Submitter : Mr. James Armbruster **Date & Time:** 10/04/2004 03:10:55

Organization : Mr. James Armbruster

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

There should be one set of prescription drug prices regardless of the prescription benefit manager. This would eliminate most of the confusion over what card to purchase.

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

A provision should be added that would allow for payment for additional drug therapy management services by the pharmacist. The seniors are the group most in need of drug therapy management by the pharmacist because per capita they take more medications than the rest of the population.

ELIGIBILITY, ELECTION, AND ENROLLMENT

There are too many plans from which to choose. Most seniors that I deal with cannot understand the programs and have to spend hours trying to figure out which card works best for them. They are ill-equipped to do this since many are of an age that they do not have typing skills and therefore cannot access the Internet. They also do not even know what questions to ask. Finally, they are being sold Medicare cards by some organizations that in some cases do not provide them with additonal benefits because they already have better prescription drug coverage through a Medigap policy.

October 1, 2004

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

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

Dear Centers for Medicare and Medicaid Services:

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

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

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

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

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

General Comments:
Subpart B. Eligibility and Enrollment

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

… We propose building on our experience in implementing the drug discount care price comparison Web site as we develop requirements for the Part D price comparison Web site, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings.

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

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

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

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

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

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

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

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

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

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

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

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

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

But that's only a first step.

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

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

c. Use of Standardized Technology (FR 46662)

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

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

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

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

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

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

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

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

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

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

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

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

Recommendations:

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

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

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

Prior Authorization

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

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

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

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

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

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

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

Recommendations:

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

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

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

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

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

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

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

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

Recommendations:

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

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

Sincerely,

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

CMS-4068-P-902

Submitter : **Date & Time:** **10/04/2004 03:10:20**

Organization : **American Society Consultant Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attached comments.

CMS-4068-P-902-Attach-1.doc

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October 1, 2004

Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS–4068–P
P. O. Box 8014
Baltimore, MD 21244-8014

File Code: CMS–4068–P

Dear Dr. McClellan :

The American Society of Consultant Pharmacists is pleased to offer comments on the CMS proposed rule for Title 1 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). This landmark legislation, and accompanying CMS regulations, will provide a drug benefit for ambulatory and institutionalized Medicare beneficiaries.

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Consultant pharmacists specializing in senior care pharmacy practice are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illness. In their role as medication therapy experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may

interfere with the goals of therapy. ASCP's 7,000 members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and in home and community-based care.

Because of the length of the CMS proposed rule, and these comments, an outline of our comments is provided below to facilitate finding ASCP comments on various issues addressed in the proposed rule.

Outline

****

1.0 Introduction

ASCP's concerns and comments relating to implementation of Medicare Part D focus on three special populations whose members overlap:

- Dual eligibles (persons who qualify for both Medicare and Medicaid)

- The frail elderly (persons aged 85 and over)
- Residents of long-term care facilities

Between 6 and 7 million Medicare beneficiaries are dual eligibles. Total health care spending for dual eligibles—across all payers—averaged about $20,840 per person in 2001, more than twice the amount for other Medicare beneficiaries. Dual eligibles represent 19% of Medicaid recipients and account for 35% of Medicaid spending. About 14% of dual eligibles are 85 years of age or older, and more than one-third are eligible for Medicare because of a disability. Almost one-quarter of duals reside in an institution, compared with only 3% of nondual eligibles. (1)

Frail elderly individuals number about 4 million in the United States. Persons in this age category (85 and over) are more likely to:

- Have multiple chronic conditions
- Take multiple medications
- Have diminished kidney or liver function
- Have difficulty swallowing or have a feeding tube inserted
- Reside in a nursing home or assisted living community
- Use home health care services or adult day services

These factors lead to special considerations in selection of appropriate drug therapy. This issue will be addressed more extensively later in this document.

At any given time, about 1.5 million individuals reside in nursing facilities. In a calendar year, approximately 3.5 million Medicare beneficiaries will spend some time in a nursing facility. An additional 1–2 million individuals reside in assisted living or board and care settings. These individuals also have special considerations related to their drug therapy because of the settings in which they reside.

