehensive as the drug coverage that these individuals currently have through Medicaid.

Without access to the coverage they need, dual eligibles may be forced to switch medications. In the treatment of HIV/AIDS, for example, such switches can be highly problematic and potentially deadly. We believe the same is true for a number of other illnesses and categories. Not ensuring continuity of care for prescription drugs for the dual eligibles could increase the costs of their care; dual eligibles with restricted access to drugs could end up requiring expensive services like hospitalization.

The regulations do provide a special enrollment period for full dual eligibles to use "at any time" (section 423.36). However, this provision of the regulations does not adequately address the needs of dual eligibles. There may not be adequate choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare managed care plans in the past. In addition, the dual eligibles are unlikely to have income or resources to pay the additional premiums (in addition to the low-income subsidy) necessary to enroll in higher cost plans that may have more comprehensive drug coverage and greater access to drugs. Moreover, the special enrollment provisions under section 423.36 do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment results in a gap in coverage of more than 63 days.

In addition, full benefit dual eligibles (and their personal representatives) should receive a notice explaining their right to a special enrollment period both when they enroll in a plan and each time the prescription drug plan changes its coverage in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

In the preamble to the proposed regulations, CMS points to the exceptions process as a means of securing coverage of off-formulary medications. But the process proposed is extremely complex and will likely be impossible to navigate for people having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy, to list just a few examples. Moreover, the timelines established are drawn out; an expedited determination could

take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request.

Congress and the Administration have promised that dual eligible beneficiaries would be better off with this new Part D drug benefit (or at least no worse off) than they were receiving drug coverage through Medicaid. To honor this commitment, coverage of medications currently available to dual eligibles and other special populations under Medicaid must be grandfathered into the new Part D benefit just as a number of states (such as Wisconsin, Oregon, Kentucky, Texas and California) have done in implementing preferred drug lists under their Medicaid programs. For dual eligibles (and for others with life-threatening diseases such as HIV/AIDS, mental illness, cancers, and other extreme conditions), Part D plans should be required to cover their existing medications. At a minimum, this protection should be given to dual eligibles, because it is likely to be impossible for dual eligibles to enroll in more generous drug plans by paying supplemental premiums or paying for off-formulary drugs on an out-of-pocket basis.

B. Comments on Subpart C —Benefits and Beneficiary Protections

Special Formulary Protections for Dual Eligibles

Section 423.120(b) outlines the requirements on Part D prescription drug plans and on Medicare Advantage plans for their drug formularies. We strongly support the suggestion in the preamble to the proposed rule that certain populations require special treatment due to their unique medical needs. Such populations include full dual eligibles as well as institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and must be protected from tiered cost-sharing that could create insurmountable access barriers. We recommend that the final rule provide for alternative, flexible formularies for special populations that include coverage for all FDA-approved covered Part D drugs with a valid prescription. Furthermore, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations ought to be made available at the preferred level of cost-sharing for each drug.

In enacting the MMA, Members of Congress and the Administration committed to the principle that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off (or at least not be made worse off) when their coverage for prescription drugs shifted from Medicaid to the new Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under section 1927 of the Social Security Act, states that elect to provide prescription drug coverage under their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products that the states cover. All drug manufacturers currently participate in the Medicaid rebate program.

Dual eligibles are the most vulnerable Medicare beneficiaries. Dual eligibles are people with disabilities and other serious conditions who tend to need a wide variety of prescription drugs. They are more than twice as likely to be in fair or poor health as other Medicare beneficiaries; they are three times more likely to have problems with Activities of Daily Living (ADLs) as other beneficiaries; and they are ten times more likely to be in a long-term care facility than other beneficiaries. In serving dual eligibles, Medicare prescription drug plans must be able to respond to a range of disabilities and conditions, such as physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as Parkinson's disease and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

This will particularly be the case for many of the dual eligibles who reside in nursing facilities and other residential facilities. Such institutionalized beneficiaries require access to flexible formularies on the basis of their complex and multiple prescription drug needs.

Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, if the final rule permits a more restrictive alternative formulary, it should ensure that all drugs included on the formulary of participating Long-Term Care (LTC) pharmacies are included in the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies should be treated by the plan as a preferred drug. Institutionalized individuals also have little or no capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provide strong protections that prevent such individuals from being charged cost-sharing. For dual eligibles who reside in institutions, a condition of eligibility requires them to pledge all but a nominal personal needs allowance, usually $30 per month, to the cost of the institutional care. (We note that individuals who require an institutional level of care but live in the community under home- and community-based Medicaid waivers should have the same special protections as institutionalized beneficiaries because of their similar substantial need for prescription drugs. Otherwise, providing greater access to drugs for institutionalized individuals than to those living in the community would have the adverse effect of reversing the continued progress states have made in moving people from nursing homes to the community setting.)

C. Comments on Subpart P — Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Automatic Eligibility and Enrollment of Dual Eligibles for Low-Income Subsidy

Section 423.773 of the proposed regulations states that both full benefit dual eligibles (as well as Medicare Savings Program beneficiaries, as discussed below) are *eligible* for the additional low income subsidies, but it does not explicitly state that these beneficiaries are to be automatically *enrolled* in the subsidy program. The regulations should clarify that an individual treated as a full subsidy individual (such as a dual eligible or a MSP beneficiary) does not have to take any further action with respect to the subsidy (i.e., to make application or in any other to way verify their status), except to the extent that they need to enroll in a Part D plan. This will

help smooth the transition from Medicaid drug coverage for dual eligibles and should improve participation for others.

Treatment of Resources

Under section 423.772, we support the proposed regulation's limitation of countable resources to liquid assets only. However, the definitions of liquid assets and what it means for an asset to be able to be converted into cash in 20 days need to be clarified. The final rule should enumerate the list of countable resources that constitute liquid assets to promote clarity for states and beneficiaries. The scope of countable liquid assets should be construed narrowly, as experience under the MSP programs shows that assets tests tend to discourage enrollment and raise administrative costs for states. Experience among the states with MSPs has shown that when states waive the assets test or make it more reasonable by excluding, for example, burial plots, burial funds and life insurance from the list of countable assets, enrollment in MSP increases, with the additional costs of enrollment at least partly offset by administrative savings.

Moreover, it is harsh and inappropriate to deny an applicant the low-income drug benefit because the applicant will not liquidate a life insurance policy or burial fund. We are especially troubled by an SSA draft of the application for the low-income subsidy that asks whether an applicant has life insurance with a face value of $1,500 or more. Such a policy should not be acceptable; low-income elderly people and people with disabilities should not be disqualified from the low-income drug benefit because they have a modest life insurance policy that is intended to cover their funeral and burial costs when they die. The Food Stamp Program, for example, entirely excludes the value of a life insurance policy from its asset test. At most, the only part of a life insurance policy that should be considered is the cash surrender value to the extent that the value exceeds some much more reasonable amount, such as $20,000.

In addition, retirement accounts such as a 401(k) plan or IRA should either be fully exempt for all beneficiaries, or fully exempt for disabled Medicare beneficiaries up to age 65, with an assumed annuity value, based on the account, considered as income for all beneficiaries aged 65 and over. If calculating an annuity value would be too complicated, a simplified approach could be used, under which a fixed percentage of such an account is treated as income each year, based on Census (or other official) life expectancy tables. In other words, if a person aged 65 is assumed to live 20 years based on the life expectancy tables, five percent of the amount in the individual's 401 (k) or IRA would be counted as income each year. These accounts would *not* be counted as assets.

This is a much fairer and more rational approach. To count such accounts as assets and disqualify people with modest account balances would undercut efforts to encourage low- and moderate-income people to build some savings that can ease their poverty throughout their old age. Counting these accounts as assets for disabled beneficiaries who are below retirement age also may reduce work incentives. If such accounts are counted as assets, such individuals may be forced to liquidate modest retirement accounts. It would be far better to preserve such accounts so that the prospect of enlarging them if an individual with a disability can return to work may operate as a work incentive.

Counting the amounts in such accounts as assets is inappropriate. Such accounts are supposed to help support these people throughout their old age. Counting such accounts as assets implies that the accounts should be emptied out now to help pay for prescriptions, with the individual then left deeper in poverty for the rest of his or her life.

(Finally, we would note that the draft SSA application contains a problematic and confusing treatment of "annuities," which the application says should be treated as an asset rather than as income. The term "annuity" is popularly used for a range of financial instruments, including "life-time annuities." And an individual with a life-time annuity *no longer owns the underlying assets*. Such an individual has essentially sold the assets to the annuity company in return for a stream of income in the form of a guaranteed monthly payment for the rest of the individual's life. In these cases, it is wholly inappropriate to count the value of the underlying assets against the asset test; the individual no longer owns the assets and has no legal access to them. Furthermore, in these cases, the monthly payments that such an individual receives from the annuity company clearly ought to be counted as income. The draft SSA application is likely to lead to confusion and erroneous determinations in this area.)

Treatment of MSP Beneficiaries by SSA

We strongly support the decision reflected in section 423.773(c) to deem Medicare Savings Program ("MSP") beneficiaries automatically eligible for the low-income subsidy. This would greatly ease the administrative burden on states and SSA while also ensuring that many more MSP beneficiaries enroll in the low-income subsidy.

We are concerned, however, that MSP beneficiaries are likely to be treated differently depending on whether they apply for the low-income subsidy through Medicaid or through a SSA office. Inequities and confusion among beneficiaries may result because SSA would apply its standard for assets which may be less generous than the asset eligibility rules for MSPs in place in some states. For example, Alabama, Arizona, Delaware, and Mississippi have eliminated the assets test under the MSP programs. Eligibility requirements for the low-income subsidy should be as generous at the SSA office for subsidy-eligible individuals as at a Medicaid office, regardless of where and how people apply within the same state. Under the proposed rules, in states that have adopted less restrictive asset methodologies, people whose assets are slightly above the limits set in section 423.773 would likely be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in section 423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy when they are more generous than under the national standard, an option discussed, though rejected, in the preamble at page 46,727. This means that for applicants from states that have eliminated the asset test or have more generous disregards under section 1902(r)(2) of the Social Security Act for MSP eligibility, SSA should apply the state's more generous rules to determine eligibility if applicable. This option is

permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. (We note that the statute should be amended to allow SSA to also apply state-specific income eligibility rules when they are more generous as well.)

The regulations should also provide that subsidy applicants who appear to have excess assets *or* incomes either be screened by SSA for eligibility in an MSP program or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, be deemed automatically eligible for the low-income subsidy under section 423.773(c) and then be enrolled in the appropriate low-income subsidy. Adopting this policy, which is not precluded by the statute, will ensure that all subsidy applicants are treated equitably and in a manner most favorable to the applicants, as well as increase participation in MSPs.

As part of this policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as it is possible that a few applicants may not wish to participate in an MSP. Under Section 1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet the eligibility requirements for an MSP but who decline to enroll in the program should still be made automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs) and other community-based organizations.

In addition, we suggest that states not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective but can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP. We include the same suggestion in our comments to section 423.904(c) discussed below.

D. Comments on Subpart S — Special Rules for States — Eligibility Determinations for Subsidies and General Payment Provisions

State Medicaid Screening for Medicare Savings Programs

We believe that section 423.904(c) of the proposed regulations regarding states' obligations to screen subsidy applicants and offer them enrollment in MSPs is inadequate. In particular, proposed section 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing further documentation or completing additional

forms. Only if enrollment is easy and convenient would Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because enrollment in an MSP may be the only entry into the subsidy for some low-income beneficiaries, a simple and easy application for MSP programs is essential.

As written, section 423.904(c) would permit states to say they have "offered enrollment" if they tell applicants that they might be eligible for an MSP and can return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen-and-enroll provision included in the new Section 1935(a)(3) of the Social Security Act that was established in Section 103(a) of the statute. The low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would make enrollment in an MSP another way to qualify for the low-income subsidy.

Moreover, it is critical that state Medicaid offices provide good quality counseling to applicants, including their potential eligibility for other benefits such as MSPs. In addition, to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, if they are more generous than the MSP standards used in the individual state, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would simply be forwarded to SSA for the actual eligibility determination for the low-income subsidy, the regulations should be clear that screening for MSP eligibility must take place prior to the transmittal of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs until after SSA processes their low-income subsidy application and provides such information back to the state Medicaid offices (if SSA in fact does so). Furthermore, an individual cannot be told by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be highly problematic for an individual to receive a notice from SSA that he or she is ineligible for the low-income subsidy, have her MSP eligibility determined by the state, and then receive a notice from the state that she is eligible for both MSP and the subsidy. Alternatively, the individual may be found ineligible for the low-income subsidy by SSA and subsequently enrolled in a MSP but never redetermined for eligibility for the low-income subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, SSA should also screen subsidy applicants for eligibility in MSPs and develop a system with states to enroll eligible beneficiaries. SSA should use the income and resource

disregards used by the state for MSPs, if they are more generous than under the uniform national definition. Applicants should not miss out on the opportunity to enroll in MSPs simply because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above would apply to enrollment through SSA.

State Medicaid Screening and Enrollment for Full Medicaid

We believe that the regulations should also ensure that beneficiaries are screened not only for MSPs but also for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. § 435.404. Ideally, all subsidy applicants would be screened for full Medicaid and offered enrollment if they qualify (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program described in 42 C.F.R. § 457.350, and in particular for states that use separate SCHIP applications as described in 42 C.F.R. § 457.350(f)(3)). Because the importance of maintaining a simple application process for the low-income subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

ATTACHMENT
Food Stamp Act [7 U.S.C. § 2020(j)] on SSA's responsibilities

Section 11(j) of the Food Stamp Act:

(1) Any individual who is an applicant for or recipient of supplemental security income or social security benefits (under regulations prescribed by the Secretary in conjunction with the Commissioner of Social Security) shall be informed of the availability of benefits under the food stamp program and informed of the availability of a simple application to participate in such program at the social security office.
(2) The Secretary and the Commissioner of Social Security shall revise the memorandum of understanding in effect on the date of enactment of the Food Security Act of 1985, regarding services to be provided in social security offices under this subsection and subsection (i), in a manner to ensure that—
(A) applicants for and recipients of social security benefits are adequately notified in social security offices that assistance may be available to them under this Act;
(B) applications for assistance under this Act from households in which all members are applicants for or recipients of supplemental security income will be forwarded immediately to the State agency in an efficient and timely manner; and
(C) the Commissioner of Social Security receives from the Secretary reimbursement for costs incurred to provide such services.

CENTER ON BUDGET AND POLICY PRIORITIES

820 First Street, NE, Suite 510, Washington, DC 20002
Tel: 202-408-1080 Fax: 202-408-1056 center@cbpp.org www.cbpp.org

October 4, 2004

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

Subject: Comments on Medicare Prescription Drug Benefit Proposed Rule
(*69 Fed. Reg. 46632-46863,* August 3, 2004)

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulations that implement the new Medicare Prescription Drug Benefit enacted in last year's Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Center on Budget and Policy Priorities is a non-profit policy organization that works at the federal and state levels on fiscal policy and public programs that affect low- and moderate-income families and individuals. Our comments here focus on the new Part D benefit as it will apply to low-income Medicare beneficiaries including those who are dually eligible for both Medicare and Medicaid.

One key issue that we believe has not received appropriate attention in the proposed regulations is the historic opportunity the new drug benefit offers in improving enrollment in various public programs such as food stamps for which many low-income elderly and disabled beneficiaries are eligible. We believe that it is important that the regulation ensures that eligible beneficiaries are connected to other benefits for which they are likely to be eligible. We recognize that one agency, the Centers for Medicare & Medicaid Services (CMS) is promulgating this regulation and that the regulation relates to programs under its purview. But, in addition to Medicare, full Medicaid, and the Medicare Savings Programs for which CMS is responsible, other programs like food stamps, SSI and Social Security are the linchpins of federal support for the members of our society who are aging or experience a disability. This low-income Medicare population cannot be expected to navigate overly complicated enrollment procedures. To the extent that the government as a whole fails to coordinate these benefits, it is failing a very vulnerable population.

In addition, as noted by numerous other groups concerned with the dual eligibles and low-income Medicare beneficiaries, we find that the regulation falls short in many other areas especially in transitioning the dual eligibles from Medicaid drug coverage to the new Medicare drug benefit, ensuring that dual eligibles have access to the drugs they need, and in the processes that are envisioned for enrolling low-income beneficiaries in the low-income subsidies.

Please find below our general comments to the proposed regulations on these issues. Please note that we have also submitted more comprehensive comments along with other groups. These comments were submitted by Families USA.

Sincerely,

Robert Greenstein Executive Director	Edwin Park Senior Health Policy Analyst	Dorothy Rosenbaum Senior Policy Analyst

cc: Eric M. Bost, Under Secretary for Food, Nutrition, and Consumer Services, U.S. Department of Agriculture

Jo Anne B. Barnhart, Commissioner, Social Security Administration

I. General Comments on Improved Coordination with Other Programs Like Food Stamps

A. Background

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Medicare Part D benefit will also be eligible for food stamps. The MMA and the proposed rule provide that applications for the Part D low-income subsidy may be filed with either a State's Medicaid program or with the Social Security Administration (SSA). The proposed rule has very little detail, however, about how the application process is likely to work. Because so many people who are eligible for but not participating in food stamps are likely to apply for the Part D subsidy, this application process presents an historic opportunity to connect eligible seniors and people with disabilities to the Food Stamp Program.

Many Medicare Beneficiaries Who Are Eligible for Part D Subsidies Also Are Eligible for Food Stamps

Many of the low-income Medicare beneficiaries who will be eligible for — and apply for — the new low-income drug subsidies that the prescription drug law provides are eligible for food stamps but not enrolled. A Medicare beneficiary will be eligible for some additional subsidy under Part D if his or her income, together with the income of any spouse who is present, is below 135 percent of the federal poverty level. The asset limit for the Part D low-income subsidy will be $6,000 for single beneficiaries and $9,000 for married couples. (Those with incomes below 150 percent of the poverty line with assets below $10,000 for individuals and $20,000 for couples receive a smaller low-income subsidy).

Food stamp eligibility rules are very similar — the universe of food stamp-eligible Medicare beneficiaries is a subset of the Part D-eligible population. Specifically, to be eligible for food stamps a household must have *net* income, after all available deductions are taken into account, below the federal poverty level and assets, not including a primary residence, personal items, and an automobile in most states, must be below $3,000.

Deductions play an important role in food stamp eligibility and benefit levels by taking into account certain household expenses in determining the amount of income that is available to purchase food. In practice, this means that a Medicare beneficiary could have gross income somewhat above the poverty level and still be eligible for food stamps. For the elderly and people with disabilities, the most important deductions are: a *medical expense deduction* for out-of-pocket medical expenses greater than $35 a month; a *dependent care deduction*, for expenses of up to $175 a month for adults who need care; and a *shelter deduction*, for households that have high shelter costs (including mortgage, rent, taxes, insurance, and utility expenses) in relation to their income.

The primary difference between the Part D subsidy eligibility and food stamp eligibility is the definition of who is considered in the family unit. For the Part D subsidy, only the Medicare beneficiary and his or her spouse, if present, will be considered unless there are related dependents who rely on the individual or his or her spouse for at least one-half of their financial support. For food stamps a household consists of individuals who live together and who purchase and prepare meals together. So in some instances where Medicare beneficiaries live

with others, the food stamp unit will include more people than the Part D family unit. USDA finds, however, that about half of elderly people who are eligible for food stamps but do not participate live alone, so in many cases there will be no difference.

Seniors and People With Disabilities Have Low Food Stamp Participation Rates, Despite Being Eligible for Sizable Benefits

Very low-income elderly and individuals with disabilities — those with annual incomes below about 75 percent of the poverty line (which is $6,788 for an individual and $8,554 for a couple) — are fairly well connected to the safety net; they are generally eligible for cash assistance under the Supplemental Security Income (SSI) Program and health coverage under Medicaid. The majority of these very low-income individuals do participate in food stamps.