2.0 Prescription Drug Plans and Medicare Drug Benefit Administration

Congress has chosen to provide a drug benefit to Medicare beneficiaries that will be offered either by Medicare Advantage programs, as part of a comprehensive health benefit, or by freestanding Prescription Drug Plans (PDPs), which will be at risk only for drug costs. Only 11% of Medicare beneficiaries currently participate in managed care programs. Among nursing home residents, fewer than 3% of residents are enrolled in managed care programs. Thus, the overwhelming majority of Medicare beneficiaries who participate in Medicare Part D will receive their drug benefit through these private entities known as PDPs. Fallback plans are to be made available by CMS in the event that no

organization offers to provide a Medicare drug benefit in one or more of the regions designated by CMS.

2.1 Prescription Drug Plans—Incentives

The insurance companies, or other entities that become PDPs for Medicare Part D, can be expected to behave as any for-profit entity would. They will seek to maximize profits and revenues. To the extent that these goals conflict with the best interests of the Medicare beneficiaries, CMS regulations are critical to ensure protections and safeguards for these beneficiaries. This is especially true for dual eligible individuals, who have no choice about whether to sign up for Medicare Part D. They will be automatically enrolled into one of these plans and will lose their Medicaid drug benefit on January 1, 2006.

Because they are at risk for medication costs, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. To maximize profits, PDPs can be expected to pursue the following strategies:

1. Enroll as many individuals as possible into their plans to maximize revenue
2. Selectively enroll lower-cost individuals
3. Deny access to higher-cost medications through formulary exclusions
4. Encourage beneficiary use of lower-cost formulary medications through strategies such as tiered co-insurance requirements
5. Discourage beneficiary use of higher-cost formulary medications through strategies such as prior authorization requirements
6. Shift costs to other payers, such as requiring beneficiaries to be hospitalized to receive intravenous medications

CMS regulations and oversight of PDPs are critical to protecting beneficiaries from strategies that prevent them from accessing needed and appropriate medications. CMS should anticipate the use or inappropriate application of these strategies by issuing regulations that ensure protection of Medicare beneficiaries, especially the dual eligible individuals.

Organizations with an interest in becoming PDPs have expressed a desire for maximum flexibility and control, with few regulations to restrict their business practices. This would, of course, be optimal for these businesses to minimize their risk and maximize their potential for profit.

On the other hand, consumer advocates have expressed concerns about the potential for these PDPs to deny access to medications, especially to dual

eligibles. Without access to a wide variety of medications, and consumer protections, dual eligible individuals may lose access to critically needed medications. Medicare beneficiaries who are not dual eligibles may choose not to enroll in Part D when it becomes available.

Recommendation: ASCP shares these concerns and urges CMS to include adequate consumer protections in the regulations so that Medicare beneficiaries will have access to needed and appropriate medications through the Medicare Part D program.

2.2 Medicare Advantage Prescription Drug Plans (MA-PD)

Medicare Advantage programs will be offering a drug benefit in 2006, and have economic incentives to use the drug benefit to help minimize overall health care costs. Although economic incentives are in better alignment with the MA-PD program, the Congressional Budget Office expects few Medicare beneficiaries to sign up for these programs. Projections are that the current enrollment of 11% of Medicare beneficiaries may increase to 13%.

A recent report by the Medicare Payment Advisory Commission revealed that Medicare pays private health plans an average of 107% of what it costs to provide coverage through traditional fee for service Medicare. This represents a premium payment to the private plans of about $50 billion over ten years. (2) At one time, Congress believed that private plans could provide comparable coverage for 95% of the cost of fee for service Medicare. Despite the theoretical alignment of economic incentives in comprehensive health plans, the cost of this approach is significantly *more* than with traditional fee for service Medicare.

3.0 Medications Excluded from Coverage Under Medicare Part D

The Medicare Modernization Act specified that certain categories of medications would not be eligible for coverage under Medicare Part D. These excluded medications are:

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.

• Outpatient drugs for which the manufacturer seeks to require associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale.
• Barbiturates.
• Benzodiazepines.