But low-income elderly and individuals with disabilities with incomes above this level — including many such people who live below the poverty line — generally do not qualify for SSI or Medicaid, and although they are eligible for food stamps, they often are not enrolled. Overall, the program serves only about a quarter of eligible elderly people and just under half of the population of eligible adults with disabilities. In total, USDA estimates that there are over 6 million seniors and adults with disabilities who are eligible for food stamps but do not receive them.[1] Of course, Medicare beneficiaries who are not receiving SSI or Medicaid are the people who will be applying for the Part D benefit through SSA or state or local offices.

For many low-income Medicare beneficiaries, Social Security benefits bring them close to or modestly above the poverty line. For such households who do not have high expenses — for example, because they live in public housing and have no out-of-pocket medical costs — the food stamp benefit for which they qualify can be relatively low, perhaps only $10 a month. If, however, such a household has high shelter expenses, out-of-pocket medical expenses, or dependent care expenses, its monthly food stamp benefit will be significantly higher. The average Social Security recipient who has medical expenses and receives food stamps qualifies for about $50 a month in benefits. A typical household with members who are elderly or disabled and very high deductions can receive close to $90 a month or more in food stamps. Outreach messages that SSA or states use may be more useful if they explain that households with high expenses will qualify for more food stamps.

Current Responsibilities of SSA and States Make Them Appropriate to Play a Role in Enrolling Medicare Beneficiaries in Food Stamps

The states and SSA each currently have responsibilities related to the Food Stamp Program. Although food stamp benefits are 100 percent federally-funded and many of the program's eligibility and benefit rules are set by federal rules, the states have primary responsibility for virtually all aspects of the administration of the program (as they do with Medicaid), including outreach, certification and enrollment, issuance, and on-going case management. States receive a 50 percent federal match for administrative costs related to food

[1] For the Food Stamp Program an individual is considered to be elderly upon turning 60. So this figure somewhat overstates the number who would also be Medicare beneficiaries.

stamps. With only a handful of exceptions, the same local agency or local office that processes Medicaid applications also determines food stamp eligibility.

The Food Stamp Act envisions that SSA will play an important role in informing seniors and people with disabilities about food stamps. Under section 11(j)(1) of the Food Stamp Act, Social Security and SSI applicants and recipients are to be "informed of the availability of a simple application to participate in [the food stamp] program at the social security office." Section 11(j)(2) of the Food Stamp Act further requires SSA to "forward immediately" to state agencies food stamp applications from households where all members are applicants for or receive SSI. Finally, section 11(j)(2)(C) provides that the Secretary of Agriculture will reimburse the Commissioner of Social Security for any costs associated with these activities. To be clear, this means that food stamps, an entitlement with open-ended funding, can fully reimburse SSA for these food stamp-related activities without Congress needing to appropriate additional funds. (See 7 U.S.C. § 2020(j) — attached.)

Unfortunately, to our knowledge, SSA and USDA are largely out of compliance with Section 11(j)(2) of the Food Stamp Act. There is no uniform simple application currently available at social security offices for applicants or recipients to use to apply for food stamps. Not many social security offices make much effort to inform Social Security or SSI applicants about the availability of food stamps. Nationwide, the total amount that SSA received from USDA for these activities was less than $10 million in fiscal year 2003.

One promising exception is the "Combined Application Projects," or CAPs, that have been implemented in four states (Mississippi, New York, South Carolina, and Washington) in the past decade. In the CAP states, for SSI applicants who live alone, SSA provides a shortened food stamp application form with just a couple of additional questions to what the SSI application gathers. Data from the SSA application and interview are transferred to the food stamp agency, and food stamp benefits are determined without the applicant having to take any further action. (See http://www.fns.usda.gov/fsp/government/caps.pdf.) SSA has agreed to allow three additional states (Florida, Massachusetts, and Pennsylvania) to adopt this model but has declined to make the option available nationwide.

B. Comments on Subpart P Section 423.774 and Subpart S Section 423.904

The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries to food stamps and other assistance programs that might help them make ends meet. We urge you in the final regulation, and through other implementation decisions, to set up an eligibility process for the Part D low-income subsidy that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other state- or SSA-administered benefits for which they may qualify. This will require CMS to work collaboratively with SSA, USDA, and state agencies. Below are some specific opportunities that we see.

- **Provide information about food stamps and other major benefits for which applicants may be eligible in any outreach materials that CMS, SSA, and state Medicaid programs design and distribute.** CMS and SSA are planning

large-scale information and outreach efforts in the lead-up to the Medicare drug benefit going into effect. Mailings, on-line resources, and other materials that are made available to low-income Medicare beneficiaries and to groups that work with such beneficiaries could easily include information about the availability of food stamps and how to apply. USDA has developed an on-line prescreening tool at http://209.48.219.49/fns/.

- **Design procedures that allow applications that are filed and other information that applicants provide to be shared between SSA, state agencies, and CMS so that it is available to all agencies.** Such data sharing would allow states to target follow-up outreach to applicants who appear to be eligible for other programs, such as food stamps. For example, states could use the information that applicants provide to them or SSA for the drug benefit to automatically fill out significant sections of a food stamp application. The state could then mail the application to the elderly individual asking him or her simply to fill in the remaining questions and mail the application back, without having to come to the food stamp office.

- **Collaborate with other federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs.** The three agencies should seek to simplify federal program rules so that low-income Medicare beneficiaries can readily access all programs for which they qualify. A model may be the SSA Combined Application Projects that now operate in a handful of states, where SSI applicants are asked only a couple of additional questions and are certified automatically for food stamps based on their SSI applications. The standardized federal rules under these projects have allowed SSI applicants who live alone to apply for food stamps with significantly less burden than would otherwise be required.

- **Develop coordinated redetermination processes that are as simple as possible for Medicare beneficiaries.** Under the regulation, CMS seems to envision that once the Part D benefit is underway, Medicare beneficiaries will have their eligibility redetermined annually. It appears that a beneficiary who receives a Part D subsidy, is a QMB, and also receives food stamps would have to reapply separately for these three benefits at different times and would potentially have to provide virtually all of the same information to three different entities. This is an unreasonable burden for a poor senior or individual with a disability who may find it difficult and confusing to navigate three separate processes. In addition, this population tends to have relatively stable income and other circumstances. One option would be for SSA and state agencies to renew Part D eligibility based on information the beneficiary has provided for other programs, such as food stamps, if it is current. Many states have successfully used this type of “passive renewal” procedure in their Medicaid and State Children’s Health Insurance Programs (SCHIP).

- **USDA can reimburse SSA for the food stamp program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.** This could include, for example, outreach mailings to Medicare beneficiaries or costs associated with making computerized information available to states.

II. General Comments on Other Proposed Regulations

A. Comments on Subpart B — Eligibility and Enrollment

Enrollment of Dual Eligibles in Medicare Part D Plans

The proposed regulations fail to address adequately how responsibility for providing drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the full dual eligibles) will be appropriately transferred from Medicaid to Medicare on January 1, 2006. There are issues both of timing and of the mechanics of instituting the enrollment process. The proposed regulations do not adequately address these issues in a way that would ensure that these 6.4 million dually eligible beneficiaries avoid a potential loss of drug benefits or a gap in drug coverage, either of which could have unfortunate health consequences for these individuals.

According to the preamble, automatic enrollment of dual eligibles as required under section 423.34(d) will not begin until the end of the initial enrollment period on May 15, 2006. However, the Medicaid drug benefit for dual eligibles will no longer be available on January 1, 2006. (Federal Medicaid matching funds will no longer be available for providing outpatient drug coverage to the dual eligibles after January 1, 2006.) Given the difficulty of appropriately educating this population about Part D plan choices, it is a near certainty that a substantial number of dual eligibles will face a several month gap in coverage between the end of Medicaid's drug benefit and the scheduled automatic enrollment. This likely scenario would directly contravene Members of Congress' and the Administration's commitment that dual eligibles will be better off under Medicare Part D (or at least not be made worse off). The most appropriate solution would be to delay the cut-off of federal Medicaid matching funds to allow more adequate time to ensure an effective transition of the dual eligibles from Medicaid to the new Medicare Part D benefit. However, that would likely require statutory changes to the MMA. At the very least, CMS needs to encourage large-scale education efforts targeted to the dual eligibles by states and other organizations and allow for an earlier auto-enrollment deadline prior to January 1, 2006 to avoid gaps in coverage for the dual eligibles.

In the preamble, CMS requests comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials are familiar with the needs of their dual eligible populations and have more data readily available on the dual eligibles in their state. They also will already be involved in the enrollment process because they are required to perform low-income subsidy enrollment; therefore, we recommend that states have the option of performing automatic enrollment. (We are concerned that under section 1860D-1(b)(1)(C) of the MMA and section 423.34(d)((2) of the proposed regulations, the auto enrollment must be conducted on a random basis, which may limit the ability of states that are conducting this auto

enrollment from moving dual eligibles to the plan that provides the greatest access to drugs. This too may require further statutory changes)

We are also extremely concerned with ensuring continuity of care for dual eligibles who have substantial drug needs. As discussed below in our comments on the need for special open formularies for the dual eligible population, for example, a disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications.

As outlined in the proposed regulations, dual eligibles would be forced to enroll (or be automatically enrolled) in the "benchmark" or average cost plans in their areas because, under the low-income subsidy, they will receive only a premium subsidy up to the cost of the premium for these plans. They will not receive additional premium subsidies for plans with premiums higher than the premium cost of a benchmark plan. The formularies for these plans, however, may not be as comprehensive as the drug coverage that these individuals currently have through Medicaid.

Without access to the coverage they need, dual eligibles may be forced to switch medications. In the treatment of HIV/AIDS, for example, such switches can be highly problematic and potentially deadly. We believe the same is true for a number of other illnesses and categories. Not ensuring continuity of care for prescription drugs for the dual eligibles could increase the costs of their care; dual eligibles with restricted access to drugs could end up requiring expensive services like hospitalization.

The regulations do provide a special enrollment period for full dual eligibles to use "at any time" (section 423.36). However, this provision of the regulations does not adequately address the needs of dual eligibles. There may not be adequate choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare managed care plans in the past. In addition, the dual eligibles are unlikely to have income or resources to pay the additional premiums (in addition to the low-income subsidy) necessary to enroll in higher cost plans that may have more comprehensive drug coverage and greater access to drugs. Moreover, the special enrollment provisions under section 423.36 do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment results in a gap in coverage of more than 63 days.

In addition, full benefit dual eligibles (and their personal representatives) should receive a notice explaining their right to a special enrollment period both when they enroll in a plan and each time the prescription drug plan changes its coverage in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

In the preamble to the proposed regulations, CMS points to the exceptions process as a means of securing coverage of off-formulary medications. But the process proposed is extremely complex and will likely be impossible to navigate for people having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy, to list just a few examples. Moreover, the timelines established are drawn out; an expedited determination could

take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request.

Congress and the Administration have promised that dual eligible beneficiaries would be better off with this new Part D drug benefit (or at least no worse off) than they were receiving drug coverage through Medicaid. To honor this commitment, coverage of medications currently available to dual eligibles and other special populations under Medicaid must be grandfathered into the new Part D benefit just as a number of states (such as Wisconsin, Oregon, Kentucky, Texas and California) have done in implementing preferred drug lists under their Medicaid programs. For dual eligibles (and for others with life-threatening diseases such as HIV/AIDS, mental illness, cancers, and other extreme conditions), Part D plans should be required to cover their existing medications. At a minimum, this protection should be given to dual eligibles, because it is likely to be impossible for dual eligibles to enroll in more generous drug plans by paying supplemental premiums or paying for off-formulary drugs on an out-of-pocket basis.

B. Comments on Subpart C —Benefits and Beneficiary Protections

Special Formulary Protections for Dual Eligibles

Section 423.120(b) outlines the requirements on Part D prescription drug plans and on Medicare Advantage plans for their drug formularies. We strongly support the suggestion in the preamble to the proposed rule that certain populations require special treatment due to their unique medical needs. Such populations include full dual eligibles as well as institutionalized populations, persons with life-threatening conditions, and persons with pharmacologically complex conditions. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and must be protected from tiered cost-sharing that could create insurmountable access barriers. We recommend that the final rule provide for alternative, flexible formularies for special populations that include coverage for all FDA-approved covered Part D drugs with a valid prescription. Furthermore, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations ought to be made available at the preferred level of cost-sharing for each drug.

In enacting the MMA, Members of Congress and the Administration committed to the principle that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off (or at least not be made worse off) when their coverage for prescription drugs shifted from Medicaid to the new Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under section 1927 of the Social Security Act, states that elect to provide prescription drug coverage under their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products that the states cover. All drug manufacturers currently participate in the Medicaid rebate program.

Dual eligibles are the most vulnerable Medicare beneficiaries. Dual eligibles are people with disabilities and other serious conditions who tend to need a wide variety of prescription drugs. They are more than twice as likely to be in fair or poor health as other Medicare beneficiaries; they are three times more likely to have problems with Activities of Daily Living (ADLs) as other beneficiaries; and they are ten times more likely to be in a long-term care facility than other beneficiaries. In serving dual eligibles, Medicare prescription drug plans must be able to respond to a range of disabilities and conditions, such as physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as Parkinson's disease and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

This will particularly be the case for many of the dual eligibles who reside in nursing facilities and other residential facilities. Such institutionalized beneficiaries require access to flexible formularies on the basis of their complex and multiple prescription drug needs.

Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, if the final rule permits a more restrictive alternative formulary, it should ensure that all drugs included on the formulary of participating Long-Term Care (LTC) pharmacies are included in the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies should be treated by the plan as a preferred drug. Institutionalized individuals also have little or no capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provide strong protections that prevent such individuals from being charged cost-sharing. For dual eligibles who reside in institutions, a condition of eligibility requires them to pledge all but a nominal personal needs allowance, usually $30 per month, to the cost of the institutional care. (We note that individuals who require an institutional level of care but live in the community under home- and community-based Medicaid waivers should have the same special protections as institutionalized beneficiaries because of their similar substantial need for prescription drugs. Otherwise, providing greater access to drugs for institutionalized individuals than to those living in the community would have the adverse effect of reversing the continued progress states have made in moving people from nursing homes to the community setting.)

C. Comments on Subpart P — Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Automatic Eligibility and Enrollment of Dual Eligibles for Low-Income Subsidy

Section 423.773 of the proposed regulations states that both full benefit dual eligibles (as well as Medicare Savings Program beneficiaries, as discussed below) are *eligible* for the additional low income subsidies, but it does not explicitly state that these beneficiaries are to be automatically *enrolled* in the subsidy program. The regulations should clarify that an individual treated as a full subsidy individual (such as a dual eligible or a MSP beneficiary) does not have to take any further action with respect to the subsidy (i.e., to make application or in any other to way verify their status), except to the extent that they need to enroll in a Part D plan. This will

help smooth the transition from Medicaid drug coverage for dual eligibles and should improve participation for others.

Treatment of Resources

Under section 423.772, we support the proposed regulation's limitation of countable resources to liquid assets only. However, the definitions of liquid assets and what it means for an asset to be able to be converted into cash in 20 days need to be clarified. The final rule should enumerate the list of countable resources that constitute liquid assets to promote clarity for states and beneficiaries. The scope of countable liquid assets should be construed narrowly, as experience under the MSP programs shows that assets tests tend to discourage enrollment and raise administrative costs for states. Experience among the states with MSPs has shown that when states waive the assets test or make it more reasonable by excluding, for example, burial plots, burial funds and life insurance from the list of countable assets, enrollment in MSP increases, with the additional costs of enrollment at least partly offset by administrative savings.

Moreover, it is harsh and inappropriate to deny an applicant the low-income drug benefit because the applicant will not liquidate a life insurance policy or burial fund. We are especially troubled by an SSA draft of the application for the low-income subsidy that asks whether an applicant has life insurance with a face value of $1,500 or more. Such a policy should not be acceptable; low-income elderly people and people with disabilities should not be disqualified from the low-income drug benefit because they have a modest life insurance policy that is intended to cover their funeral and burial costs when they die. The Food Stamp Program, for example, entirely excludes the value of a life insurance policy from its asset test. At most, the only part of a life insurance policy that should be considered is the cash surrender value to the extent that the value exceeds some much more reasonable amount, such as $20,000.

In addition, retirement accounts such as a 401(k) plan or IRA should either be fully exempt for all beneficiaries, or fully exempt for disabled Medicare beneficiaries up to age 65, with an assumed annuity value, based on the account, considered as income for all beneficiaries aged 65 and over. If calculating an annuity value would be too complicated, a simplified approach could be used, under which a fixed percentage of such an account is treated as income each year, based on Census (or other official) life expectancy tables. In other words, if a person aged 65 is assumed to live 20 years based on the life expectancy tables, five percent of the amount in the individual's 401 (k) or IRA would be counted as income each year. These accounts would *not* be counted as assets.

This is a much fairer and more rational approach. To count such accounts as assets and disqualify people with modest account balances would undercut efforts to encourage low- and moderate-income people to build some savings that can ease their poverty throughout their old age. Counting these accounts as assets for disabled beneficiaries who are below retirement age also may reduce work incentives. If such accounts are counted as assets, such individuals may be forced to liquidate modest retirement accounts. It would be far better to preserve such accounts so that the prospect of enlarging them if an individual with a disability can return to work may operate as a work incentive.

Counting the amounts in such accounts as assets is inappropriate. Such accounts are supposed to help support these people throughout their old age. Counting such accounts as assets implies that the accounts should be emptied out now to help pay for prescriptions, with the individual then left deeper in poverty for the rest of his or her life.

(Finally, we would note that the draft SSA application contains a problematic and confusing treatment of "annuities," which the application says should be treated as an asset rather than as income. The term "annuity" is popularly used for a range of financial instruments, including "life-time annuities." And an individual with a life-time annuity *no longer owns the underlying assets*. Such an individual has essentially sold the assets to the annuity company in return for a stream of income in the form of a guaranteed monthly payment for the rest of the individual's life. In these cases, it is wholly inappropriate to count the value of the underlying assets against the asset test; the individual no longer owns the assets and has no legal access to them. Furthermore, in these cases, the monthly payments that such an individual receives from the annuity company clearly ought to be counted as income. The draft SSA application is likely to lead to confusion and erroneous determinations in this area.)

Treatment of MSP Beneficiaries by SSA

We strongly support the decision reflected in section 423.773(c) to deem Medicare Savings Program ("MSP") beneficiaries automatically eligible for the low-income subsidy. This would greatly ease the administrative burden on states and SSA while also ensuring that many more MSP beneficiaries enroll in the low-income subsidy.

We are concerned, however, that MSP beneficiaries are likely to be treated differently depending on whether they apply for the low-income subsidy through Medicaid or through a SSA office. Inequities and confusion among beneficiaries may result because SSA would apply its standard for assets which may be less generous than the asset eligibility rules for MSPs in place in some states. For example, Alabama, Arizona, Delaware, and Mississippi have eliminated the assets test under the MSP programs. Eligibility requirements for the low-income subsidy should be as generous at the SSA office for subsidy-eligible individuals as at a Medicaid office, regardless of where and how people apply within the same state. Under the proposed rules, in states that have adopted less restrictive asset methodologies, people whose assets are slightly above the limits set in section 423.773 would likely be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in section 423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the low-income subsidy.

To resolve this problem, we propose that SSA should apply state-specific asset eligibility rules in determining eligibility for the low-income subsidy when they are more generous than under the national standard, an option discussed, though rejected, in the preamble at page 46,727. This means that for applicants from states that have eliminated the asset test or have more generous disregards under section 1902(r)(2) of the Social Security Act for MSP eligibility, SSA should apply the state's more generous rules to determine eligibility if applicable. This option is

permitted under Section 1860D-14(a)(3)(E)(iv) of the statute. (We note that the statute should be amended to allow SSA to also apply state-specific income eligibility rules when they are more generous as well.)

The regulations should also provide that subsidy applicants who appear to have excess assets *or* incomes either be screened by SSA for eligibility in an MSP program or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, be deemed automatically eligible for the low-income subsidy under section 423.773(c) and then be enrolled in the appropriate low-income subsidy. Adopting this policy, which is not precluded by the statute, will ensure that all subsidy applicants are treated equitably and in a manner most favorable to the applicants, as well as increase participation in MSPs.

As part of this policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as it is possible that a few applicants may not wish to participate in an MSP. Under Section 1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet the eligibility requirements for an MSP but who decline to enroll in the program should still be made automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs) and other community-based organizations.

In addition, we suggest that states not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective but can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP. We include the same suggestion in our comments to section 423.904(c) discussed below.

D. Comments on Subpart S — Special Rules for States — Eligibility Determinations for Subsidies and General Payment Provisions

State Medicaid Screening for Medicare Savings Programs

We believe that section 423.904(c) of the proposed regulations regarding states' obligations to screen subsidy applicants and offer them enrollment in MSPs is inadequate. In particular, proposed section 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing further documentation or completing additional

forms. Only if enrollment is easy and convenient would Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because enrollment in an MSP may be the only entry into the subsidy for some low-income beneficiaries, a simple and easy application for MSP programs is essential.

As written, section 423.904(c) would permit states to say they have "offered enrollment" if they tell applicants that they might be eligible for an MSP and can return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen-and-enroll provision included in the new Section 1935(a)(3) of the Social Security Act that was established in Section 103(a) of the statute. The low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would make enrollment in an MSP another way to qualify for the low-income subsidy.

Moreover, it is critical that state Medicaid offices provide good quality counseling to applicants, including their potential eligibility for other benefits such as MSPs. In addition, to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, if they are more generous than the MSP standards used in the individual state, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would simply be forwarded to SSA for the actual eligibility determination for the low-income subsidy, the regulations should be clear that screening for MSP eligibility must take place prior to the transmittal of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs until after SSA processes their low-income subsidy application and provides such information back to the state Medicaid offices (if SSA in fact does so). Furthermore, an individual cannot be told by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be highly problematic for an individual to receive a notice from SSA that he or she is ineligible for the low-income subsidy, have her MSP eligibility determined by the state, and then receive a notice from the state that she is eligible for both MSP and the subsidy. Alternatively, the individual may be found ineligible for the low-income subsidy by SSA and subsequently enrolled in a MSP but never redetermined for eligibility for the low-income subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, SSA should also screen subsidy applicants for eligibility in MSPs and develop a system with states to enroll eligible beneficiaries. SSA should use the income and resource

disregards used by the state for MSPs, if they are more generous than under the uniform national definition. Applicants should not miss out on the opportunity to enroll in MSPs simply because they apply through SSA rather than state Medicaid offices. The same concerns about beneficiary education and estate recovery discussed above would apply to enrollment through SSA.

State Medicaid Screening and Enrollment for Full Medicaid

We believe that the regulations should also ensure that beneficiaries are screened not only for MSPs but also for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. § 435.404. Ideally, all subsidy applicants would be screened for full Medicaid and offered enrollment if they qualify (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program described in 42 C.F.R. § 457.350, and in particular for states that use separate SCHIP applications as described in 42 C.F.R. § 457.350(f)(3)). Because the importance of maintaining a simple application process for the low-income subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

ATTACHMENT
Food Stamp Act [7 U.S.C. § 2020(j)] on SSA's responsibilities

Section 11(j) of the Food Stamp Act:

(1) Any individual who is an applicant for or recipient of supplemental security income or social security benefits (under regulations prescribed by the Secretary in conjunction with the Commissioner of Social Security) shall be informed of the availability of benefits under the food stamp program and informed of the availability of a simple application to participate in such program at the social security office.
(2) The Secretary and the Commissioner of Social Security shall revise the memorandum of understanding in effect on the date of enactment of the Food Security Act of 1985, regarding services to be provided in social security offices under this subsection and subsection (i), in a manner to ensure that—
(A) applicants for and recipients of social security benefits are adequately notified in social security offices that assistance may be available to them under this Act;
(B) applications for assistance under this Act from households in which all members are applicants for or recipients of supplemental security income will be forwarded immediately to the State agency in an efficient and timely manner; and
(C) the Commissioner of Social Security receives from the Secretary reimbursement for costs incurred to provide such services.

CMS-4068-P-1168

Submitter : **Date & Time:** **10/04/2004 09:10:18**

Organization : **America's Health Insurance Plans**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments

CMS-4068-P-1168-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1169

Submitter : Ms. Stephanie Altman **Date & Time:** 10/04/2004 08:10:20

Organization : Health and Disability Advocates

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Enclosed please find comments and recommendations regarding 42 CFR Parts 403, 411, 417, and 423, the Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule, which was released for comment on August 3, 2004.

CMS-4068-P-1169-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1170

Submitter : Mr. James Jorling **Date & Time:** 10/04/2004 08:10:26

Organization : Affiliated Computer Services, Inc. (ACS)

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Comments are attached.

CMS-4068-P-1170-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

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CMS-4068-P-1171

Submitter : Karen Kaczmarek **Date & Time:** 10/04/2004 08:10:43

Organization : KBK Consulting LLC

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached word document.

CMS-4068-P-1171-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1172

Submitter : **Date & Time:** 10/04/2004 08:10:49

Organization :

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Comments: As a result of the Olmstead decision, states have been moving seniors and persons with SSI benefits from institutions into less restrictive placements. These placements include ICF/MR facilities for the disabled, community care, and assisted living facilities for the aged. In addition to these less restrictive institutional settings, states have implemented waiver programs for home and community based care as an alternative to placement in a nursing home. Medicare beneficiaries spend down their assets until they are forced into nursing homes. These alternatives provide Medicare eligible beneficiaries with a choice of placement. Exclusive contracts with a long term care pharmacy should not be the deciding factor on whether or not to extend the definition of long term care facility to other forms of housing other than traditional nursing homes; the beneficiaries? qualification for Medicare and their placement should be the deciding factor. States can identify Medicare eligible individuals who were institutionalized, and can also identify those individuals that, if it were not for the Olmstead decision or an 1115 waiver, would be institutionalized. These individuals are low income Medicare beneficiaries; having a Medicare prescription benefit at no cost will allow their income to be used for daily living expenses and not on prescriptions.

Comments: The State of Georgia believes that the regulations should be amended to clarify that the above restrictions do not preclude a PDP sponsor or MA organization from adjusting its formulary after the time of its bid (on or before March 1, 2005) and before the initial enrollment period for beneficiaries (November 15, 2005), as long as such adjustments do not have the effect of violating other applicable requirements respecting formularies.

Accordingly the regulations should be clarified to state that, as long as 30 days notice is provided to CMS, such a formulary change is permissible. Specifically, since any such changes would occur prior to the benefit year (e.g., before January 1, 2006), prior to the beneficiary election period (e.g., proper to November 15, 2005), it should be made clear that no notice would be required for affected enrollees, authorized prescribers, pharmacies, and pharmacists (since the plan would not yet be in effect).

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

As PDPs and MA-PDs coordinate benefits with secondary payers, or when drug plans include in their networks certain pharmacies, such as 340B entities, we recognize that a duplicate rebate problem may arise; i.e., a manufacturer may be expected to pay both a rebate negotiated with a Part D drug plan and an additional rebate negotiated or required under a different state or federal program. The risk of manufacturers paying duplicate rebates on the same drug is inevitable if CMS is successful in encouraging supplemental drug coverage by secondary payers. However, while the drug industry?s concern about duplicate discount arrangements is justified, we do not believe that it is the role of the Secretary to address this problem. The Medicare prescription drug benefit relies on market forces to set drug prices, and we believe that market forces will ensure that the matter of duplicate rebates is handled appropriately. Furthermore, we do not believe that the MMA provides CMS with the authority to prohibit duplicate rebate arrangements, and we believe that an attempt by CMS to do so would prove ineffective due to the complex interrelationships of multiple state and federal drug discount programs.

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

Comments: The State of Georgia believes that the regulations should be amended to clarify that the above restrictions do not preclude a PDP sponsor or MA organization from adjusting its formulary after the time of its bid (on or before March 1, 2005) and before the initial enrollment period for beneficiaries (November 15, 2005), as long as such adjustments do not have the effect of violating other applicable requirements respecting formularies.

Accordingly the regulations should be clarified to state that, as long as 30 days notice is provided to CMS, such a formulary change is permissible. Specifically, since any such changes would occur prior to the benefit year (e.g., before January 1, 2006), prior to the beneficiary election period (e.g., proper to November 15, 2005), it should be made clear that no notice would be required for affected enrollees, authorized prescribers, pharmacies, and pharmacists (since the plan would not yet be in effect).

ELIGIBILITY, ELECTION, AND ENROLLMENT

Comments: CMS has solicited comment on the question of whether the federal government (CMS or its contractor) or the States (or their contracted entities) should have responsibility for administering the ?random? automatic enrollment process for full benefit dual-eligible individuals who do not otherwise enroll in an MA-PD or PDP. See 69 Fed. Reg. 46,639 (Aug. 3, 2004). CMS posits that State responsibility for this function might be appropriate because of the States? more immediate access to Medicaid eligibility changes and their experience with random assignments through their Medicaid programs.

The State of Georgia strongly opposes imposing this additional administrative burden, which CMS accurately describes in the Federal Register as ?a new national workload of indeterminate size,? on the States. As a threshold matter, the governing legislation is clear that this responsibility should fall upon the federal government. Section 1860D-1(b)(1)(C) of the Act unambiguously directs that, if there is more than one prescription drug plan available to a full-benefit dual eligible individual who has failed to enroll in a PDP or MA-PD plan, ?[t]he Secretary shall enroll such an individual on a random basis among all such plans in the PDP region? (emphasis added).

Given this express designation of responsibility, neither the Secretary nor CMS has authority, by administrative regulation, to impose responsibility for the auto-enrollment function on the States. The preamble to the proposed rule suggests that administrative costs of auto-enrollment activities by the States might have to be borne, at least in some substantial part, by the States themselves. Moreover, even if administrative costs of carrying out this function were to be fully federally reimbursed (as would be more appropriate, given that the Part D program falls within the federal Medicare program, not the joint state/federal Medicaid program), it would nevertheless constitute a substantial, additional administrative burden on the States that they are not equipped to perform.

As the preamble to the proposed regulation acknowledges, CMS? assumption of the auto-enrollment responsibility will further the goals of national uniformity in, and facilitate federal oversight over, the process. Auto-enrollment will require accurate and timely information flow between CMS and the States in any event. There is no reason to assume that transmission of accurate Medicaid eligibility data from the States to CMS would be inherently any more problematic than transmission of accurate and timely Part D data from CMS to the States. Accordingly, Georgia believes there is no legitimate rationale for transferring to the States an administrative responsibility that Congress clearly indicated should fall upon the federal government.

CMS-4068-P-1173

Submitter : Dr. John Wilhelm **Date & Time:** 10/04/2004 08:10:41

Organization : Chicago Department of Public Health

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on this issue that affects the health and well being of so many Chicagoans.

The Chicago Department of Public Health [CDPH], as the public health authority of the third-largest city in the United States, helps assure that public health needs are addressed and that Chicago residents have access to quality care. CDPH, through its citywide network of 7 primary care, 5 specialty care, and 14 mental health clinics, provides effective, accessible health services to the un- and under-insured and to those from underserved communities. Last year more than 250,000 health care visits and millions of prescription drugs, many of them to Medicare beneficiaries, were provided to patients in CDPH clinics and pharmacies.

Our concerns about the Medicare Part D regulations derive not only from our public health responsibilities but also from our role in providing clinical services. Because we see the results of policy decisions in our clinics each day, we believe that we have a unique perspective about how these regulations will affect those Medicare beneficiaries that are least able to manage them.

CMS-4068-P-1174

Submitter : Dr. Mike Grunske **Date & Time:** 10/04/2004 08:10:28

Organization : Aurora Health Care - St. Luke's Medical Center

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

I write today to offer comments regarding the proposed Medicare Part D rules. As a clinical pharmacist who works in a physician's office, I am deeply concerned with the rules as they are currently proposed. My current job position is an excellent example of how a properly designed Medicare benefit could result in excellent patient care, in a very cost effective manner. As a medication expert, I work in a physician?s office where I do not dispense medications. Rather, I work side-by-side with physicians helping to provide direct patient care to their patients with complicated medication regimens. They refer their patients to me for appointments, where I can help care for their patients with a myriad of conditions: diabetes, hypertension, anticoagulation, smoking cessation, hyperlipidemia, etc. As a medication expert, I have 6 years of collegiate experience (including graduate level work) and pharmacy residency training. I am the medication expert to which my physicians can send their patients for quality, cost-effective pharmaceutical care.

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 community and hospital pharmacists around the nation are being considered. All pharmacists want this program to work.

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

? CMS rules must allow for clinical pharmacists 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.

? CMS rules must allow for COMMUNITY pharmacies and pharmacists participate in MTM as well as be equal level providers of medication related services.

Subpart C: 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 my patients will be able to continue to use the pharmacy of their choosing.

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 primary 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.

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.

CMS-4068-P-1175

Submitter : Miss. Heather Olson **Date & Time:** 10/04/2004 08:10:49

Organization : Iowa Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find IHA's comments on the Medicare proposed rule to implement the Medicare Prescription Drug Benefit.

Heather Olson

CMS-4068-P-1175-Attach-1.doc

October 3, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4069-P
P. O. Box 8014
Baltimore, MD 21244-8014

RE: Medicare Program; Prescription Drug Benefit. Proposed Rule, August 3, 2004 *Federal Register*.

On behalf of the 116 hospitals in Iowa, the Iowa Hospital Association (IHA) appreciates the opportunity to provide comment to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to establish the Medicare Prescription Drug Plan (PDP). In this era of providing health care, medical conditions are primarily treated with prescription drugs, without which many individuals would require hospitalization. The IHA understands the critical need to provide prescription drug coverage to individuals enrolled in the Medicare program and to make the program more consistent with private health care insurance. However, IHA is taking this opportunity to provide a comment to the CMS on its proposed rule to implement this PDP.

Subpart A—Part D Enrollment Process

IHA requests CMS clarify its proposals surrounding provisions involving Medicare and Medicaid dual eligibles, and clearly illustrate any potential negative impact those provisions may have on state Medicaid funding. Iowa, like many states, is in a severe budget crisis and is looking for ways in which to address Medicaid budget shortfalls at a time when enrollment is at its peak with no signs of slowing in the future. In times of economic downturn, the federal government cannot place additional financial burden on states to fund this dually financed health care program. When the Medicaid program suffers financially, the effects are shifted primarily to health care providers and occasionally to beneficiaries who are enrolled in the Medicaid program. **Iowa hospitals have not seen a Medicaid payment increase for the past five years**. IHA opposes any provision that would shift the financial responsibility of the federal government to the states as a result of this Medicare PDP and urge that CMS revisit such provisions.

Thank you for the opportunity to provide comment. Please contact me at 515/288-1955 with any questions regarding IHA's comments.

Sincerely,

Heather Olson
Director, Finance Policy

cc: Iowa Congressional Delegation
IHA Board of Trustees
Iowa Hospitals

CMS-4068-P-1176

Submitter : Ms. Melissa Meekins **Date & Time:** 10/04/2004 08:10:55

Organization : The Ohio State University-Pharmacy Student

Category : Individual

Issue Areas/Comments

Issues 1-10

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

In summary, MTM Programs will be required to be established by plans to provide services that will optimize therapeutic outcomes for the targeted beneficiaries. Pharmacists are the medication experts on the health care team, thus the ideal providers of these MTM services. CMS must clarify that plans cannot require beneficiaries to obtain MTM services from a specific provider, such as a preferred pharmacy. Requiring beneficiaries to obtain MTM services from a specific provider would disrupt existing patient-pharmacist relationships. Plans should also be required to inform pharmacists when their patients are eligible for MTM services. Also, plans should be required to inform beneficiaries when they are eligible to receive MTM services, as well as choices for where to receive MTM services (including the local pharmacies). CMS must also clarify that plans cannot prohibit pharmacists from providing MTM services to non-targeted beneficiaries. Pharmacists should be able to bill patients directly for MTM services, so even if it is not a covered benefit for the non-targeted beneficiaries. As for fees paid by the plan, all providers should receive the same fee for MTM services. For example, the fee should not be different for a preferred versus non-preferred pharmacy. With regard to the services offered, I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004. Thank you for considering my view on these specifics of the MTM Programs.

CMS-4068-P-1177

Submitter : Dr. Christopher Miller **Date & Time:** 10/04/2004 08:10:26

Organization : Integrity Healthcare Services, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1177-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1178

Submitter : Mr. Allen Dallavis **Date & Time:** 10/04/2004 08:10:59

Organization : St. John's Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-4068-P-1178-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1179

Submitter : Dr. Carrie Sorenson **Date & Time:** 10/04/2004 08:10:18

Organization : Dr. Carrie Sorenson

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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 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 highly trained and experienced in MTM and patient access to these professionals is very practical.
Thank you for your consideration.

CMS-4068-P-1180

Submitter : Steve Tucker **Date & Time:** 10/04/2004 08:10:49

Organization : PacifiCare Health Systems, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached are two documents. One is our cover letter. The other is our detailed comments.

CMS-4068-P-1180-Attach-2.doc

CMS-4068-P-1180-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1181

Submitter : Mr. Kevin O'Leary **Date & Time:** 10/04/2004 08:10:32

Organization : Roche Laboratories Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4068-P-1181-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1182

Submitter : Sandy Praeger **Date & Time:** 10/04/2004 08:10:36

Organization : National Association of Insurance Commissioners

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Comments included in attached letter

CMS-4068-P-1182-Attach-1.doc

NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS

EXECUTIVE HEADQUARTERS

2301 McGee Street
Suite 800
Kansas City MO
64108-2662
voice 816-842-3600
fax 816-783-8175

FEDERAL AND INTERNATIONAL RELATIONS

Hall of the States
444 North Capitol St NW
Suite 701
Washington DC
20001-1509
voice 202-624-7790
fax 202-624-8579

SECURITIES VALUATION OFFICE

48 Wall Street
6th Floor
New York NY
10005-2906
voice 212-398-9000
fax 212-382-4207

WORLD WIDE WEB

www.naic.org

October 4, 2004

Dr. Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244

Dear Administrator McClellan:

On behalf of the National Association of Insurance Commissioners (NAIC), I hereby submit these comments on the proposed rule entitled, "Medicare Program; Medicare Prescription Drug Benefit," published in the *Federal Register* on August 3, 2004.

As you know, the NAIC, as required under the Medicare Modernization Act of 2003 (MMA), has played a significant role in the development of regulations to implement the provisions of the MMA. The NAIC has adopted, within the timeframe mandated by law, major changes to the Medigap regulations, conforming them to the requirements of the MMA. We are confident these changes will be adopted by the states and the Medigap reforms will be in place well before the January 1, 2006, implementation date.

NAIC members and staff have collaborated with the Centers for Medicare & Medicaid Services (CMS) in the development of solvency standards for Medicare Prescription Drug Plans (PDPs) that receive a waiver from state licensure. I would like to compliment the CMS staff on their hard work and professionalism. It was a very cooperative process that yielded a good product.

The NAIC also drafted, through an open, public process, and submitted to CMS a letter of notification that Medigap insurers would be required to send to beneficiaries that have prescription drug coverage. This consultation by the NAIC was required by the MMA. As will be highlighted later, we are concerned about the changes that have been made to our draft of the letter.

I believe it is important to note that the NAIC – the commissioners, state regulators, and staff – have been working diligently since enactment of the MMA to assist CMS and the states in the implementation of the Act. Our comments here, we hope, will be accepted as a continuation of our efforts to provide helpful and beneficial recommendations.

Preamble

Subpart A – General Provisions

In the preamble, under subpart A(2) beginning on page 46635, several concepts are discussed and comments are requested. The NAIC provides the following comments on the issues of: actuarial equivalence (b(i)), creditable coverage (b(ii)), PDP Regions (b(iii)), and beneficiary education (b(v)).

Actuarial Equivalence

The NAIC agrees with the statement that there is not a generally accepted definition of actuarial equivalence. The Actuarial Standards of Practice and Actuarial Compliance Guidelines of the Actuarial Standards Board include no such definition. The relatively general definition of actuarial equivalence found on page 46635 of the preamble seems reasonable for the purposes for which it is intended.