At the present time, states have the option of excluding any of the medications in the above categories from their drug benefit for individuals currently enrolled in Medicaid. Dual eligibles in all states, however, will lose access to all these drug categories under Medicare Part D in 2006. States have the option of continuing to cover these categories of excluded medications using state Medicaid funds if they so choose.

Recommendation: ASCP is extremely concerned about the loss of coverage for these medications for dual eligibles, especially the benzodiazepines, which are covered by nearly every state. ASCP urges CMS to explore administrative or legislative remedies to ensure coverage of these excluded medications in 2006.

3.1 Benzodiazepines and Barbiturates

Benzodiazepine medications are hypnotic-anxiolytics used to treat anxiety, insomnia, muscle spasm and seizures. Within the benzodiazepine class of medications there is great variation in drug characteristics such as half-life and duration of effect in the body, blood-brain barrier penetration, metabolic pathways and their associated consequences. Approximately 10% of nursing home residents receive anxiolytics, most commonly benzodiazepines. (3) Benzodiazepines are the 13th leading class of medications in the United States with 71 million prescriptions dispensed in 2002. (4)

Other classes of anxiolytic-hypnotic medications are available for management of chronic anxiety or sleep disorders. No suitable substitute exists, however, for clonazepam in management of certain types of seizure disorders. Without benzodiazepines, acute anxiety and agitation will also have to be managed with alternative medications that are either more toxic, more expensive, or both.

Meprobamate is an old antianxiety agent that is highly addictive and sedating. It is on the "Beers list" (5) of medications considered to be generally inappropriate for use in the elderly. Antipsychotic medications can be used but can produce significantly more side effects, such as extrapyramidal symptoms. The atypical antipsychotics are also much more expensive than generic benzodiazepine medications.

Benzodiazepines are taken by an estimated one million dual eligible individuals. When coverage of benzodiazepines is abruptly terminated on January 1, 2006, the likely result will be a flooding of emergency rooms and thousands of hospitalizations resulting from withdrawal symptoms of benzodiazepine cessation, and exacerbations of acute anxiety.

Only benzodiazepines can be used to arrest acute seizure disorders (status epilepticus) in patients with epilepsy. By 75 years of age, 3% of the general population has developed epilepsy. The prevalence of epilepsy is much higher in older patients. (6) It has been well documented, that prompt administration of benzodiazepines is a first-line intervention to arrest seizures in patients with status epilepticus. (7) In nursing home patients, lorazepam can be given safely with a small definable risk of adverse effects as it has a short half-life, is not affected by the aging consequences of drug metabolism through the liver, and exhibits no significant drug interactions. The risk of untreated status epilepticus is brain damage and death if seizures are allowed to continue for greater than 2.5 hours. (8) Without access to benzodiazepines, such as lorazepam, patients with status epilepticus will require hospitalization. The clinical and economic consequences of unchecked status epilepticus are staggering. (9)

Barbiturates, like benzodiazepines, are useful in treating seizure disorders. Barbiturates are used much less often than benzodiazepines, but for patients with certain seizures disorders, drugs such as phenobarbital, are indicated. (10) Many elderly patients have been maintained on phenobarbital successfully for years. (11) Drug discontinuation and drug switching in elderly nursing home residents has been shown to cause therapeutic destabilization and seizure exacerbation. (12)

3.2 Over-the-Counter (OTC) Agents

There are over 80 therapeutic categories of OTC agents, covering a variety of clinical needs including smoking cessation assistance, cough/cold preparations and bowel assistance products. OTC products are considered safe for use by the general population if the entire label information is read and comprehended. In the outpatient setting, OTC medications are often purchased by patients for self-treatment of minor conditions.

In the nursing home setting, however, all medications, including OTC medications, require an order from the physician prior to administration to the resident. The distinction between prescription and OTC medications is almost meaningless, with OTC medicines usually being treated in the same way as prescription drugs. In states where Medicaid programs do not pay for OTC

medications, the Medicaid per diem reimbursement for the nursing home is adjusted to allow the nursing home to purchase OTC medications and maintain them as floor stock for their residents.