Creditable Coverage

There is some concern about the statements found on page 46740 of the preamble regarding creditable coverage. Section 3(b)2 states that, "In developing standards for actuarial equivalence, our intent is to consider how to maximize coverage for retirees while limiting costs for the government, and the retiree drug subsidy is one important option for achieving this objective" and, "The definition of actuarial equivalence in this context may have an impact on our policy objectives." From these statements it might be perceived that the definition of actuarial equivalence could be manipulated to achieve various goals. Actuarial equivalence is the state of equality of the relative value of two or more sets of data determined by applying comparable sets of assumptions to the data and comparing the resulting values calculated using actuarial principles. The ability to design a regulation to achieve policy goals is a function of which data sets, i.e. gross costs or net costs, are compared and the consequences of those data sets achieving actuarial equivalence, and is not a function of the definition of actuarial equivalency itself.

With regard to the "net" test of the "two prong" approach in section 3(b)2 on the same page of the preamble (pg. 46740), the NAIC would note that determining the amount of retiree premium for the drug portion only of the benefit package may not be as straightforward as it might seem. It is unlikely that retiree health benefit plans would include a separate identifiable premium for the prescription drug benefits. If this is the case, an estimate of the portion of the total premiums related to drug benefits would have to be made prior to using it in the "net value" calculation described and it might be wise to address this issue.

PDP Regions

The NAIC would note that establishing 50 PDP regions, one for each state, would likely result in the largest number of participating plans and, thus, greatest amount of competition. There are many health insurance plans that are licensed and operate within only one state. Creating multi-state regions could preclude these plans from participating as a PDP.

It should also be noted, however, that should multi-state regions be created there is no reason to believe that state regulations would, in any way, prevent plans from participating. Many plans already sell insurance in multiple states, meeting the various requirements of the states in which they are licensed. Selling in multiple states would be especially easy for PDPs since for them most state health insurance regulations are preempted.

Beneficiary Education

As noted in the preamble, on page 46636, the MMA authorizes $200 million per year for beneficiary education beginning in fiscal year 2006. The NAIC agrees that education of Medicare beneficiaries must be a priority and recommends strongly that a significant portion of this funding go to State Health Insurance Assistance Programs (known as SHIPs). The SHIPs have extensive experience providing effective education, counseling and outreach services to Medicare beneficiaries throughout the country. Typically, they are the first to receive questions and complaints from Medicare recipients. In fact, they are often the only human beings the beneficiary can contact. SHIPs must be adequately funded and their counselors fully trained to meet the challenges ahead.

Subpart B – Eligibility and Enrollment

Disenrollment by the PDP

In the preamble, under subpart B(6) on page 46641, CMS seeks comment on the disenrollment of PDP beneficiaries if they are out of the service area for more than 6 months, as is required under the Medicare Advantage (MA) rules. The NAIC notes that there is a significant difference between the way MA benefits are accessed and the way PDP benefits are likely to be accessed. MA benefits typically must be accessed through a network of providers in a certain service area, thus rendering the 6-month rule reasonable. On the other hand, PDP benefits – prescriptions – will likely be accessible through a national network of pharmacies and/or mail order pharmacies. This makes living in the service area less necessary and the 6-month rule less reasonable. Permitting PDP beneficiaries to remain in their plan longer would be of great benefit to them and the NAIC would recommend a more liberal rule in this case.

Marketing Materials

In the preamble, under subpart B(9) on page 46644, CMS requests comments on the possibility of PDP sponsors marketing other products to Medicare beneficiaries. The example given is of financial services, but the NAIC would be more concerned about the offering of other health coverage. The Medigap regulations (attached at Appendix A) require a Medigap carrier offering other coverage to disclose that it is not Medicare supplemental insurance and that there may be some duplication. The NAIC would recommend that any PDP sponsor offering other health coverage also be required to provide such notices and also specify that any premiums associated with the benefits will not be subsidized.

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

In subpart I(3) of the preamble, on page 46696, the issue of state law preemption is addressed. The NAIC supports the view put forth in the preamble that the preemption language should be applied narrowly, not preempting in areas where CMS does not have specific authority to regulate.

Subpart M-Grievances, Coverage Determinations, Reconsiderations, and Appeals

Preemption of State Law

In subpart M(8) of the preamble, on page 46723, the issue of federal preemption of state law is addressed as it relates to grievance and appeals rules. Again, the proposed rule seeks to define federal preemptive authority narrowly so as to preserve important protections for consumers under state law. The NAIC supports this interpretation.

In the same subpart, on page 46723, CMS raises concern about the adequacy of the federal grievance requirements. The NAIC shares this concern. In fact, we urge CMS to begin a thorough review of both the grievance and appeals procedures required under federal law for PDPs and MAs. Specifically, the following areas should be reviewed to determine their adequacy: 1) what determinations or decisions may be appealed; 2) the timeframes for both beneficiaries and insurers; and 3) who within the insurance company can review a grievance or appeal.

The NAIC has developed both grievance and appeals models that have been used by states to implement procedures that effectively protect consumers. We offer to assist CMS in any review of federal grievance and appeals requirements to be applied to PDPs and MAs.

Proposed Rule

Licensing Waiver Eligibility

Section 423.410 of the proposed rule lists as one of the grounds for federal approval of a waiver from state licensure the following:

> *(c)(3) Denial of application based on application of solvency requirements.*
>
> > *(i)* The State has denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements that are different from the solvency standards CMS established under 423.420; or
> >
> > *(ii)* CMS determines that the State has imposed, as a condition for licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes pursuant to 423.420.

This language is inconsistent with language in the preamble (page 46695) that requires the State solvency standards to be "more stringent" than the federal standards. In resolving this contradiction, the NAIC recommends that CMS adopt the "more stringent" language, thus allowing waivers only in those cases where state solvency standards are higher than federal standards, not just "different." Such a standard would be easier to enforce, limit the number of plans that may apply for a waiver, and be more consistent with the overall intent of providing a waiver.

The NAIC is also concerned about language in (b)(2) of section 423.410. This provision states that no application for a waiver is necessary if "CMS determines that the State does not have a licensing process for potential PDP sponsors." The NAIC would like clarification – at the very least in the preamble – that if a State has a process for licensure through which a PDP may receive a license – be it as an insurance company or as a limited benefit plan – then the State is considered to have a "licensing process for potential PDP sponsors." The rule should be clear that States are not required to adopt laws or regulations creating a specific licensing process for PDPs.

Finally, the NAIC is very concerned about (e) of section 423.410. This provision would, in plan years beginning before January 1, 2008, allow a waiver to be granted to any PDP sponsor as soon as a "substantially complete" licensure application is filed with a State, as long as that State has a process for licensing PDPs or their sponsors. First, the NAIC seeks a clarification of what constitutes a "substantially complete" application. We suggest it means an application that contains all information necessary for a state to review it for licensure. Second, this provision appears inconsistent with the rest of the legislation, which seeks to preserve state licensure and solvency oversight unless the state discriminates against PDPs. This would allow almost all PDPs to receive a waiver.

CMS has stated on several occasions its intent to use the waiver authority sparingly to preserve important state oversight and ensure that few seniors are not subjected to the

potential shortcomings of unlicensed plans. The NAIC requests that language clearly stating this intent be included in the preamble.

Definition of Medicare Supplemental Policy

Section 403.205(d) of the proposed rule specifically states that a rider attached to an individual policy is a Medicare supplemental policy. The NAIC supports this definition, which is consistent with the NAIC model regulation and with principles of insurance law. Although the NAIC model does not specifically address riders, state regulators understand that if a rider is attached to the Medigap policy, it becomes part of the policy. That is black-letter insurance law.

The NAIC is concerned, however, about the extension of the definition of a Medicare supplemental policy to include "a stand-alone limited health benefit plan." The NAIC believes that those products for which a disclosure notice must be provided by the Medigap issuer to the insured (see Appendix A) are clearly not Medicare supplemental policies. The Preamble could address those products specifically or the definition itself could be amended and clarified.

Disclosure Notice

As stated at the beginning of this letter, the NAIC crafted a disclosure notice to be sent by Medigap carriers to beneficiaries with prescription drug coverage. The proposed notice was drafted utilizing an open, public process and met the requirements of the MMA. The NAIC-recommended notice (attached at Appendix B) was forwarded to CMS, which was mandated by the MMA to consult with the NAIC in drafting the notice.

While the disclosure notice in the preamble under Subpart T (page 46760) is an improvement over previous CMS drafts, the NAIC remains concerned that the proposed notice continues to exceed the scope and purpose of the requirements of the MMA. The proposed notice does incorporate most of the content from NAIC's draft, but it adds what the NAIC believes to be misleading language in an attempt to persuade beneficiaries to enroll in Medicare Part D. The proposed notice makes generalized, subjective judgments regarding the relative value of the enrollee's current Medigap plan when compared to the new Part D.

The NAIC version of the disclosure notice is limited to the information required by the MMA. The proposed notice in Subpart T far exceeds the MMA requirements. The CMS draft pursues a confusing and technical approach to the notice, attempting to provide its reader with a legal and detailed description—complete with acronyms and policy jargon—of the entire Part D and Medicare Advantage programs. The NAIC believes there are other, more appropriate forums for explaining these programs and discussing whether a beneficiary would benefit from disenrolling from their Medigap policy. We also echo the concerns of the insurance industry that it may be inappropriate for private Medigap issuers to promote disenrollment from their own insurance products.

We specifically object to the following passages:

> "The coverage options that will be available to you under Part D beginning January 1, 2006 will provide greater value than your current coverage."

Value can be measured in many ways, not just in monetary value of benefits. For example, if a Medigap insured has been with the issuer for a number of years, and the insured's drug costs are such that he or she is content with the level of coverage provided under the Medigap policy, that particular insured may conclude the Medigap coverage provides a better value. The insured stays with a company he or she knows and trusts, one that provides reliable customer service, and one that has proven staying power in the marketplace. There is no promise in MMA that the PDP one signs up for on January 1, 2006 will still be available on January 1, 2008. The stability of something known and proven may be of more value than experimenting with an unknown and unproven PDP.

> "However, because the outpatient prescription drug benefit in your policy *is not equal in value* to the Medicare Part D benefit, you should keep in mind that you will probably be charged higher Part D premiums if you want to enroll in Medicare Part D after May 15, 2006." [Emphasis added]

While it may in fact be true that any given Medigap prescription drug plan may be of lesser actuarial value than the new Medicare Part D benefit, the language used above is overbroad and non-specific as to the question of actuarial equivalence between the two policies. At no point within the proposed notice in Subpart T is the concept of actuarial equivalence—nor how it is relevant to the choices a Medigap beneficiary must make—explained. It is the belief of the NAIC that the addition of the above sentence is confusing, potentially inaccurate and irrelevant to the purpose of the notice as prescribed in MMA.

> "If you in enroll in a Medicare Advantage plan that covers prescription drugs, you will get all your Medicare benefits from that plan and *you may get little benefit from a Medigap policy*.' [Emphasis added]

Section 1882(a)(3)(A)(i) of the Social Security Act prohibits the sale of Medigap or other health insurance policies that duplicate benefits to individuals enrolled in Medicare Part C (Medicare Advantage). The NAIC is concerned that this language is confusing in that it may suggest to the beneficiary that it is possible to maintain a Medigap policy while enrolled in Medicare Advantage.

> "You will pay this higher premium for as long as you have Part D coverage. Also, *the longer you wait to join Part D*, the higher your premium will be." [Emphasis added]

While factually accurate, the NAIC finds this language troubling because the context within which it is placed suggests to the beneficiary that enrollment in Part D is required,

and that further delay portends dire financial penalties for having done so. This is precisely the type of "push" advertising technique that the NAIC and its members consistently oppose and prohibit at the state regulatory level.

In contrast, the NAIC's draft attempts to lead the reader through a simplified format that explains the policyholder's options in easier-to-read language. Our draft is limited in scope to what must be conveyed according to MMA—the options available to a Medigap beneficiary with prescription drug coverage in the new Medicare Part D environment, noting that the changes required by law may affect Medigap premiums in the future. Most importantly, the NAIC draft is short in length without sacrificing effectiveness, thereby increasing the likelihood that the beneficiary will read the entire notice.

The NAIC appreciates the opportunity to offer these comments. If you have any questions please contact me or Mary Beth Senkewicz, Senior Counsel for Health Policy in the NAIC Washington, DC office (202-624-7790).

Sincerely,

Sandy Praeger

Sandy Praeger
Chair, NAIC Health Insurance and Managed Care (B) Committee
Commissioner of Insurance, State of Kansas

Attachments:

APPENDIX A – DISCLOSURE STATEMENTS
APPENDIX B – NAIC's DRAFT DISCLOSURE NOTICE

APPENDIX A – DISCLOSURE STATEMENTS

[APPENDIX C of the MODEL REGULATION TO IMPLEMENT THE NAIC MEDICARE SUPPLEMENT INSURANCE MINIMUM STANDARDS MODEL ACT as adopted September 8, 2004]

DISCLOSURE STATEMENTS

Instructions for Use of the Disclosure Statements for Health Insurance Policies Sold to Medicare Beneficiaries that Duplicate Medicare

1. Section 1882 (d) of the federal Social Security Act [42 U.S.C. 1395ss] prohibits the sale of a health insurance policy (the term policy includes certificate) to Medicare beneficiaries that duplicates Medicare benefits unless it will pay benefits without regard to a beneficiary's other health coverage and it includes the prescribed disclosure statement on or together with the application for the policy.
2. All types of health insurance policies that duplicate Medicare shall include one of the attached disclosure statements, according to the particular policy type involved, on the application or together with the application. The disclosure statement may not vary from the attached statements in terms of language or format (type size, type proportional spacing, bold character, line spacing, and usage of boxes around text).
3. State and federal law prohibits insurers from selling a Medicare supplement policy to a person that already has a Medicare supplement policy except as a replacement policy.
4. Property/casualty and life insurance policies are not considered health insurance.
5. Disability income policies are not considered to provide benefits that duplicate Medicare.
6. Long-term care insurance policies that coordinate with Medicare and other health insurance are not considered to provide benefits that duplicate Medicare.
7. The federal law does not preempt state laws that are more stringent than the federal requirements.
8. The federal law does not preempt existing state form filing requirements.
9. Section 1882 of the federal Social Security Act was amended in Subsection (d)(3)(A) to allow for alternative disclosure statements. The disclosure statements already in Appendix C remain. Carriers may use either disclosure statement with the requisite insurance product. However, carriers should use either the original disclosure statements or the alternative disclosure statements and not use both simultaneously.

[Original disclosure statement for policies that provide benefits for expenses incurred for an accidental injury only.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses that result from accidental injury. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- hospital or medical expenses up to the maximum stated in the policy

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Original disclosure statement for policies that provide benefits for specified limited services.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits, if you meet the policy conditions, for expenses relating to the specific services listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when:

- any of the services covered by the policy are also covered by Medicare

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Original disclosure statement for policies that reimburse expenses incurred for specified diseases or other specified impairments. This includes expense-incurred cancer, specified disease and other types of health insurance policies that limit reimbursement to named medical conditions.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses only when you are treated for one of the specific diseases or health conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- hospital or medical expenses up to the maximum stated in the policy

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Original disclosure statement for policies that pay fixed dollar amounts for specified diseases or other specified impairments. This includes cancer, specified disease, and other health insurance policies that pay a scheduled benefit or specific payment based on diagnosis of the conditions named in the policy.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance pays a fixed amount, regardless of your expenses, if you meet the policy conditions, for one of the specific diseases or health conditions named in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits because Medicare generally pays for most of the expenses for the diagnosis and treatment of the specific conditions or diagnoses named in the policy.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Original disclosure statement for indemnity policies and other policies that pay a fixed dollar amount per day, excluding long-term care policies.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance pays a fixed dollar amount, regardless of your expenses, for each day you meet the policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when:

- any expenses or services covered by the policy are also covered by Medicare

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- hospice
- other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Original disclosure statement for policies that provide benefits upon both an expense-incurred and fixed indemnity basis.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance pays limited reimbursement for expenses if you meet the conditions listed in the policy. It also pays a fixed amount, regardless of your expenses, if you meet other policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when:

- any expenses or services covered by the policy are also covered by Medicare; or
- it pays the fixed dollar amount stated in the policy and Medicare covers the same event

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice care
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items & services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Original disclosure statement for other health insurance policies not specifically identified in the preceding statements.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits if you meet the conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- the benefits stated in the policy and coverage for the same event is provided by Medicare

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for policies that provide benefits for expenses incurred for an accidental injury only.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses that result from accidental injury. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for policies that provide benefits for specified limited services.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits under this policy.

This insurance provides limited benefits, if you meet the policy conditions, for expenses relating to the specific services listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior] [health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for policies that reimburse expenses incurred for specified diseases or other specified impairments. This includes expense-incurred cancer, specified disease and other types of health insurance policies that limit reimbursement to named medical conditions.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy. Medicare generally pays for most or all of these expenses.

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses only when you are treated for one of the specific diseases or health conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for policies that pay fixed dollar amounts for specified diseases or other specified impairments. This includes cancer, specified disease, and other health insurance policies that pay a scheduled benefit or specific payment based on diagnosis of the conditions named in the policy.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance pays a fixed amount, regardless of your expenses, if you meet the policy conditions, for one of the specific diseases or health conditions named in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for indemnity policies and other policies that pay a fixed dollar amount per day, excluding long-term care policies.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance pays a fixed dollar amount, regardless of your expenses, for each day you meet the policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for policies that provide benefits upon both an expense-incurred and fixed indemnity basis.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance pays limited reimbursement for expenses if you meet the conditions listed in the policy. It also pays a fixed amount, regardless of your expenses, if you meet other policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice care
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items & services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

[Alternative disclosure statement for other health insurance policies not specifically identified in the preceding statements.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance provides limited benefits if you meet the conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- [outpatient prescription drugs if you are enrolled in Medicare Part D]
- other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the *Guide to Health Insurance for People with Medicare*, available from the insurance company.
√ For help in understanding your health insurance, contact your state insurance department or your state [senior][health] insurance [counseling][assistance] program [SHIP].

Drafting Note: Insurers insert reference to: outpatient prescription drugs and state health insurance assistance program (SHIP) above when new notices need to be printed after December 31, 2005.

APPENDIX B – NAIC's DRAFT DISCLOSURE NOTICE

[NAIC's proposed Medigap Disclosure Notice, prepared and approved by its Senior Issues Task Force. This draft notice was transmitted to CMS Administrator Dr. Mark McClellan on May 20, 2004]

Important Notice To Medicare Supplement Policyholders That Have Prescription Drug Benefits

You have a Medicare Supplement policy from [name of company] that includes an outpatient prescription drug benefit. Please read this entire notice about your Medicare Supplement policy and the new Medicare Prescription Drug program (Medicare Part D).

You can enroll in the new Medicare Prescription Drug program (Medicare Part D) from November 15, 2005 to May 15, 2006. Medicare Part D is voluntary; you can choose to enroll or not to enroll. More information about Medicare Part D is available from Medicare (1-800 MEDICARE or www.medicare.gov).

If You Do Not Enroll in Part D

If you do not enroll in the new Medicare Prescription Drug Program (Medicare Part D) and you want to keep a Medicare Supplement policy, you can keep your current Medicare Supplement policy without changes. You do not need to do anything in reply to this notice. (There will be penalties if you enroll after May 15, 2006. Make sure you read the section called "If You Enroll in Medicare Part D After May 15, 2006).

If You Enroll in Part D By May 15, 2006

If you enroll in the new Medicare Prescription Drug Program (Medicare Part D) by May 15, 2006, **you must choose one of the following options**:

> **Option #1:** You can keep your current Medicare Supplement policy but Federal law requires us to remove the prescription drug coverage, and your premium may change. [In your case, the new premium will be [insurer insert dollar amount of premium]]; If you choose this option, you must notify us promptly [insert options for notifying issuer] **or**
>
> **Option #2:** You can cancel your existing policy [and enroll in one of our Plans [A, B, C, F, K or L][insurer insert those plans of above you currently offer or any others you may want to offer] regardless of your health.]. [Descriptions of these Plans and their current premiums are enclosed –**OR-** If you would like information about one or more of these plans, please contact us at 1-800-000-0000 or www.issuer.com]. [If you want a new Medicare Supplement policy, you must apply for it within 63 days of your enrollment in the new Medicare Prescription Drug Program (Medicare Part D).].

If You Enroll in Medicare Part D After May 15, 2006

If you do not enroll in Medicare Part D during the initial Part D enrollment period**,** but want to do so after May 15, 2006, you need to know [three] things.

1. There are limitations on when you can enroll in Part D. Generally, you will only be able to enroll between November 15th and December 31st each year.

2. Since you will be enrolling late, and your current outpatient prescription drug benefit is not equivalent to the Part D benefit, you will have to pay a higher monthly premium for Part D than if you enrolled by May 15, 2006. You will pay a higher premium for as long as you have Part D coverage.

[3. You may not be able to enroll in another Medicare Supplement policy with our company, as was the case had you enrolled in Part D before May 16, 2006. You will be able to keep your current policy with the drug benefit removed. Please contact us at 1-800-000-0000 or www.issuer.com for more information.]

If you enroll in Part D after May 15, 2006, please let us know as soon as possible. Federal law requires us to remove the prescription drug benefit from your Medicare Supplement policy and your premium may change .

Effect on Premiums

In making your decision about what to do, please keep in mind that the law requires us to make changes to our plans. These changes will have an effect on future premiums. Please contact us so we can discuss the likely differences in premiums over time among your different choices.

Assistance

If you need help understanding your choices, please contact us at [insert insurer number and website address].

Your State Health Insurance Assistance Program (SHIP) can help you with information about your Medicare Supplement policy and the new Medicare Prescription Drug Program (Medicare Part D). You can reach the SHIP Program [at insert SHIP number – OR by finding your state's Program number on the next page].

For more information about Medicare Part D, call 1-800-MEDICARE. Information is also available on the Internet at www.medicare.gov.

Submitter : Mr. Phillip Stoddard **Date & Time:** 10/04/2004 08:10:17

Organization : Michigan Office of Retirement Services

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The Michigan Public School Employees Retirement System is a statewide public employee plan administered by the Office of Retirement Services. The Michigan Public School Employees Retirement System provides retirees and eligible dependents with comprehensive health, dental and vision benefits at a cost of $680.3 million. Prescription drug costs are $250 million. Approximately, 66% of the membership is Medicare eligible. The health care plan is a self-funded plan administered by Blue Cross Blue Shield of Michigan.

The new Part D program could provide much needed assistance to the retirement system in preserving the health care coverage for retired school employees in the long term. In an open door forum sponsored by CMS, it was stated that CMS was looking for comments concerning the use of payments from alternative vehicles such as Health Savings Accounts and Medical Savings Accounts towards the calculation of true out-of-pocket (TrOOP) costs. Once money is deposited into these vehicles, the money is the account holder?s. Therefore, we feel that any money withdrawn from these accounts to pay for the deductible, the 25% cost share, or the coverage gap should be used in the calculation of the TrOOP requirement for catastrophic coverage.

CMS-4068-P-1184

Submitter : Sandra Longworth **Date & Time:** 10/04/2004 08:10:57

Organization : NYS Office for the Aging

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

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

Re: CMS-4068-P (42CFR Parts 403 and 408)
Medicare Program; Medicare Prescription Drug Benefit

Dear Sir and Madam:

Pursuant to the publication of the above captioned Proposed Rule in the Federal Register (Vol. 69, No. 148 dated August 3, 2004), the New York State Office for the Aging reviewed the document. This review generated several concerns regarding the impact of the proposed rule on Medicare beneficiaries and the state-operated Elderly Pharmaceutical Insurance Coverage (EPIC) Program.

Before moving to our specific comments related to the individual sections in the Proposed Regulation, we want to note that the sheer size and complexity of these regulations is a testament to the fact that the new Medicare Modernization Act is terribly confusing to most Medicare beneficiaries. This confusion will make enrollment and use of the new program very difficult, particularly for the frail elderly, the lower income, those with chronic illnesses, and those with English literacy problems. In general, whenever it is possible and whenever it is pro-consumer, CMS should seek to simplify the new program.

A summary of our major concerns by subpart are listed below.

Subpart B ? Eligibility and Enrollment

Sections 423.30 / 423.48 - Outreach and Funding for State Health Insurance Programs (SHIPs) - The drug benefit under the Medicare Modernization Act is extremely complicated. The complexity and magnitude of Medicare changes will be very confusing for beneficiaries. The structure of the benefit itself is difficult to understand. The actual benefit packages will differ. Plan formularies, drug prices and network pharmacies will vary. These factors will make it extremely difficult for beneficiaries to understand their options and make an informed choice. Beneficiaries will also have to decide whether to purchase Part D, and whether to stay in Original Medicare and enroll in a prescription drug plan (PDP) or to join a Medicare Advantage plan that has prescription drug coverage (MA-PD). In essence, seniors will be required to have a more active role in their Medicare coverage -- both in deciding whether or not to enroll in Part D and in selecting Part D coverage.
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 posting of comparative information on the Medicare web site will not be adequate. While the 1-800 number will also be available, it cannot meet the individual counseling needs of all Medicare beneficiaries.
Given our knowledge gained in administering the State Health Insurance Program (SHIP) in New York State and our awareness of the difficulties that beneficiaries have with understanding complex information, a massive education campaign will not be enough. A significant number of

beneficiaries will require one-on-one counseling. In order to provide the necessary infrastructure at the state and local levels to accommodate the increased demand for one-on-one counseling and assistance, SHIPs should be funded at a minimum of $1 per Medicare beneficiary or $41 million, and the $1 per Medicare beneficiary should be increased annually at the rate of inflation.

Information Provided - The plan 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 processes. 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.
It is also critical that plan information be provided in a manner that beneficiaries with all levels of/or lack of education can understand and co

CMS-4068-P-1185

Submitter : Dr. Kate Kelly **Date & Time:** 10/04/2004 08:10:46

Organization : Institute for Safe Medication Practices

Category : Other

Issue Areas/Comments

Issues 1-10

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

Our primary concern is that the proposed regulation may require the use of error rates for benchmarking individual plans & that enrollees could use these rates to compare & choose their individual plans.
It is not possible to set a benchmark as the true incidence of medication errors varies & depends heavily on the frequency with which events are identified & reported. At present, there is no consistent process among healthcare organizations, much less community pharmacy, for detecting & reporting errors. Since many medication errors cause no harm to patients, they remain undetected or unreported. Yet, organizations frequently depend on spontaneous voluntary error reports alone to determine a medication error rate. The inherent variability of determining an error rate in this way invalidates the measurement. A high error rate may suggest either unsafe medication practices or an organizational culture that promotes error reporting. Conversely, a low error rate may suggest either successful error prevention strategies or a punitive culture that inhibits error reporting.
Of equal concern is the mistaken belief that these error rates can be used to compare organizations. According to The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), the "Use of medication error rates to compare health care organizations is of no value." The Council has taken this position for the following reasons:
Differences in culture among health care organizations can lead to significant differences in the level of reporting of medication errors.
Differences in the definition of a medication error among health care organizations can lead to significant differences in the reporting & classification of medication errors.
Differences in the patient populations served by various health care organizations can lead to significant differences in the number & severity of medication errors occurring among organizations.
Differences in the type(s) of reporting & detection systems for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.
According to the statement, The NCC MERP believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Health care organizations should monitor actual & potential medication errors that occur within their organization & investigate the root cause of errors with the goal of identifying ways to improve the medication use system to prevent future errors and potential patient harm. The value of medication error reporting is to provide the information that allows an organization to identify weaknesses in its medication use system & to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the health care organization's analysis of the information, and its actions to improve the system to prevent harm to patients."
When organizations focus attention on maintaining a low error rate, the error itself, rather than its correction, is given disproportionate attention. This promotes an unproductive cycle of underreporting of errors, resulting in unrecognized weaknesses in the medication use system. Thus, low error rates can result in a false sense of security & a tacit acceptance of preventable errors.
ISMP recommends that the CMS program requirements for a quality assurance program would incorporate the following:1)Periodic self-assessment of the plan with regards to known safe medication practices.2)A robust internal error reporting program as well as evidence that errors are shared confidentially with national reporting programs.3)Evidence that internal error reports & information from external programs are used to make system improvements within the organization

CMS-4068-P-1185-Attach-1.doc

Submitter : Mr. Larry Wagenknecht **Date & Time:** 10/04/2004 08:10:52

Organization : Michigan Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BACKGROUND

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. The Michigan Pharmacists Association offers the following comments for consideration as CMS develops the final regulation.

BENEFITS AND BENEFICIARY PROTECTIONS

Subpart C: Benefits & Beneficiary Protections
? The pharmacy access standard should be revised 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 patients will be able to continue to use local community pharmacies.

? CMS should require plans to offer standardized procedures and guidelines in their contract to all pharmacies. 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, thereby 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.
? The playing field should be level between all pharmacy providers.
? Plans must allow beneficiaries to obtain the same benefits at a community pharmacy as those offered through mail order, such as a 90-day supply.
? Plans should not be allowed to charge a higher price for an extended supply obtained from a community pharmacy. CMS should clarify that the price difference must be directly related to the difference in service costs, not the cost of the drug product. This eliminates the possibility of coercing beneficiaries away from their pharmacy of choice by promoting a cost-difference.

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

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? CMS should not allow plans to independently choose providers for medication therapy management services to prevent the plans from choosing less qualified providers. However, we recognize that different beneficiaries will require different MTM services, such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc.
? MTM services should be performed by the pharmacy profession, and should not be connected with a plan. Pharmacists are the ideal healthcare professionals to determine which services each beneficiary needs.
? CMS should to define ?multiple chronic diseases? to ensure that the procedures and guidelines are standardized for all plans.

? The Medication Therapy Management Program should be structured as follows:
? Targeted Beneficiaries
? Patients with two or more chronic diseases and two or more drugs should qualify for MTM services.
? Plans should be required to identify newly targeted beneficiaries on a monthly basis.
? Plans should be required to inform pharmacists of patients eligible for MTM services.

? Pharmacists and physicians should be able to readily identify eligible beneficiaries.
? Plans must be required to inform beneficiaries when they are eligible for MTM services and inform them about their choices for obtaining MTM services, including their local pharmacy.
? Once a beneficiary becomes eligible for MTM services, the beneficiary should remain eligible for the entire year.
? Plans should not prohibit pharmacists from providing MTM services to non-targeted beneficiaries. Pharmacists should be allowed to provide MTM services to non-targeted beneficiaries, and be allowed to bill patients directly for the services.
? Providers
? Plans cannot require beneficiaries to obtain MTM services from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTM services from a specific provider would disrupt existing patient-pharmacist relationships.
? Fees
? Plans must be required to pay the same fee for MTM services to all providers.
? CMS must carefully evaluate each plan?s application to provide an MTM benefit. Fees should be commensurate with the services rendered.
? Services
? MTM services are independent of, but can occur in conjunction with, the provision of a medication product.
? Different beneficiaries will require different MTM services such as performing a health assessment, formulating a medication treatment plan, monitoring and evaluating a patient?s response to therapy, etc.
? Face-to-face interaction between the pharmacist and the patient must occur with the initial assessment, which is the preferred method of the delivery of patient care.
? The Michigan Pharmacists Association supports the MTM services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004.

In conclusion, the Michigan Pharmacists Association urges CMS to revise the Medicare Prescription Drug Benefit regulations to incorporate the bulleted points presented in this communication.

Thank you in advance for your consideration.

Sincerely,

Larry Wagenknecht, CEO
Michaigan Pharmacists Association
517-377-0226
Larry@michiganpharmacists.org

CMS-4068-P-1186-Attach-1.doc

CMS-4068-P-1186-Attach-1.doc

CMS-4068-P-1186-Attach-1.doc

Submitter : Mr. Mark Campbell **Date & Time:** 10/04/2004 10:10:09

Organization : Innoviant

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Section 423.56 Procedures to determine and document creditable status of prescription drug coverage

Request for Comments: Format, placement and timing of the notice of credible coverage.

Comment: We urge CMS to issue a model notice of credible coverage. Sound health care policy requires that retirees be adequately informed of the nature of their coverage so they may make wise health care decisions, especially in light of the penalty that will apply to retirees who fail to enroll in part D.

We believe there will be an enormous benefit in requiring plan sponsors to use a standard format in providing this notice. Retirees will not be served well to the extent they receive incomplete or confusing notices. CMS should allow plans to include this information as part of the Summary Plan Description when the plan does provide credible coverage. Plan sponsors should be permitted to transmit this notice electronically when the retiree has agreed to accept plan communications in that manner.

An important issue is the timing of the issuance of the first ?Annual Coordinated Enrollment Period? for Part D. Given the fact that plan sponsors must have applied for the subsidy by September 30, 2005, employers will know by that date whether they are providing credible coverage or not. Accordingly, we recommend to CMS that it require plan sponsors to issue the first notice of credible coverage by October 15, 2005.As a general matter, at least 30 days advance notice of credible coverage will protect retirees by providing them with adequate time to make the important decision of whether to enroll in part D or not without facing a penalty, especially when coverage has been reduced. At the same time, 30 day notice will assure plan sponsors, PBAs and other service providers that they will have the opportunity to prepare for plan changes

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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

Section 423.132 Public disclosure of pharmaceutical prices for equivalent drugs

Request for Comments: The requirement that PDPs and MA plans be required to ensure that pharmacies inform beneficiaries of any differential in price between a covered drug and the lowest priced generic version of that drug.

Comment: The intended goal of this section ? lowering prescription costs by encouraging the use of low cost generic drugs - is certainly commendable. As a PBA we regularly promote the use of generics and recommend pharmacy benefit designs that increase the use of generic drugs. However, we believe this requirement will be impracticable for PDPs and MA plans to administer, as well as for retail pharmacies to implement.

It is our understanding that most state pharmacy practice laws require that pharmacists inform patients of the availability of a generic drug, whenever one may replace a prescribed brand name drug. Furthermore, a common feature of PBA pharmacy benefits are incentives encouraging the use of generics whenever medically appropriate. In most instances, commercial pharmacy benefits are designed so that the requirement proposed by the rule would not be necessary.

CMS offers several situations where this requirement may be waived. It is our recommendation that the requirement for pharmacies to inform patients of the differential in price between the brand and lowest cost generic alternative be waived entirely. Our recommendation is that PDPs and MA plans be required to ensure that pharmacies inform beneficiaries of the availability of a lower cost generic drug, whenever such an alternative

exists for a brand name drug and that MA and PDP plan benefit designs be used as the primary driver to generic drug utilization.

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

Request for Comments: Guidance to drug plans on the identification of beneficiaries who should be targeted for Medication Therapy Management Programs (MTMP).

Comment: Beneficiaries who are identified in the rule as those who might benefit from MTMP services are those with multiple chronic diseases, who use multiple covered Part D drugs, or those who are likely to incur expenses above a pre-designated level. From the perspective of a pharmacy benefits administrator (PBA) and a prescription drug plan, we recognize that information pertaining to the diagnosis is not a typical component of prescription drug claims. When formulating its guidance, CMS should be aware that PDPs may not be able to accurately identify a target population for MTMP services using only multiple chronic diseases as a criteria.

Patients using multiple medications are at greater risk for adverse reactions and medical expenses. PBAs and PDPs are able to accurately identify such patients. Patients who are likely to have drug expenses greater than a threshold are also readily identifiable through prescription claims analysis.

We recommend that each of these populations be identified as potential candidates for MTMP services, and that patients with multiple chronic diseases be an optional (rather than mandatory) criteria for targeted MTMP services.

GENERAL PROVISIONS

Section 423.884 (a) Requirements for qualified retiree prescription drug plans.

Request for Comments: Determination of actuarial equivalency.

Comment: Given CMS's stated goal of maintaining the greatest levels of employer-provided retiree coverage at the lowest possible cost to the government, we believe that the proposed two-prong approach for determining actuarial equivalence is more sensible than a one-prong test based solely on plan design.

It is not enough for CMS to look at plan features for purposes of making the actuarial calculation. Although Congress may not have mandated that retiree contributions be taken into account for determining actuarial equivalence, we would urge CMS to rationalize the legislation and provide that amounts paid by retirees to participate in the plan be netted out of the equivalence calculation. Any other approach may create windfalls for employers and unnecessarily increase the costs associated with the administration of this program.

Moreover, we believe that a reasonable interpretation of the statutory language contained in the Act provides CMS with the legal authority to implement this type of rule.

Request for Comments: Determination of TrOOP

Comment: We recommend that CMS treat amounts distributed from consumer based health care arrangements, including Health Savings Accounts, where the amounts contained in the account are based solely on employee contributions. Many employers have established plans that are funded solely by employees. It does not make sense, from a policy perspective, for CMS to treat distributions from these accounts any differently than other individual expenditures of health care dollars. A rule that does not allow distributions from these accounts to count as TrOOP will harm older Americans who have planned and saved for their health care needs in retirement.

Request for Comments: Integrated Plan Designs and Contributions

Comment: Although it may not be current industry practice for plan sponsors break out their benefit premium costs for prescription drugs and the medical component separately, we believe this is primarily attributable to industry practice. We do not believe it is too burdensome for plans to separately account for these amounts. Given the trend towards consumer driven health care, we believe it is important that individual members know how their health care dollars are being spent.

We agree with the CMS? view to apply the actuarial equivalence test to all group health plans sponsored by an employer or labor organization as a

whole, with the standard met if on average the actuarial value of the retiree drug coverage under the combined plans is at least equal to the value of prescription drug coverage under part D.

Section 423.884 (b) Requirements for qualified retiree prescription drug plans.

Request for Comments: Sponsor Application for Subsidy Payment

Comment: Given the cyclical nature of prescription drug business, we believe it is important that CMS not adopt a rule that encourages plan sponsors to migrate from a plan year to a calendar year basis. Plan sponsors, PBAs, and other service providers have limited resources with which to operate.

We believe it is in the best interests of all the parties involved, including CMS, to create flexibility by offering employers the choice to apply for the subsidy on a plan year basis. This would enable plans to better manage workloads and associated costs.

A related issue is the frequency with which subsidy payments would be made by CMS. In particular, CMS has requested comments with respect to biannual, quarterly and monthly payment periods. While we are sensitive to the interests of employers, especially small employers, in receiving frequent payments, we believe that it would be unworkable for PBAs to provide monthly data collection services. Rather than adopting a variable approach based on the size of the plan sponsor,be uniform.

Submitter : Ms. Rebecca Burkholder **Date & Time:** 10/04/2004 08:10:00

Organization : National Consumers League

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Section 423.34 Enrollment Process
We propose that, at the time of enrollment, participating plans should be required to request the following data from their enrollees: (1) the enrollee's drug allergies and intolerances; (2) the enrollee's health conditions and diseases; (3) over-the-counter medications, dietary supplements, vitamins, and herbals consumed by the enrollee. This information should be collected through a consumer-friendly instrument ? available both electronically and in a paper-based format. Plans should also require that, upon the enrollee?s request, the information on allergies and intolerances, and health conditions and diseases, could be verified by a physician, or other health care professional. The enrollee would provide the contact information for the appropriate health care professional.

This information, along with the list of prescription medications from the plan, could by translated by the plan into a medication record. This consumer- friendly record could then be distributed to the beneficiary, maintained by the patient, and updated with the assistance of the plan at regular intervals - at least annually. Such a record could be useful for the consumer on multiple levels - not only to keep track of medications and avoid interactions /allergic reactions, but also in emergency situations when consumers are not able to communicate complete information to the treating health care professionals.

This information would be collected by the plan when the consumer enrolls in the plan, or by a pharmacist when the consumer initially uses the plan. It should be make clear to the consumer that they have the option to not provide this information, and that this information would be confidential and used only for the purpose of improving the safety of the consumer's medication therapy. This information could not be used in any other manner (e.g., for marketing purposes by the health plan).

NCL believes that there are many benefits to getting patients to maintain an accurate record of all medications. A primary objective of the SOS Rx project on promoting the personal medication record is to get people to use some tool that will help them manage their medications, regardless of the tool medium or format (electronic, paper, etc.). In the end, consumers should have a role in ensuring that a complete, accurate, and updated list of medications and supplements is available to all of their health care providers so as to maximize therapeutic benefit and minimize the risk of adverse reactions.

Thank you for this opportunity to comment.