Many OTC drugs are a necessary adjunct to maximize the benefit from prescription agents. Iron supplementation is needed with the erythropoetic therapies Procrit® (13) and Aranesp® (14). Calcium supplementation is necessary with osteoporosis therapies such as Actonel® (15) and Miacalcin® (16). Acetaminophen is considered first line therapy for the treatment of mild to moderate musculoskeletal pain in the elderly. (17) Stool softeners or laxatives are necessary to prevent or treat opioid-induced constipation. (18) When OTC medications are a necessary concomitant therapy, there is risk of therapeutic failure when the covered entity is used alone.

Many other OTC agents are currently covered under state Medicaid programs. Gastroesophogeal Reflux Disease (GERD) is common among the elderly. (19) The most recent trend in coverage for Medicaid patients is the transition to Prilosec-OTC®, (omeprazole) from legend proton pump inhibitors. Eight states, Florida, Illinois, Indiana, Kansas, Kentucky, Missouri, North Carolina, and Wisconsin, provide Medicaid coverage for this OTC product because of its lower cost.

Loss of OTC coverage with the implementation of Part D will lead to cost-shifting to an already burdened elderly population. For dual eligibles residing in nursing facilities, the resident or family member will likely request the physician to prescribe a more expensive covered prescription medication at an additional cost to the program. When health plans are prohibited from using OTC medications for the standard benefit, cost savings that could result from use of OTC medications will not occur. The likely result is higher overall costs for the drug benefit, especially for dual eligibles with little or no cash to pay for OTC medications.

3.3 Medications Used for Unintended Weight Loss

Unintended weight loss is a life threatening condition, particularly in the frail elderly. Patients suffering from involuntary weight loss may suffer significant decline in health and function, resulting in a higher risk for infection, depression, and death. Approximately 13% of ambulatory older patients and 50- 60% of nursing home residents suffer from involuntary weight loss. (20)

The incidence of unintended weight loss is measured through the Minimum Data Set (MDS) in every skilled nursing facility and reported to CMS. Specifically, the facilities must report weight loss of 5% in the past 30 days, 7.5%

weight loss in 3 months, or 10% weight loss in 6 months, or a dietary intake of less than 75% at most meals.

Unintended weight loss is a significant problem with the frail elderly, and if left untreated creates serious side effects for the patient. Some of the consequences of unintended weight loss include; infections, falls, hip fractures, immune dysfunction, anemia, decreased cognition, muscle loss, osteoporosis, and pressure ulcers. Several medications are utilized to increase weight or enhance appetite that may have other primary indications. Examples include:

Megestrol Acetate

- Megace® (megestrol acetate) is a synthetic, antineoplastic and progestational drug that is FDA-approved for the palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic disease). Megestrol oral suspension is indicated for treatment of anorexia and cachexia or unexplained significant weight loss in patients with a diagnosis of AIDS. Doses of 400 mg to 800mg per day in AIDS patients were found to be clinically effective.

Mirtazapine

- Residents in nursing centers may suffer from unintended weight loss for different reasons than ambulatory patients. Studies have shown as many as 36% of nursing home residents with unintentional weight loss suffer from depression. Psychiatric disorders, including depression, account for 58% of cases in these residents. Remeron® (mirtazapine) has been shown to increase appetite and promote weight gain while it also treats underlying depression.

Dronabinol

- This cannabinoid is indicated for the treatment of anorexia accompanied by weight loss. There have been promising weight gain results in studies of patients with Alzheimer's disease as well. Other potential benefits of dronabinol are its antiemetic and analgesic effects.

Cyproheptadine

- This antihistamine causes a mild increase in appetite with a decrease in weight loss. Periactin® (cyproheptadine) is often used to increase appetite in the elderly, however it is on the Beers list, and may be considered potentially inappropriate due to adverse drug reactions. The Medicare benefit also covers the younger disabled population, which may benefit from this drug and not have the risk of heightened side effects in younger patients.