Sincerely,

Linda F. Golodner
President, National Consumers League

CMS-4068-P-1188-Attach-1.doc

CMS-4068-P-1189

Submitter : Ms. Linda Vukelich **Date & Time:** 10/04/2004 08:10:53

Organization : Minnesota Psychiatric Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

As you implement the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), the members of the Minnesota Psychiatric Society ask you to ensure that Medicare beneficiaries with mental illnesses receive their medically necessary prescriptions under the new Part D prescription drug benefit.

The proposed rule seems to indicate that, given the unique clinical nature of beneficiaries with mental illnesses, as well as the therapeutic non-interchangeability of medicines used to treat this highly vulnerable and sensitive population, the traditional formulary structures and exceptions procedures as proposed by CMS will not ensure adequate coverage for dual eligible beneficiaries and seniors facing major mental disabilities. For example, there are no provisions in the proposed rule that ensure continuity of care for those dual eligible beneficiaries and non-dual eligible beneficiaries who are stabilized on certain drugs.

It is critically important that people with mental illness receive medication best suited to them at the outset of treatment because the chance of recovery diminishes significantly if the first course of treatment fails. Thus utilization management techniques, like 'fail first' and step therapy, that require individuals to try other medications first before they may receive coverage for the medication prescribed by their physician can have severe and permanent effects on individuals with mental health disorders.

Limits on access to appropriate medications and delays that can result from policies like prior authorization can cause relapses and can impair their ability to recover. Moreover, these policies may also impose a significant risk of death since persons with depression or schizophrenia are at significantly higher risk of suicide compared to the general population.

MPS urges CMS to require that prescription drug plans offering the new Medicare Part D benefit incorporate an alternative formulary for mental health medications. This alternate formulary would be for a class of enrollees who have a primary diagnosis as defined by the DSM-IV-TR and for whom a physician has determined that it is medically necessary that their medical condition be treated pharmacologically. This formulary would provide access to the full array of mental health medications for individuals with mental illnesses diagnoses, including dual eligible beneficiaries, without fail first, prior authorization, step therapy, therapeutic substitution, or any similar restrictive policies.

Minnesota recognizes the unique needs of individuals with mental illness and provides an exemption from co-payments for antipsychotics in our Medicaid program.

The physician members of the Minnesota Psychiatric Society advocate for quality care for all patients and urge you to consider their patients in this process. Please establish an alternative formulary structure for Medicare beneficiaries with mental illnesses to ensure that they continue to have access to life-enhancing and life-saving prescription medications. Thank you for your attention to this critical matter.

CMS-4068-P-1189-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D.
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

As you implement the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), the members of the Minnesota Psychiatric Society ask you to ensure that Medicare beneficiaries with mental illnesses receive their medically necessary prescriptions under the new Part D prescription drug benefit.

CMS is on record as recognizing the unique and vulnerable nature of this population by specifically requesting that groups representing beneficiaries with mental illnesses comment on the best mechanism to provide clinically appropriate access to these populations.

The proposed rule seems to indicate that, given the unique clinical nature of beneficiaries with mental illnesses, as well as the therapeutic non-interchangeability of medicines used to treat this highly vulnerable and sensitive population, the traditional formulary structures and exceptions procedures as proposed by CMS will not ensure adequate coverage for dual eligible beneficiaries and seniors facing major mental disabilities. For example, there are no provisions in the proposed rule that ensure continuity of care for those dual eligible beneficiaries and non-dual eligible beneficiaries who are stabilized on certain drugs.

It is critically important that people with mental illness receive medication best suited to them at the outset of treatment because the chance of recovery diminishes significantly if the first course of treatment fails. Thus utilization management techniques, like "fail first" and step therapy, that require individuals to try other medications first before they may receive coverage for the medication prescribed by their physician can have severe and permanent effects on individuals with mental health disorders.

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mental health medications for individuals with mental illnesses diagnoses, including dual eligible beneficiaries, without fail first, prior authorization, step therapy, therapeutic substitution, or any similar restrictive policies.

Minnesota recognizes the unique needs of individuals with mental illness and provides an exemption from co-payments for antipsychotics in our Medicaid program.

The physician members of the Minnesota Psychiatric Society advocate for quality care for all patients and urge you to consider their patients in this process. Please establish an alternative formulary structure for Medicare beneficiaries with mental illnesses to ensure that they continue to have access to life-enhancing and life-saving prescription medications. Thank you for your attention to this critical matter.

Sincerely,

Linda Vukelich
Executive Director
Minnesota Psychiatric Society

CMS-4068-P-1190

Submitter : Ms. Ghita Worcester **Date & Time:** 10/04/2004 08:10:08

Organization : UCare Minnesota

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter for UCare Minnesota's attached comments for Title I

CMS-4068-P-1190-Attach-1.doc

CMS-4068-P-1190-Attach-2.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

2. Commenter was referring to another attachment of another comment or and did not attach that comment.

3. Some cases where 2 or more attachments are listed and we did not received them, it may be due to the fact that the commenter tried to attached the same file several times, which resulted in and indication that we may have received several file, but CMS has only received one.

4. The commenter has requested that his/her attachment not be display on the web page.

If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

Submitter : Mrs. Pamela Pepe **Date & Time:** 10/04/2004 08:10:05

Organization : Serono, Inc.

Category : Private Industry

Issue Areas/Comments

Issues 1-10

BACKGROUND

October 4, 2004

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC

By Electronic Delivery to: http://www.cms.hhs.gov/regulations/ecomments

RE: CMS-4068-P, Medicare Program: Medicare Prescription Drug Benefit

Dear Dr. McClellan,

Serono is pleased to offer our comments on the above-referenced proposed rule.

Serono is a global biotechnology leader and a developer of recombinant prescription medicines. We offer six recombinant products in five disease areas, including the world's fastest growing multiple sclerosis therapy, RebifO. We are the world leader in infertility treatment, and also offer the only growth hormone approved for the treatment of HIV-associated wasting, and the only needle-free growth hormone delivery system, available with both our pediatric growth and HIV-associated wasting therapies.
Serono?s multiple sclerosis product, RebifO, is a covered product under the Medicare Replacement Drug Demonstration (Demo), enacted as part of the Medicare Prescription Drug and Modernization Act of 2003 (MMA). As you know, the Demo is statutorily mandated to parallel, to the extent possible, the impending Part D benefit. We were pleased to have the opportunity to work with Members of Congress and their staff, in the effort to ensure that the Demo would be consistent with Part D, so as to minimize the risk of beneficiary confusion once they rolled from Medicare coverage under the Demo, to Part D. As a result, we have gained significant insight into the benefits and challenges ahead for many of the stakeholders under Part D, and endeavor with these comments to offer specific comments that will aide the implementation of Part D.

Our comments are as follows:

BENEFITS AND BENEFICIARY PROTECTIONS

Bona Fide Charities to Help Patients with High Co-Payments

As is the case with many biologics, therapy costs are high relative to e.g., a pill to treat hypertension. We know from our coverage experience in the Demo, that patients who take our product under the Part D benefit will both enter and exit the so-called ?donut hole? (the amount above $2,250 that is not paid until the beneficiary has paid $3,600 in out of pocket costs). More importantly, we know that the full value of the Part D benefit may be forever out of reach for many high co-pay beneficiaries unless they receive some kind of financial assistance. As we know, the majority of beneficiaries live solely on their Social Security income. Therefore, only a small percentage of Medicare beneficiaries have income sufficient to cover the initial $3,600 out-of-pocket requirement, plus the 5% co-pay on all therapy costs over $5,100.
Accordingly, we agree that bona fide charities unaffiliated with employers or insurers? should be allowed to assist ?Part D enrollees with covered

Part D expenditures and hav[e] those expenditures count toward enrollee?s incurred costs,? in order to satisfy the patient?s annual $3,600 out of pocket maximum. We also agree with CMS? comment that ?the number of people who are both assisted by charitable organizations and have expenditures high enough to qualify for protection against high out-of-pocket expenditures would be small,? and that ?it is a desirable goal to allow appropriate charitable assistance to count toward enrollees? incurred costs

In that same vein, we encourage PDPs to include in their HIPAA patient consent forms, the patient?s permission to share their protected health information with applicable 501(c)(3) organizations. We have found during the Demo that even though charitable funding is available to enrollees, the Medicare contractor operating the Demo has determined that the current consent form does not permit them to coordinate patient assistance due to HIPAA privacy limitations.

Coordination of Benefits

The agency notes in this proposed rule the need for PDPs to coordinate with other ?secondary? payers, to determine, and ideally minimize, the co-payment actually required by the beneficiary.

In keeping with our comments immediately above, we strongly encourage CMS to facilitate the coordination of benefits for high co-payment/donut hole patients in need of patient assistance, which is available through bona fide charitable organizations. Ideally, there would be real-time processing of beneficiary co-payment assistance, in order to reduce the beneficiary?s out of pocket costs during the period of time they are in the donut hole.

In the meantime, we have listed our relevant patient assistance programs with CMS for inclusion in the ?Prescription Drug and Other Assistance Programs web site, to which patients may be referred if they are interested in the Demo, but need financial assistance.

Beneficiary Protections

We note in the proposed rule that PDPs are guaranteed a 1 year commitment by their Part D enrollees ? meaning the patients are liable for their premium costs if they switch to another PDP during that one-year contract period. However, as proposed, PDP formularies can be changed monthly. We think greater parity is needed to protect beneficiaries worried that their PDP will drop costly medicines once they've secured a one-year contractual commitment from the beneficiary.

Such tactics are indeed uncommon among PBMs operating in the private sector today. However, many of today?s PBMs will be tomorrow?s PDPs. As part of that transition, they will become risk-bearing entities for the first time, making their behavior unpredictable. Therefore, we urge CMS to minimize beneficiary risk by providing beneficiaries with the same one-year protection as the PDP receives.

For patients that take therapies for chronic conditions, such as Serono?s product RebifO, for the relapsing forms of mult

ELIGIBILITY, ELECTION, AND ENROLLMENT

Beneficiary Enrollment - Dissemination of Plan Information

We agree with CMS that plans must disseminate information in a ?clear, accurate and standardized form at the time of enrollment and annually.? Based on our experience with the Demonstration program, we make the following very specific recommendation regarding information provided to beneficiaries:

a. All printed materials should appear in font Size 12, at a minimum, so beneficiaries may read them;
b. Forms should be clearly numbered, such as ?Page 1 of 4, Page 2 of 4,? and so-forth;
c. To the extent there are multiple forms to enroll in Part D, e.g., the enrollment form, the form requesting low-income subsidy assistance, the form for physician certification of the patient?s disease state (by ICD-9 code or otherwise), these all should be listed and briefly explained in one cover page, which briefly explains each of the attachments, and identifies that they are, e.g.,

? Attachment A ? Enrollment for Part D, with a brief explanation such as ?To elect Part D coverage, this form must be completed in full. If you believe your income is such that you will qualify for full or partial subsidy, you must also complete Form B [if physician certification is required, you must complete Form C, and so forth].?
? Attachment B ? Income Subsidy Request, with a brief explanation such as ?Financial assistance is available under Part D for the cost of monthly premiums, annual deductibles, and co-payments, based on your income. To determine your eligibility for assistance, Attachment B must be completed and submitted along with Attachment A.?
? Attachment C ? Physician Certification, with a brief explanation regarding the need for a patient?s health care provider to certify their medical condition.
? All forms should be clearly paginated, such as A1 of 5, A2 of 5 and so forth, including the instruction pages relevant to each attachment;

d. Each and every page of every form should have the name, address, phone number and web address of the Prescription Drug Plan (PDP) offering Part D prescription coverage. The lack of this clarity in the Demo resulted in some patients and physicians attempting to send one or more of the required forms to the only named entities on the page, specifically, either The Department of Health and Human Services or the Office of Management and Budget.
e. Request that the beneficiary provide not only their legal mailing address (that which ties to their Medicare enrollment card), but also the address to where product should be shipped. These are frequently different, and particularly in the case of biologics such as those Serono manufactures, product integrity requires timely receipt by the beneficiary.

CMS-4068-P-1191-Attach-1.rtf

CMS-4068-P-1191-Attach-2.txt

CMS-4068-P-1191-Attach-1.rtf

CMS-4068-P-1191-Attach-2.txt

CMS-4068-P-1191-Attach-1.rtf

CMS-4068-P-1191-Attach-2.txt

Serono, Inc.

Government Affairs

1700 Rockville Pike, Suite 210
Rockville, MD 20852

October 4, 2004

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC

By Electronic Delivery to: http://www.cms.hhs.gov/regulations/ecomments

RE: CMS-4068-P, Medicare Program: Medicare Prescription Drug Benefit

Dear Dr. McClellan,

Serono is pleased to offer our comments on the above-referenced proposed rule.

Serono is a global biotechnology leader and a developer of recombinant prescription medicines. We offer six recombinant products in five disease areas, including the world's fastest growing multiple sclerosis therapy, Rebif?. We are the world leader in infertility treatment, and also offer the only growth hormone approved for the treatment of HIV-associated wasting, and the only needle-free growth hormone delivery system, available with both our pediatric growth and HIV-associated wasting therapies.

Serono's multiple sclerosis product, Rebif?, is a covered product under the Medicare Replacement Drug Demonstration (Demo), enacted as part of the Medicare Prescription Drug and Modernization Act of 2003 (MMA). As you know, the Demo is statutorily mandated to parallel, to the extent possible, the impending Part D benefit. We were pleased to have the opportunity to work with Members of Congress and their staff, in the effort to ensure that the Demo would be consistent with Part D, so as to minimize the risk of beneficiary confusion once they rolled from Medicare coverage under the Demo, to Part D. As a result, we have gained significant insight into the benefits and challenges ahead for many of the stakeholders under Part D, and endeavor with these comments to offer specific comments that will aide

the implementation of Part D.

Our comments are as follows:

Beneficiary Enrollment - Dissemination of Plan Information

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d. Each and every page of every form should have the name, address, phone number and web address of the Prescription Drug Plan (PDP) offering Part D prescription coverage. The lack of this clarity in the Demo resulted in some patients and physicians attempting to send one or more of the required forms to the only named entities on the page, specifically, either The Department of Health and Human Services or the Office of Management and Budget.
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As is the case with many biologics, therapy costs are high relative to e.g., a pill to treat hypertension. We know from our coverage experience in the Demo, that patients who take our product under the Part D benefit will both enter and exit the so-called "donut hole" (the amount above $2,250 that is not paid until the beneficiary has paid $3,600 in out of pocket costs). More importantly, we know that the full value of the Part D benefit may be forever out of reach for many high co-pay beneficiaries unless they receive some kind of financial assistance. As we know, the majority of beneficiaries live solely on their Social Security income. Therefore, only a small percentage of Medicare beneficiaries have income sufficient to cover the initial $3,600 out-of-pocket requirement, plus the 5% co-pay on all therapy costs over $5,100.

Accordingly, we agree that "bona fide charities unaffiliated with employers or insurers" should be allowed to assist "Part D enrollees with covered Part D expenditures and hav[e] those expenditures count toward enrollee's incurred costs," in order to satisfy the patient's annual $3,600 out of pocket maximum. We also agree with CMS' comment that "the number of people who are both assisted by charitable organizations and have expenditures high enough to qualify for protection against high out-of-pocket expenditures would be small," and that "it is a desirable goal to allow appropriate charitable assistance to count toward enrollees' incurred costs

In that same vein, we encourage PDPs to include in their HIPAA patient consent forms, the patient's permission to share their protected health information with applicable 501(c)(3) organizations. We have found during the Demo that even though charitable funding is available to enrollees, the Medicare contractor operating the Demo has determined that the current consent form does not permit them to coordinate patient assistance due to HIPAA privacy limitations.

Coordination of Benefits

The agency notes in this proposed rule the need for PDPs to coordinate with other "secondary" payers, to determine, and ideally minimize, the co-payment actually required by the beneficiary.

In keeping with our comments immediately above, we strongly encourage CMS to facilitate the coordination of benefits for high co-payment/donut hole patients in need of patient assistance, which is available through bona fide charitable organizations. Ideally, there would be real-time processing of beneficiary co-payment assistance, in order to reduce the beneficiary's out of pocket costs during the period of time they are in the donut hole.

In the meantime, we have listed our relevant patient assistance programs with CMS for inclusion in the "Prescription Drug and Other Assistance Programs web site, to which patients may be referred if they are interested in the Demo, but need financial assistance.

Beneficiary Protections

We note in the proposed rule that PDPs are guaranteed a 1 year commitment by their Part D enrollees – meaning the patients are liable for their premium costs if they switch to another PDP during that one-year contract period. However, as proposed, PDP formularies can be changed monthly. We think greater parity is needed to protect beneficiaries worried that their PDP will drop costly medicines once they've secured a one-year contractual commitment from the beneficiary. Such tactics are indeed uncommon among PBMs operating in the private sector today. However, many of today's PBMs will be tomorrow's PDPs. As part of that transition, they will become risk-bearing entities for the first time, making their behavior unpredictable. Therefore, we urge CMS to minimize beneficiary risk by providing beneficiaries with the same one-year protection as the PDP receives. For patients that take therapies for chronic conditions, such as Serono's product Rebif?, for the relapsing forms of multiple sclerosis, it is imperative that medications proven to work for that patient remain available for the period of the contract. Accordingly, we urge CMS to amend the 30-day "appropriate notice" to allow new therapies to be added with 30 days notice (along with the corresponding co-payment requirements), while therapies available when the beneficiary signed the contract, must remain in effect for the duration of the one-year policy.

We strongly support CMS' proposal to waive late enrollment penalties, when patients enroll in Part D for the first time solely because their previous provider terminated their coverage.

We also support CMS' proposal to expand to the degree possible creditable insurance coverage from plans that provide prescription drug coverage, as some form of supplemental or "wrap-around" benefit to Part D. Particularly for beneficiaries above 150% of the Federal Poverty Level who will enter the donut hole, the need for all possible sources of coverage is critical.

Dispensing Fee and/or Home Infusion Services

We encourage CMS to ensure that PDPs provide for a dispensing fee that adequately covers the shipping and handling of biologics that have a limited shelf life. The handling of biologics that require refrigeration, constitution or particular storage are indeed more expensive than oral forms of medication, and pharmacies must be adequately compensated for handling them, or they will be discouraged from offering them to the Part D enrollees. Also, improper or poor handling of any of Serono's products would result in costly wastage for which no reimbursement mechanism is available. Accordingly, we need to take all possible steps to ensure skilled pharmacists are handling and shipping these types of products.

In a related vein, we recognize the potential need under any of the options discussed in the proposed rule for a pharmacist to be paid for any administrations he or she performs, but unlike e.g., vaccines, Serono products are not pharmacist administered, so we take no position on the any of the three options. Not addressed in the rule is whether physicians can administer a Part D drug when medically necessary, and bill solely for their time and service under Part B using the appropriate CPT code. For patients with chronic, degenerative diseases such as multiple sclerosis, we believe it is imperative that policy takes into account the patient's state during a relapse, which includes but is not limited to, blindness, paralysis,

and cognitive impairment. While we expect patients taking our product, Rebif?, will routinely self-administer their injections at home, we wish to clarify that they may ask their physician to perform the injection when they are unable to.

On a related note, a question that arose during the implementation of the Demo was Medicare coverage policy regarding physicians or their staff who, in the incident-to setting, teach/train patients how to self-inject. It is our understanding from Mary Stojak at CMS that Medicare coverage policy allows for physician payment of such training under Part B, even when the therapy itself is not covered. We seek confirmation from CMS that this policy will be in effect under Part D. We also wish to confirm that CPT 99211 would be the appropriate billing code.

Medicaid Dual Eligibles

We understand from CMS staff that approximately 10 million Medicaid/Medicare "dual eligibles" will shift from Medicaid as their primary prescription drug benefit, to Medicare. Of that, approximately four million are expected to qualify for the full low- income subsidy, meaning they will pay nothing for their therapy. For many of these patients, this could represent a substantial reduction in the current drug costs, depending upon the co-payments required by the state in which they live. The remainder of the dual eligibles, however, may see an increase over their current costs, making it more costly to fill their prescription under Medicare than under their former state Medicaid program.