Oxandrolone

- This anabolic hormone is approved by the FDA for the treatment of involuntary weight loss and as adjunctive therapy to promote weight gain after weight loss following major surgery, chronic infections or severe trauma. (28) It also is indicated to offset the protein catabolism associated with prolonged corticosteroid use, which is common with long-term care residents with COPD or arthritis.

Additional costs to the health care system are likely to occur with the exclusion of medications to manage weight loss from Part D benefits. Also, because nursing facilities are required by regulation to evaluate and manage issues of weight loss, the exclusion of medications to treat this issue creates a regulatory and financial burden for the system.

4.0 Dispensing Fee Definition

CMS is soliciting comments on three options regarding the definition of dispensing fee. In the preamble to the proposed rule, CMS notes that options two and three, if adopted, would be applicable to home infusion therapy. ASCP supports all three options, i.e. a three tiered dispensing fee approach. In addition, ASCP suggests that options two and three would be extremely helpful in assuring the provision of needed supplies and pharmacy services to residents of long-term care facilities

Option one appears to be a standard dispensing fee that would be provided to a community pharmacy for dispensing a typical prescription. Option two could provide a mechanism to reimburse long-term care pharmacies for the special packaging, delivery, and other services needed by residents of long-term care settings. This higher level of dispensing fee would help assure that these specialized pharmacy services needed by long-term care residents will still be able to be provided under Medicare Part D.

This multi-level dispensing fee approach is used by a number of state Medicaid programs to provide additional compensation to long-term care pharmacies for the specialized services they provide. The higher costs associated with dispensing medications to long-term care residents have been documented in a number of studies. A study conducted by BDO Seidman, and sponsored by the Long Term Care Pharmacy Alliance, is one example. (21) Another study is in progress now by the Senior Care Pharmacy Alliance.

Dispensing fees may also be developed and paid in response to specific services provided by the pharmacy. For example, separate fees could be provided for special packaging, delivery, and other pertinent pharmacy services. For each

medication order, the applicable fees would be layered to determine the total dispensing fee.

This approach could also be used in the community pharmacy setting, where occasional patients may need medications delivered due to inability to travel (e.g. homebound home health patients). The delivery fee could be a separate fee added on where applicable. Special packaging is also needed by some high-risk older adults in the community, as part of a program of care that enables them to continue their residence at home instead of moving to a nursing facility, for example.

Option three can be used to support not only home infusion therapy for ambulatory Medicare beneficiaries, but also infusion therapy for institutionalized Medicare beneficiaries. Long-term care pharmacies routinely provide infusion therapies for nursing home residents, including intravenous hydration and intravenous antibiotics. These pharmacies often have staff nurses and pharmacists who are directly involved in providing and monitoring these services.

State Medicaid programs regularly pay for infusion therapies for nursing home residents because it is much less expensive than transferring the resident to the hospital to receive these therapies. Residents in skilled beds (Medicare Part A) also regularly receive intravenous therapies.

Recommendation: ASCP recommends that CMS adopt a multi-tier dispensing fee approach, using all three of the options presented. Option one is appropriate for standard dispensing by a community pharmacy. Option two can provide a higher level dispensing fee for prescriptions for long-term care residents, with special packaging, delivery, and other support services. Option three can support the provision of supplies and clinical monitoring for infusion therapy for institutionalized Medicare beneficiaries.

5.0 Definition of Long-Term Care Facility

ASCP strongly supports defining the term long-term care facility to include skilled nursing facility, nursing facility, and intermediate care facilities for the mentally retarded (ICF/MR). Residents of ICF/MR are generally served by long-term care pharmacies, with the same services provided to nursing home residents, including special packaging and delivery services. Approximately two-thirds of ICF/MR residents are dual eligible individuals. Including ICF/MRs in the definition is appropriate and logical.

It should be noted, however, that only about 120,000 ICF/MR beds are currently available in the United States. In recent years, the trend has been to move these individuals into group homes, or less structured settings. These group homes are also often served by long-term care pharmacies, and some of the group homes retain an affiliation with an ICF/MR. ASCP supports including these group homes in the definition of long-term care facility.