Included in that population are patients who take Serostim?, a treatment manufactured by Serono to restore lean body mass (a condition known as "wasting") for HIV patients who experience wasting. This is an extremely vulnerable population, and we encourage the agency to take every step possible to limit the risk that these dual eligible patients will be unable to afford their co-pays.

We also note that the agency expects about one-half of the current patients in the AIDS Drug Assistance Program (ADAP), a program through the Ryan White CARE Act, to not only move to Part D, but to qualify for full Medicare low-income subsidies, with another 30% likely to qualify for partial income subsidies. We also recognize that many ADAP plans participate in the 340B drug pricing program, which allows certain federally-funded grantees, including the ADAPs, to receive discounted outpatient prescription medication from manufacturers and wholesalers. According to CMS, half of the states purchase their drugs directly at a discounted rate, securing the product discount up-front while the other half participate in "the rebate model" and receive a rebate subsequent to purchase from manufacturers. As CMS urges the ADAPs to move to the up-front discounted method and away from rebates, we once again urge CMS to protect these fragile beneficiaries from Medicare donut hole-type co-payments, the cost of which will likely put treatment out of their reach.

Also, in general, we support the proposal to restrict Medicare coverage based on the current restrictions in the Medicaid program – limited to those in 1927(d)(2), such as products for cough and cold, or hair growth. In that context, on February 23, 1999, in a letter written by Sally Richardson, Director of the Center for Medicaid and State Operations, HCFA determined that "all states must provide coverage of the drug [Serostim?] as indicated for AIDS wasting and cachexia. We raise this issue now to ensure that

when the Medicaid dual eligibles, many of whom have AIDS, move from Medicaid to Medicare on January 1, their access to Serostim? remains intact.

Formulary Placement/USP Guidelines

To date, the USP guidelines do not provide for the four injectable therapies Serono will have covered under Part D. The four therapies are: Saizen?, Serostim?, Rebif? and Zorbtive?. We have commented separately on this to USP, but strongly urge CMS to ensure that the USP Guidelines, as they are considered, modified and finalized by CMS, protect access to these products. Failure to do so will result in denied access for medications patients already have under Medicaid. This is particularly relevant for the dual eligible population who, just because they are being automatically reassigned to Medicare for their pharmaceutical coverage, nevertheless must maintain their treatment.

Also, we strongly support the requirement in the proposed rule, that P&T committees include and consider information other than cost before establishing formulary placement. This information includes pharmacoeconomic data, randomized clinical trials, outcomes research data, safety and efficacy.

Finally, we strongly urge CMS to ensure that the USP guidelines provide for therapies already available to the Medicaid population, to prevent disruption in beneficiary access.

Part B vs. Part D Covered Drugs

We agree with CMS that, “One goal of Part D is to fill any gaps in existing Part B coverage of drugs. Part B has a limited and specific drug benefit covering drugs furnished “incident to” a physician’s service . . . Part D cannot pay for these drugs because payment is available under Part B.” [Page 46646]

However, on Pages 46702-3 of the proposed rule, CMS notes “However, that same [Part B covered] drug can be covered under Part D when picked up at a retail pharmacy to be self-administered by the patient.” In the paragraph following, CMS essentially repeats page 46646, by saying, “We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B.”

We seek clarity between what appear to be two different coverage opinions. Under current policy, CMS allows Part B coverage and reimbursement of intramuscular injections administered incident-to (in the physician office). In a May 2002 Program Memorandum, HCFA/now CMS determined that intramuscular injections were “not routinely self-administered,” and that the nature of intramuscular injections requires administration in the physician office. As a result, HCFA determined that intramuscular injections were eligible for Medicare coverage under Part B. Conversely, in the same Program Memorandum, subcutaneous injections were determined to “be routinely self-administered” and thus did not require physician administration. As a result, subcutaneous injections were excluded

from Part B coverage.

CMS' existing Medicare coverage and payment policy is that intramuscular injections should be presumed to require physician administration, and are not normally self-administered. Thus, such injections and are paid for only when provided in the physician office. We find it inconsistent to suggest that Medicare Part D should provide coverage of intramuscularly injected therapies, as Part D is an outpatient drug benefit for products patients can take or administer on their own.

We seek clarity on this issue, as Serono is a company that primarily manufacturers injectable therapies. Coverage eligibility in the Medicare and private sectors are a factor in the determination of how best to bring a product to market, and also how best to explain its likely insurance coverage to patients.

We believe the most rational policy would allow for payment of all injectable therapies under Part D, with Part B coverage applying only to the physician's time in the cases where the patient, due to their disease state, cannot self-inject. Of utmost concern to Serono, is that Medicare coverage policy allows for an injection (whether intramuscular or subcutaneous) to be administered incident-to, with the physician's time billable under Part B (using the appropriate CPT code), while the therapy itself is covered under Part D.

We sincerely appreciate the opportunity to provide these comments to the agency, and look forward to working together to implement the Part D Drug Benefit.

Sincerely,

Pamela Slane Pepe
Executive Director, Government Policy
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1700 Rockville Pike, Suite 210
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The Honorable Mark McClellan

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We sincerely appreciate the opportunity to provide these comments to the agency, and look forward to working together to implement the Part D Drug Benefit.

Sincerely,

Pamela Slane Pepe
Executive Director, Government Policy
Serono, Inc.
1700 Rockville Pike, Suite 210
Rockville, MD 20852
(301) 770-3050
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The Honorable Mark McClellan

CMS-4068-P-1192

Submitter : Ms. Cynthia Sloat **Date & Time:** 10/04/2004 08:10:05

Organization : Ford Motor Company

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments

CMS-4068-P-1192-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

1. Commenter failed to complete all steps required in order to attach their attachment.

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If you wish to view an attachment that has not been posted on the web page, please contact 410-786-9994 or 410-786-7195. They can schedule an appointment for you to view these attachments.

CMS-4068-P-1193

Submitter : Mr. Nicholas Goschy **Date & Time:** 10/04/2004 08:10:27

Organization : Tennessee Valley Authority

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4068-P-1193-Attach-1.doc

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CMS-4068-P-1194

Submitter : Mrs. Anne DiRenzo **Date & Time:** 10/04/2004 08:10:49

Organization : MediLink Homecare, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached word document

CMS-4068-P-1194-Attach-1.doc

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Submitter : Mr. Dan Walden **Date & Time:** 10/04/2004 08:10:02

Organization : Medco Health Solutions, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached Word document.

CMS-4068-P-1195-Attach-1.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

This is being attached to this comment to explain why there may not be an attachment provided as indicated by the commenter. Attachments are not received on particular comments and the following are reasons why.

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CMS-4068-P-1196

Submitter : **Date & Time:** **10/04/2004 08:10:12**

Organization : **Walgreens**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C, please revise the pharmacy access standards to ensure that plans meet the TRICARE pharmacy access requirements on a local (zip code) level, not on the plan's regional or "average" overall level. Requiring a plan to meet the standard on a local level is the only way to make sure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intent to provide a level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

Under Subpart D, please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries.

Thank you for making the needed revisions to best serve all Medicare beneficiaries.

Submitter : Dev Chatterji **Date & Time:** 10/04/2004 08:10:32

Organization : UNC School of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

Center 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:

I would like to thank you for the opportunity to comment on the proposed regulation to implement the Medicare Prescription Drug Benefit. This regulation, if implemented, will provide significant opportunities for the profession of pharmacy. I am offering the following comments for review as CMS develops the final regulation

Subpart C: Benefits & Beneficiary Protections
The pharmacy access standards, while good in trying to ensure convenient beneficiary access, may not be accounting for all patients by having plans meet the access standards ?on average? across the service area. This may not be as a big a problem in urban and suburban areas, but patients in rural areas may be denied convenient access if the standards aren?t modified to meet access on a local level. Rural patients are probably the ones who would benefit most from this prescription drug benefit so modifying the pharmacy access standards to ensure that all beneficiaries have convenient access to a local pharmacy is strongly preferred.

It is apparent 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. While there is nothing wrong with establishing preferred and non-preferred pharmacies, this takes away the patient?s ability to use the pharmacy and pharmacists of their choice because not all pharmacies will be preferred pharmacies. This is an important point to take into consideration in developing the final regulation

Subpart D: Cost Control& Quality Improvement Requirements for Prescription Drug Benefit Plans
I strongly support the plans to establish a medication therapy management program. Pharmacists would be ideal as the primary providers for MTM (medication therapy management) services. Being the top providers of drug information and having extensive knowledge about disease states and proper pharmacotherapy, pharmacists can finally use their training to provide this service for patients and be reimbursed for doing so.
Implementing a MTM program with pharmacists as the central providers is a significant opportunity for the profession to advance. I?m glad that CMS recognizes pharmacist?s expertise in medication therapy management and plans to establish this program.

I advise CMS to review my comments and take them into consideration when developing the final regulation. Thank you for your time and I appreciate your consideration for my comments.

Sincerely,

Dev Chatterji
Doctor of Pharmacy (Pharm.D. Candidate)
School of Pharmacy
UNC-Chapel Hill
Tel: 919-414-5280
Email: chat@email.unc.edu

CMS-4068-P-1198

Submitter : Ms. Carolyn Carlson **Date & Time:** 10/04/2004 08:10:38

Organization : Horizon Healthcare Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAIDE SERVIVICES
7500 SECURITY BLVD
BALTIMORE, MARYLAND 21244

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CMS-4068-P-1199

Submitter : Mr. Steven Lieberman **Date & Time:** 10/04/2004 08:10:07

Organization : The Moran Company

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

Our comments are attached.

CMS-4068-P-1199-Attach-1.doc

1655 N. Fort Myer Drive Arlington, VA 22209 (703) 465-9970 Fax (703) 465-9969

Comments Submitted Electronically

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, Md 21244-8014
http://www.cms.hhs.gov/regulations/ecomments

Dear Sir or Madam:

I am writing on behalf of The Moran Company, an analytic consulting company, regarding the notice of proposed rulemaking (NPRM) issued on August 3, 2004 by the Centers for Medicare and Medicaid Services (CMS) to implement the new Medicare Prescription Drug Benefit established by Title I of the Medicare Modernization Act (MMA). Several of my comments also overlap with the Medicare Advantage (MA) program established by an NPRM also issued on August 3, 2004 for Title II of the MMA. Where the provisions interrelate, this letter includes comments on both Title I and II of MMA. We have also separately filled comments on Title II of MMA.

Subpart K: Title I 423.503 (d); Title I 423.507(b)(3) & Title I 423.509(d) [Section 1857(h)] & Title II 422.502; Title II 422.506; Title II 422.510

Issues:

Denial of an application leads to written notice that the applicant does not meet the contract requirements, leading to a right of the applicant to request reconsideration. A related issue concerns the right to appeal a CMS non-renewal of a contract or CMS termination of a contract.

Comments:

Does this section, which addresses redetermination and appeals rights of the applicant, apply to an impasse between CMS and the PDP or MA-PD on negotiations for a final bid? In other words, does failure by the PDP or MA-PD to come to an agreement with CMS on an acceptable *bid* trigger reconsidered determination rights, or are those rights limited to the CMS' determination concerning the potential PDP or MA-PD's *application*?

Since the CMS decision to *renew* a contract is not based on the bid submitted for the new year, do the reconsidered determination rights apply to an impasse over a bid for the upcoming year?

Is the negotiation process associated with the review of the bid the opportunity for CMS and the PDP and MA-PD to discuss any elements of the bid that do not meet CMS requirements, or only those that meet the requirements? Can the bidder to change the bid to come into compliance within the allotted time frame?

Presumably, failure of a plan to come into compliance with the program's requirements by a set date when the national average and regional benchmarks must be calculated would preclude the contracted organization from being able to offer a plan in the upcoming year. Would failure by the PDP or MA-PD to come into compliance effectively terminate (or, for the first contract year, 2006, not initiate) the contract – and, therefore, would the rights for a reconsidered determination not apply?

Since the MMA states that the Title I reg must create operational and administrative requirements in Part D similar to those provided for in Part C, must the Title II regulations apply the same rules as Title I in this matter? Presently, the Title II language governs the appeals process for terminations of contracts, and not the decision to deny a contract in the first place, is this the opportunity for the plan to demonstrate to CMS's satisfaction that its bid for the upcoming year does in fact meet their requirements?

Subpart K: Title I 423.503(a)(2) Title I 423.503(c)(2) & Subpart N: Title I 423.645(b); Title I 423.651(b); Title I 423.666 & & Title II 422.502(a)(2); Title II 422.502(e)(1); Title II 422.501(d)

Issues:

Completeness check w/ 10 day notice for PDP
Completeness check w/ 30 day notice for MA

Letter of intent to deny w/ 10 day response to cure for PDP
Letter of intent to deny w/ 60 day response to cure for MA

MA plan has 4 months to resubmit an application that has been denied

PDPs have 15 days to file for a reconsideration of a denial of a contract by CMS.

PDPs have 15 days to file for an appeal (hearing) of a denial of a contract by CMS

PDPs have 15 days to file for review of a hearing decision to uphold the termination by the CMS Administrator

Comments:

The final regulations are likely to be published no earlier than January, 2004. Because the final requirements for applications for MA-PDs and PDPs has to follow that date and applicants need time to put their applications together, it seems there will be a short period for CMS to do its review and approval of applicants before bids are due on June 6, 2005.

It would seem essential for CMS to streamline the review process; this comment asks how CMS will streamline or otherwise modify the processes in order to meet the operational requirements imposed by the statute in conjunction with the Administrative Procedures Act? It seems problematic to fit all these steps, such as the completeness check, redetermination and appeal following denial, and their associated timeframes, into an overall timeframe that would allow approval to be complete before bids are accepted on June 6, 2005.

Might it make sense for CMS to allow applicants to submit bids even if final determination is not made to keep the process moving, and only include the bids in the calculation of the national average and regional benchmarks if a favorable determination occurs by the date when these final calculations must begin? This could effectively allow more time for plans to complete the approval process without necessarily being unduly constrained by the June 6th due date. Such an accommodation would seem squarely in the public interest: for a modest procedural modification, a more competitive and administratively feasible system would be permitted.

Some plans may be in an appeal process that is not finalized by the date when final national average and regional benchmark calculations must begin. Would there need to be a cut-off point when an applicant would not be allowed to offer a PDP or MA-PD plan effective January 1, 2006 to maintain the integrity of the overall process? And if so, what good faith efforts could CMS take to expedite the redetermination and appeal processes to help plans get through these processes before the cut off date?

It appears that certain timelines in the Title I and Title II regulations that concern the application approval process do not line up. Should CMS attempt to facilitate the coordination of the review and approval processes between the MA and drug benefit provisions so that these can be as seamless as possible to the plans?

Subpart K: Title I 423.506(b) & Related provisions under MA

Issue:

12 month term of Contract

Comment:

If contracts are assigned before 1/1/06, then the life of the contract in Year One would probably need to be longer than 12 months to cover the start up period.

Subpart G: Title I Subpart B 423.34(d)

Issue:

Special Rule for enrolling full benefit dual eligibles

Comment:

Should CMS consider auto-assigning all low-income subsidy individuals to prescription drug plans, in addition to full benefit dual eligibles? A strong public policy argument can be made in favor of extending auto-assignment beyond full benefit dual eligibles to other individuals receiving (or, indeed, eligible for) the low-income subsidy. Not only would such administrative action be consistent with the objectives of extending affordable prescription drug coverage to low income seniors and disabled individuals, it would also benefit the program by assuring a large risk-pool of participants. Because such low-income subsidy individuals would only be assigned to plans with below average premiums, it would constitute a strong incentive for prescription drug plans to offer low-price bids, thereby enhancing competition. (This strategy – of enhancing competition, regardless of whether auto-assignment is extended to low-income subsidy beneficiaries – is both critical and critically dependent on at least adequate risk-adjustment for low-income subsidy eligibles, as already noted in the CMS preamble to the NPRM.)

Subpart P: Title I, 423.772; & Subparts P and S: 423.774 and 423.904; 423.773(c) & 423.904 (c)(3) and Subpart B 423.34(d); Subpart P & S 423.773(c) & 423.904(c)(3)

Issues:

Definition of resources; Determinations of eligibility for the low-income subsidy; Effective period for deemed populations and retroactivity; Treatment of medically needy as full subsidy eligibles

Comments:

The definition refers to section 1613 of the Act, which addresses exclusions from resources under the SSI program. This section also addresses transfers of assets. The NPRM is unclear how transfers of assets for less than fair market value should be handled with the respect to the low-income subsidy program.

The NPRM is unclear whether the state's obligation under the law to determine eligibility for the low-income subsidy program is met by states determining eligibility for the deemed Medicaid population (i.e., full benefit duals and Medicare Savings Program groups). CMS should clarify whether states can meet their obligation by submitting all the applications taken by a state to SSA for processing, in which case SSA would be responsible for redeterminations and appeals.

What is the date of eligibility for the deemed populations? How does CMS intend to handle retroactive eligibility under Medicaid with respect to the subsidy? Will there be retroactive eligibility for the subsidy and retroactive enrollment in prescription drug plans?

How should CMS treat the medically needy and individuals who cycle on and off Medicaid? Can – and should – CMS consider a guaranteed period of eligibility for administrative simplification purposes?

Subpart S: Title I 423.904 (c)

Issue:

Screen and enroll for MSP provision

Comment:

Should CMS consider sharing low-income subsidy information from SSA with states in order to assist states in identifying individuals eligible for Medicare Savings Programs?

Thank you for the opportunity to comment on this important regulation.

Sincerely,

Steven M. Lieberman
Partner

CMS-4068-P-1200

Submitter : **Date & Time:** **10/04/2004 08:10:58**

Organization : **National Minority Health Month Foundation**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-1200-Attach-1.doc

October 4, 2004

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

RE: Comments on Proposed Regulations for the Medicare Prescription Drug Benefit
File Code: CMS-4068-P

INTRODUCTION

The National Minority Health Month Foundation (the Foundation) appreciates the opportunity to submit comments on the above reference proposed regulations for the Medicare Prescription Drug Benefit, as authorized by Title I of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA).

The Foundation is a not-for-profit 501(c)(3) organization dedicated to reducing disparities in health status among racial and ethnic groups that are a statistical minority of the population in the United States. The Foundation advocates the use of data-driven and evidence-based responses to eliminating the disproportionately high levels of morbidity and mortality in all racial and ethnic minority communities – morbidity and mortality associated with conditions for which there are effective treatments that are currently available or on the horizon.

Minorities now comprise approximately twenty percent of the elderly Medicare population. By the year 2050, it is estimated that nearly 1 in 2 Americans will be members of a racial or ethnic minority; i.e., African-American, Hispanic, Asian, or American Indian (*National Healthcare Disparities Report*, DHHS, 2003). The percent of minorities in the Medicare-eligible populations is expected to grow, as well. Minority groups experience a disproportionate incidence of the chronic diseases that account for the majority of deaths and medical care costs each year. African-Americans and other racial and ethnic minorities experience not only higher incidence of chronic and acute conditions that are disabling and foreshorten the lifespan, but also experience higher rates of poverty.

Accordingly, the comments submitted by the Foundation focus on selected issues that may have particular impact on the ability of communities of color to access essential, efficacious medications. Lack of comment on other aspects of the proposed regulations for Part D (and for Part C) must in no way be construed to suggest that their implementation, as drafted, will not adversely affect the ability of communities of color to access essential health services, nor as endorsement by the Foundation of the language. It is a reflection only of the practical limitations of human resources that dictate a focus on a limited number of issues within these complex and cumbersome regulations.

1200 New Hampshire Avenue, N.W., Suite 575
Washington, D.C. 20036
Tel: 202-347-3820 · Fax: 202-223-7567

GENERAL COMMENT

CMS must assure that the focus on cost containment in the Part D Prescription Drug benefit not result in a de facto increase in demand for inpatient and outpatient services — increases triggered at numerous stages of the Part D prescription drug delivery continuum by:

- Lack of access to medications during the transition/voluntary enrollment periods;
- High co-pays;
- Premium creep;
- Lack of geographic access to preferred network providers;
- Failure of the formularies to cover essential medications or all indications of a drug, including off label uses;
- Difficulty in meeting out-of-pocket minimums as a result of the manner in which TrOOP is calculated;
- The ability of the Medicare Advantage program to preempt state laws regarding mandatory coverage; and
- Burdensome grievance and waiver processes.