Another recent trend is the increasing use of home and community based waiver programs (e.g. 1915c) to place nursing home eligible individuals into alternative settings, such as assisted living or board and care homes. These settings are also generally served by long-term care pharmacies and the residents of these facilities also need specialized packaging, delivery, and other pharmacy support services. These pharmacy services are needed to help ensure accurate and efficient administration of medications to residents, and to prevent diversion of controlled substances stored and administered in the facilities.

Residents of long-term care facilities are exempt from prescription drug co-pay requirements by the Medicare Modernization Act. If states use waiver programs to place nursing home eligible individuals in alternative settings, they would be required to pay the co-pays (or the state would need to pay it). Including these alternative settings in the definition of long-term care facility removes the perverse economic incentive of the state to place these individuals into nursing homes.

It should be noted that low-income nursing home eligible Medicare beneficiaries who are placed into alternative settings, such as assisted living, often are provided with only a minimal cash allowance (e.g. $20 per month) to pay for haircuts and incidentals. For these individuals, prescription drug co-pays could serve as a significant deterrent to placement in these alternative settings, forcing them into the more expensive nursing home setting.

Recommendation: Expand the definition of "long-term care facility" to include residents of intermediate care facilities for the mentally retarded, group homes, and any facilities recognized by State law as eligible for payment under Sections 1915(c), 1616(e), and 1115.

6.0 Pharmacy Access Standards

ASCP believes that it is important to preserve and enhance the "one nursing home – one LTC pharmacy" paradigm currently used in today's health care system. Although the preamble to the proposed regulations suggests that CMS views this as an important consideration (22), the proposed regulations

themselves do not address the issue of a one nursing home - one LTC pharmacy relationship. Yet, the maintenance of this relationship is critical to providing prescription drugs to nursing residents in a safe and efficient manner. Without such a direct relationship, nursing facilities may not be able to meet federal requirements relating to pharmacy services and medication errors.

Unfortunately, the MMA and the proposed regulation could put this paradigm at risk because it is virtually certain that Medicare beneficiaries entering nursing homes (and those already in nursing homes who choose a PDP either during the initial enrollment period, auto enrollment, or subsequent open enrollment periods) will be members of a variety of different PDPs. These plans may contract with different pharmacies or use different formularies and different packaging and delivery systems from those previously used by the one LTC pharmacy serving the facility. As a result, every LTC medication nurse will be forced to manage different formularies and multiple packaging and delivery systems from different pharmacies for residents in his/her unit, and adjust to different delivery schedules, medication labeling styles and other processes, creating increased opportunities for medication administration errors. Attending physicians also will be confused by different distribution and administration channels and complexities in having to address multiple and distinct formularies. This creates inefficiency and a large margin for medical error given the many competing demands already placed on nursing home physicians and staff – problems that today's health care marketplace has overcome through the one-on-one relationship typically found in LTC pharmacy.

CMS requests comments on whether it should require or encourage PDP plans to contract with LTC pharmacies or allow LTC pharmacy to provide drugs to beneficiaries as out-of-network providers. ASCP believes that CMS has struck a reasonable balance by permitting LTC pharmacy to either provide the benefit as an "in-network" or "out of network" provider, as market forces will allow. Without an out-of-network option, we expect plans to treat LTC pharmacy lno different than retail pharmacies, which, in turn, would preclude LTC pharmacies from providing the necessary suite of services that beneficiaries currently enjoy and require. By permitting, but not requiring or prohibiting LTC pharmacies to serve as "in-network" providers, CMS will give LTC pharmacies and PDPs the appropriate negotiating flexibility to reach mutually satisfactory arrangements for providing services to LTC residents.

Allowing LTC pharmacies the ability to serve Medicare beneficiaries as either in-network or out-of-network providers achieves numerous goals. First, it accomplishes the primary goal of preserving the one-on-one nursing home/pharmacy relationship described above. Second, it gives the LTC

pharmacy leverage to negotiate a fair reimbursement from the PDPs by giving LTC pharmacies the ability to aggregate a group of LTC resident beneficiaries and more efficiently and effectively allow them to be enrolled in any one (or group) of PDP plans. Third, it allows a PDP the incentive and interest to work with the LTC pharmacy to become a nursing home's "preferred provider." For beneficiaries already in nursing facilities, LTC pharmacy has an incentive to work with LTC residents to educate them for the purposes of having them enroll in the most beneficial network for their needs, and beneficiaries would have an interest in doing so to avoid paying out-of-pocket the differential between the in-network and out-of-network cost. Thus, the option preserves maximum flexibility by each of the market participants – the beneficiary, the pharmacy, and the PDP or MA-PD plan.

Although ASCP believes that CMS has struck the correct balance by encouraging, but not requiring, PDPs to contract with LTC pharmacies, the manner by which CMS "encourages" a PDP to contract with a LTC pharmacy is not clear. The regulations must provide an incentive for PDPs to bring LTC pharmacies into their networks. CMS has proposed several standards for pharmacy access, as well as other provisions upon which a plan bid will be measured. At the end of our comments on this section, ASCP will propose long-term care standards that CMS should incorporate into its regulations to ensure that plans do not discriminate against LTC residents. We believe that, in order to meet these standards, plans will be encouraged to contract with LTC pharmacies that can provide the services that are required for institutionalized patients.

In circumstances where a plan has not contracted with the LTC pharmacy servicing the institution, the proposed regulatory text does not explicitly permit LTC residents to access the pharmacy as an out-of-network provider. We are concerned that plans, though allowing access to some out-of-network providers, will not necessarily allow patient access to all out-of-work providers. As a result, patient access to the particular pharmacy servicing that facility could be threatened. Therefore, ASCP believes that the regulatory text should explicitly state that residents will have access to any pharmacy that services that facility.

We are also concerned that the provisions for fallback plans do not specifically require beneficiary access to out-of-network pharmacies, as is required for PDPs and MA-PD plans in Section 423.124. CMS states in Section 423.855 that a fallback plans is required to be a PDP sponsor except that it does not have to be a risk-bearing entity. CMS also defines a Fallback Prescription Drug Plan as a plan providing access to negotiated prices, in the same manner as PDPs and MA-PD plans. Nevertheless, CMS does not clarify in Section 423.124 that fallback plans are subject to the same requirements as PDPs and MA-PD plans with regard to

out-of network pharmacy access and payment. Therefore, we encourage CMS to make this requirement explicit in the final regulations.

In addition, we encourage CMS to ensure that plans do not have the ability to presumptively include LTC pharmacies in their pharmacy networks based on a pre-existing relationship with the plan sponsor outside of the context of Part D. It is important to note that the Medicare population is unique, and has more extensive pharmaceutical needs that require a broader array of pharmacy services. LTC pharmacies should be able to pro-actively elect to participate in a network providing the Medicare Part D benefit to ensure that the plan and LTC pharmacy have negotiated a mutually beneficial contract. "Passive enrollment" strategies should not be permitted in establishing these relationships.

Recommendation: ASCP proposes the following revision of Section 423.124:

> **(a) Out-of-network access to covered part D drugs. A PDP sponsor, MA organization offering an MA-PD plan, *and fallback plans* must assure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy.** ***For enrollees residing in a long term care facility, a PDP sponsor, MA organization, or fallback plan must provide the enrollee access to covered Part D drugs dispensed at any out-of-network long term care pharmacy that is contracted to provide pharmacy services to the long-term facility.***
> **(b) Financial responsibility for out-of-network access to covered Part D drugs.**
> **(1) A Part D enrollee is financially responsible for any deductible or cost-sharing (relative to the plan allowance, as described in Sec. 423.100, for that covered Part D drug).**
> **(2) Any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance (including any applicable beneficiary cost-sharing) for that covered Part D drug, *except for cost-sharing subject to Section 423.782.***

Recommendations:

- CMS should encourage, but not require, PDP plans to contract with LTC pharmacies.

- CMS also should explicitly preserve, and enhance, the language in proposed section 423.124 to specifically permit LTC residents to access LTC pharmacies as out-of-network providers.

- The final rule should explicitly state that fallback plans are subject to the requirements in Section 423.124 for out-of-network pharmacy access and payment.