As noted in *Prevention Makes Common "Cents"* (DHHS, September 2003), "A small number of chronic disorders such as diabetes and cardiovascular diseases account for the majority of deaths each year, and the medical care costs of people with chronic diseases account for more than 75 percent of the nation's medical care costs." This report documents more specifically that:

- Approximately 129 million U.S. adults are overweight or obese, which costs this Nation anywhere from $69 billion to $117 billion per year.

- In 2000, an estimated 17 million people (6.2 percent of the population) had diabetes, costing the U.S. approximately $132 billion. People with diabetes lost more than 8 days per year from work, accounting for 14 million disability days.

- Heart disease and stroke are the first and third leading causes of death in the United States. In 2003 alone, 1.1 million Americans will have a heart attack. Cardiovascular diseases cost the Nation more than $300 million each year.

- Approximately 23 million adults and 9 million children have been diagnosed with asthma at some point within their lifetime, with costs near $14 billion per year.

Minority groups experience a disproportionate incidence of these diseases, and a resulting disproportionate share of the social and economic costs that attend these diseases -- costs that will have a collateral impact on all individuals, employers, and insurers in the country. They are, thus, more vulnerable to disruptions in

the existing health care infrastructure and often their health status more compromised when they seek care.

The health status disparities experienced by communities of color result from a combination of factors, including, but not limited to, financial and geographic access barriers to quality health care (including pharmaceuticals), as well as bias in the manner in which health services are delivered. This bias is documented in the report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare* (Institute of Medicine, 2002), which advanced the understanding of the issues that contribute to and attend racial and ethnic disparities. The report noted that, "Racial and ethnic disparities in healthcare exist and, because they are associated with worse outcomes in many cases, are unacceptable". Citing the multi-factorial nature of the causes, the report concluded that, "Many sources – including health systems, healthcare providers, patients, and utilization managers—may contribute to racial and ethnic disparities in healthcare. This includes, but is not limited to, "…bias, stereotyping, prejudice, and clinical uncertainty on the part of healthcare providers." The building of effective solutions, therefore, requires an understanding of all the causes and the strategic targeting of effective remedies.

The Foundation strongly encourages the CMS/DHHS to make every effort to assure that final regulations, and the policy and practice that are the outgrowth of those, are designed to minimize the negative impact of the financial incentives that are built into the new programs to encourage the participation of private plans and the help offset their financial risk. Privatizing components of Medicare does not and cannot relieve CMS/DHSS of their responsibility to vulnerable citizens of the United States to assure that they are not victimized by market forces.

REQUEST FOR AN INTERIM RULE AND A SECOND PUBLIC COMMENT PERIOD

Given the massive amount of information contained in both sets of proposed regulations, and the requests by CMS for suggestions through the public comments regarding the manner in which critical provisions should be designed, it is recommended that, following the close of the current public comment period, CMS issue an interim rule that can be made available for public comment. This will be viewed as a good faith effort on the part of CMS to meet the needs of affected communities.

NEED TO INVEST IN AND PLACE A PRIORITY ON HEALTH LITERACY

CMS must assure that communications from CMS to beneficiary populations are developed with input from communities of color to help assure that the documents are culturally competent, comprehensible by non-clinicians, and do not serve to discourage participation in these programs. This is particularly critical given the confusing and complex nature of the changes. Failure to communicate effectively to affected populations in a manner that is clear, concise, and culturally competent will in itself serve to discourage enrollment by eligible populations.

NEED TO EVALUATE THE IMPACT ON HEALTH STATUS OUTCOMES

CMS must assure that data are collected, analyzed, and reported regarding the impact of the Prescription Drug Program and the Medicare Advantage Program on the health status of minority beneficiaries at the community (at least zip code) level. Failure to do so will enable results to be aggregated in a manner that

masks the impact on communities of color. In the Regulatory Impact Statement, CMS notes that, "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". Accordingly, we encourage CMS/DHHS to fund Section 1013 of the MMS - Research on Outcomes of Health Care Items and Services. We urge the Department to include this funding in annual budget requests as a priority. We encourage the CMS/DHHS to assure that external contractors engaged to conduct this research have knowledge about the health status outcomes of racial and ethnic minority populations. We also encourage the CMS/DHHS to assure that these evaluations reflect outcomes assessments at the zip code level to assure that the health status of minority populations is not masked by aggregating the assessments to the county, state or national levels.

ANTI-DISCRIMINATION PROVISION

The MMA provides CMS with an important tool to protect Medicare beneficiaries from discrimination by Part D plans. Specifically, the MMA authorizes CMS to reject a prescription drug plan if the plan's design or benefits are "likely to substantially discourage enrollment by certain Part D eligible individuals". This provision vests CMS with the authority to conduct a comprehensive review of plans for potentially discriminatory designs and reject those plans that do not pass muster. Further, the language of this anti-discrimination provision is notably broad in apparent recognition that design and benefits of plans may discriminate against beneficiaries in numerous ways.

Despite the breadth of the anti-discrimination provision of the MMA, the proposed rule implementing Part D indicates that CMS may apply the language narrowly. The preamble language to the proposed rule interprets the anti-discrimination provision to mean that CMS must examine whether a plan discourages beneficiary 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." This will include reviewing a plan's benefit design, such as initial coverage limit, tiered cost sharing, formulary categories and classes, and the particular drugs included on the formulary in each category, as well as any discriminatory use of prior authorization or other coverage restrictions.

This interpretation of the anti-discrimination provision is exceedingly narrow, because it would permit plans to discriminate against certain groups of Part D enrollees, such as minorities, with particular characteristics that affect how they respond to certain medications. For instance, clinical evidence demonstrates that certain drugs may be more efficacious for—minority populations. Such is the case with BiDil®, which is being investigated for its potential to reduce mortality and hospitalization for African-American heart failure patients. The opposite is also true. Certain drugs are less effective in minority populations, as is true for enalapril, known commercially as Vasotec, an ACE inhibitor used in treatment of hypertension. According to the enalapril package insert, "it should be noted that in controlled clinical trials ACE inhibitors have an effect on blood pressure that is less in black patients than in non-blacks. In addition, it should be noted that black patients receiving ACE inhibitors have been reported to have a higher incidence of angioedema compared to non-blacks."

Under CMS's interpretation of the anti-discrimination provision, a formulary could discourage enrollment by minorities by excluding a drug that is particularly efficacious for minority enrollees and still be approved by CMS because the formulary would not be discouraging enrollment on the basis of "health status". Accordingly, CMS should give the anti-discrimination provision its intended, broad meaning and ensure that beneficiaries have access to the most efficacious medications available. To that end, when CMS reviews a plan's formulary and benefits design—including utilization management tools such as step therapy, prior authorization, and tiered cost-sharing in their formularies—CMS also should review the extent to which the plan might discourage enrollment of minorities by excluding drugs that are especially efficacious for them or by making such drugs more costly than the less effective alternatives.

ASSURE THE DEVELOPMENT OF FORMULARIES THAT MEET THE NEEDS OF ALL BENEFICIARIES WITHOUT THE REQUIREMENT OF WAIVERS OR APPEALS

Generally, minority populations are underserved in the healthcare marketplace. They are less likely to be given higher quality pharmaceuticals than other patients, and often pay more for the pharmaceuticals they do receive. This predisposition of the health care delivery system toward withholding innovative medications from minorities further reinforces the need for drug formularies that do not discriminate against minorities. The peer-reviewed medical literature has demonstrated that racial differences play a role in efficacy results, metabolism, and adverse event profiles associated with the use of pharmaceuticals. Genetic variations contribute to differences in drug metabolism and responsiveness in many conditions common in minorities both across and within racial and ethnic groups. Hispanic subgroups in the United States metabolize drugs differently depending on their genetic heritage, which can vary from 31% American Indian, 8% African, and 61% Spanish among Mexican Americans, to 18% American Indian, 37% African, and 45% Spanish among Puerto Ricans, and 18% American Indian, 20% African, and 62% Spanish among Cubans (Hanis et al, *Diabetes Care*, 14:618-627, 1991). Genetic diversity among the individuals classified as African Americans exists, as well.

The differential responses of minorities to drug therapies have been well documented and this body of information and our understanding of these differences continues to grow. As minority patients are increasingly being included in clinical drug trials, even more data and information is becoming available concerning differences in responses to drug therapies within and among races. The formularies developed by the Prescription Drug Plans (and the USP Model Guidelines which influence their content) must be designed to assure access to current and developing pharmaceuticals that will be efficacious in minority groups, but perhaps not as efficacious in non-minority groups or groups classified as Caucasian. If required, appropriate provisions must be made for alternative formularies to meet this requirement. CMS must establish a formal process for consulting with physicians and pharmacists of color to assure that formulary guidelines, and the formularies approved for the Prescription Drug Programs are appropriate to meet the prescription drug needs of communities of color. The USP Model Guidelines must not afford to Prescription Drug Plans a "safe harbor" if they fail to meet this requirement.

In addition, CMS must develop and enforce a mechanism to ensure the timely and regular evaluation of medical evidence and its translation to optimal pharmaceutical therapy for minorities. Further, DHHS must

assure that a specific and transparent process for evaluating new data regarding race or ethnicity-based differences in response to drug therapies and appropriate adjustments to the PDP drug formularies.

CMS must assure that the formularies developed by the Prescription Drug Plans assure initial, continuous, and affordable access to pharmaceuticals, with particular attention paid to pharmaceuticals that may be uniquely efficacious in racial and ethnic minority populations. They must be responsive to the treatment areas in which significant racial disparities exist and establish appropriate pharmacologic classes or alternative formularies consistent with current medical evidence for such differences. For example, where there is a selective benefit demonstrated in African Americans, or the basis for approval and labeling identifies a benefit in this population, the pharmaceutical product should be made available. Exclusion from the PDP drug formularies of a product that has been clearly demonstrated through clinical studies to provide a significant benefit in a minority population would further promulgate minority disparities and discourage enrollment of minorities. These accommodations are necessary to assure that the PDP formularies do not discourage minority enrollment by excluding drugs preferentially beneficial to minorities or may not only include drugs that are less effective or ineffective in minorities. Medicare patients, and the physicians that provide services to them, must have access to all available medications and therapies that have demonstrated benefit in treating conditions most efficaciously in all populations, including African Americans and other minority populations.

To implement the provisions outlines above, the Foundation requests that CMS/DHHS make a concerted effort to elicit comments on the proposed regulations from the minority medical associations, the minority nurses associations, minority pharmacists and other organized groups that have expertise in treating minority elderly and disabled populations. The issuance of an interim rule and a second public comment period associated with that interim rule will create a window of opportunity to do so prior to finalizing the regulations. Further, there must be included in the regulations a requirement that an advisory committee be developed to assure the ongoing review and oversight of these providers.

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 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.

SPECIAL TREATMENT FOR SPECIFIC POPULATIONS

The Foundation supports 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 allow for alternative, flexible formularies for these 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. These Special Populations should be defined to include:

- Dual Eligibles,
- Institutionalized Populations,
- Persons with Life-Threatening Conditions,
- Persons with Pharmacologically Complex Conditions, and
- Populations who reside in geographic areas with documented disparities in health status and access to essential health services,
- Populations for whom Medicare has documented disparities in health status and access to essential health services,
- Racial “minorities” who have historically been underrepresented in clinical drug trials.

We recommend that the final rule require that the Secretary 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 include:

- Individuals with conditions that are recognized for their pharmacological complexity, and must include, but not be limited to, conditions such as sickle cell disease, epilepsy, Alzheimer’s disease, multiple sclerosis, mental illness, and HIV/AIDS.

- Individuals with conditions that require multiple medications to treat many conditions.

- Individuals 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

Prior to enrolling in a specific PDP, if an enrollee has tried a preferred therapy under medical supervision and the enrollee or enrollee's physician can document that that preferred drug is not appropriate, the PDP must 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 must be deemed sufficient evidence for coverage appeals and requests for formulary exceptions.

ESTABLISH 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, significant advances in the clinical management of disease are reported monthly, making it essential that the final rule require regular ongoing and timely review of their formulary protocols and procedures. This is particularly critical for racial and ethnic minorities to assure that the advances associated with pharmaceuticals that are uniquely efficacious for their conditions and chemistry are incorporated into the formularies as soon as they are available.

ACCESS TO COVERED PART D DRUGS AT OUT OF NETWORK PHARMACIES

The provisions in the final rule out-of-network access standards may not be sufficient to provide for access to covered Part D drugs for all populations. Standards must be established to assure that all beneficiaries have reasonable geographic access to network pharmacies at all times, including, but not limited to emergencies. For emergencies, the final rule must establish requirements that PDPs allow for the dispensing of a temporary supply of a drug wherever a prescription is presented, regardless of the network status of the pharmacy. 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.

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, including 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; 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; 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 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.

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. 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 at his confirmation hearing in the Senate Finance Committee, Dr. Mark McClellan stated 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." Accordingly, 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 among commercial insurers and with Medicaid. 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 burdens with respect to time needed to complete the prior authorization process, expense, and information documentation must be negligible.

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 that 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 for Medicare, hospitals or physicians. 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 months any prescription drug regimen for all individuals who have been stabilized on a course of treatment. Moreover, the plan must provide a determination within the first month of enrollment for all covered Part D drugs that are part of the treatment regimen and notify the beneficiary in writing 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 to implement these same cost management techniques as alternatives to the more common approaches that restrict beneficiary access to medications. 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.

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 the doctor to certify that the drug is not as effective or causes adverse effects.

- The preamble states that a PD's 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.

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 an exception to a plan's tiered cost-sharing structure other than on a case-by-case basis.

NEED FOR TECHNICAL AND CORRECTIVE AMENDMENTS

The National Minority Health Month Foundation recognizes that some of the constraints associated with improving the Prescription Drug Program and the Medicare Advantage Program require action within the legislative arena. Therefore, we urge CMS/DHHS to take advantage of the law's provision calling for the submission of technical and corrective amendments. The Foundation recommends that, at a minimum, the CMS/DHSS submit technical or corrective amendments to Congress as appropriate to address the following issues:

- The MMA creates incentives for lowering prices that may create incentives for reducing access to essential medications. PDPs and MA-PDs are paid based on what they bid. Bids are based on

expected prices, utilization, and administrative expenses. This may also create an incentive to reduce appropriate use of prescription drugs. While there is some overutilization in the system that should be reduced, there is also evidence of underutilization. The law provides no incentive for plans to address underutilization since doing so will increase costs and decrease profits. In addition, because stand-alone insurers reap no benefit from increased drug spending that decreases hospital or other service use, they have little incentive to make this kind of investment. The MMA should be amended to move away from a capitation model that creates a financial incentive for under-use toward a pay for-performance model where incentives are aligned to encourage use of appropriate prescription drugs.

- The MMA locks beneficiaries into drug plans that could change during the year. However, while beneficiaries will be locked into a plan for a year, there is no prohibition on plans changing their formularies, cost sharing, or pharmacy networks during the year. The only requirement is that they provide notice through the Internet or a toll-free number. The law prohibits the Secretary from implementing regulations that impose new significant requirements on PDP sponsors or plans except for at the beginning of the year. The MMA should be amended to allow beneficiaries to switch plans during the year if cost sharing increases significantly.

- The MMA does not ensure that low-income enrollees pay low or no premium. The law provides full premium subsidies for a large fraction of low-income beneficiaries, but that subsidy only extends to plans with premiums below the "low-income benchmark" (1860D-14(b); p. 49-50). This could mean low-income beneficiaries could have no choice of drug plans if they want to stay in traditional Medicare and receive the full premium subsidy. Since these low-income beneficiaries also qualify for reduced cost sharing for on-formulary drugs, this single plan choice could provide affordable access even if it has drugs in classes with high cost sharing for other enrollees. However, if the plan has a restricted formulary, aggressive cost management tools like "fail first" procedures, or a limited pharmacy network, then the low-income individual may have to pay a premium to join a different plan to access needed drugs. The MMA should be amended to ensure that low-income beneficiaries who want to stay in traditional Medicare have a choice of two drug plans; and to ensure that low-income beneficiaries who qualify for a full premium subsidy get it regardless of plan choice.

- The MMA allows for late enrollment fee charges to low-income beneficiaries. Low-income individuals who otherwise qualify for a full premium subsidy will have to pay part of a late enrollment penalty. Specifically, those with income that qualifies them for a full premium subsidy, including Medicare-Medicaid dual eligibles, will pay 20 percent of any penalty for up to 60 months (five years) (1860D-14(a)(1)(A)(ii), p. 44). Those with income between 135 and 150 percent of poverty pay it on a sliding scale (1860D-14(a)(2)(A), p. 45). This could have serious implications for some, including nursing home residents. The MMA should be amended to eliminate the late enrollment penalty for the lowest-income beneficiaries (e.g., dual eligibles), or for all individuals qualifying for a full premium subsidy. The MMA should also be amended to protect personal needs allowances for nursing home residents from Part D premium penalties.

- The MMA allows plans to change formularies during the year. Prescription drug plans and Medicare Advantage drug plans may remove a drug or change its preferred or tiered status at any time so long as appropriate notice is given (1860D-4(b)(3)(E), p. 22). Thus, a beneficiary may enroll in a plan because a specific set of drugs is on its preferred. The MMA should be amended to prohibit mid-year changes that increase enrollee cost sharing; and to grandfather access to preferred or lower cost sharing for those who use the drug during the year prior to the change.

- The MMA allows drug cost sharing to be higher at out-of-network pharmacies. The MMA should be amended to prohibit mid-year changes in the pharmacy network since some enrollees, especially in rural or underserved urban areas, may choose a plan because the local pharmacy is included. The law should be amended to require plans to take into account special access needs of vulnerable populations, as designated by the Secretary.

- The MMA places no explicit limits on cost management tools. The law explicitly allows plans to use cost management tools such as formularies, but does not restrict some practices that could cause access problems. The MMA should be amended to require the Medicare Payment Assessment Commission, in its annual report to Congress, to identify practices that potentially discourage access rather than over-utilization and prohibit such practices by law.

- The MMA does not require that payments for off-formulary drugs be counted toward the catastrophic benefit. Only out-of-pocket payments for on-formulary drugs count towards the threshold (1860D-2(b)(4)(C)(i), p. 14). The MMA should be amended to provide true out-of-pocket protection by counting beneficiary spending on all drugs that are permitted to be covered by Medicare.

- The MMA allows for complicated enrollment processes that vary by type of assistance and can vary among states. States do not have an incentive to aggressively enroll beneficiaries since those that they find who are also eligible for full Medicaid coverage would result in new state costs. The MMA should be amended to require states and SSA to use the same, simple application form that has individuals self-declare their income and assets; to allow for mail-in applications; to limit eligibility redeterminations to no more than once a year; to require retroactive eligibility to cover drug costs that were incurred while applicants were waiting for their applications to be processed; and to allow prescription drug plans to make beneficiaries presumptively eligible to ensure that they have access to plans and affordable drugs.

These comments would not have been possible without the efforts of the organizations that have made an extraordinary commitment of time and resources to monitor and inform the legislative and administrative process that attended the passage of the MMA and the creation of the proposed administrative. Regulations. These include, but are not limited to, the Kaiser Family Foundation, Families USA, the Center for American Progress, and the National Urban League. The Foundation also acknowledges the input of

the Thought Leaders in Minority Health – Medicare, who convened to provide specific input to assure that the needs of racial and ethnic minorities are reflected in the program designs.

The National Minority Health Month Foundation will continue its efforts to engage all stakeholders in a concerted effort to eliminate health status disparities for all populations.

Sincerely,
Gary A. Puckrein, PhD
Executive Director

GAP:GCW/mp

c: The Honorable Donna M. Christian-Christensen, Chair, Legislative Black Caucus Health Braintrust
Dr. Winston Price, President, National Medical Association
Dr. Randall Maxey, President, Alliance of Minority Medical Associations
NMHMF Stakeholders Register

1200 New Hampshire Avenue, N.W., Suite 575
Washington, D.C. 20036
Tel: 202-347-3820 · Fax: 202-223-7567