- Plans should not be allowed to presumptively include LTC pharmacies in their pharmacy networks based on pre-existing relationships outside the context of Part D.

7.0 Formulary Requirements

7.1 Introduction

In the Medicare Modernization Act, Congress expected that formularies would be used as a tool by Prescription Drug Plans and Medicare Advantage plans to control drug costs. Formularies are widely used now by the managed care industry. Congress charged the United States Pharmacopoeia with creation of a list of therapeutic categories and classes to serve as a framework for formulary development by the PDPs that are expected to provide a drug benefit for Medicare beneficiaries under Medicare Part D. Although not required to use the USP framework, PDPs with formularies that are consistent with USP's model guidelines avoid regulatory review of whether their formulary's categories and classes have been defined "to substantially discourage enrollment by certain Part D eligible individuals under the plan." This formulary framework is designed to prevent PDPs from "cherry picking" healthy individuals to join their programs.

Congress also charged CMS with oversight of the formularies and cost-containment strategies and tools used by PDPs and MA-PDs in implementation of Medicare Part D. The fundamental purpose of the USP Model Guidelines and CMS oversight, therefore, appears to be protection of Medicare beneficiaries. One important goal in this regard is to assure that certain categories of beneficiaries should not be discouraged from enrolling because of the nature of the formulary of the PDP.

The medications offered in the formulary of the Prescription Drug Plans would not necessarily be readily available to prescribers and patients. Plans have the option of placing these medications into multiple "tiers" with varying cost to patients; impose the use of prior authorization requirements; or use other management tools to restrict access to medications included on their formularies.

Medications not included on the formulary of the PDP will be denied to the beneficiary, or will require even more burdensome procedures (an exceptions process) for access by the beneficiary and/or physician. The CMS draft regulations for Title I have outlined an appeals process and grievance procedures that might be used for the beneficiary to obtain access to nonformulary medications. But even with these procedures, the PDPs may still be able to deny access to medically necessary medications.

The Medicare beneficiaries who are most at risk from restricted access to medications are the 6 million dual eligibles (those with both Medicare and Medicaid coverage), the 4 million frail elderly (those age 85 and over), and residents of nursing homes and assisted living communities, numbering approximately 3 and one-half million. These individuals frequently take eight or more medications and have multiple chronic conditions. For these patients, selecting an appropriate therapeutic agent requires careful consideration of:

- Drug side effects and specifically the capacity of the drug to cause or worsen geriatric conditions such as falls, urinary incontinence, mental confusion, and delirium
- Drug contraindications with co-morbid conditions
- Kidney and liver function of the patient
- Drug interactions
- Appropriate dosage form, such as liquids for those who have difficulty swallowing
- And a number of other factors

These frail elderly individuals and long-term care residents need access to a wide variety of medications and dosage forms to appropriately manage their multiple chronic conditions and medical problems. For this reason, ASCP is extremely concerned with the possible denial of access to medically necessary medications by vulnerable Medicare beneficiaries. A limited formulary would require very frequent use of burdensome administrative procedures for access to nonformulary or restricted medications for these populations.

7.2 General Formulary Concerns

ASCP has three fundamental concerns with the application of drug formularies to elderly populations. J. D. Kleinke has noted, in an article in *Health Affairs* (23) that only three studies (24-26) have been conducted that explore the relationship between use of drugs and other services across large populations. All three are associative; two focus on narrow clinical areas; and two use proxies (formulary status and reimbursement) as markers for drug

utilization. Most remarkably, all three studies prove the drug utilization management hypothesis in reverse: The more a third-party payer limits patients' access to drugs, the higher its total health care costs are in excess of drug-cost savings.

Horn and colleagues (27) conducted a follow-up study focused on elderly individuals to examine whether restrictive formularies are associated with differences in healthcare resource utilization, including number of physician office visits, prescriptions, and hospitalizations. Patients enrolled in six health maintenance organizations in six different states were studied. The authors found that more restrictive formularies were associated with higher overall health care costs, and that this association was more pronounced in the elderly.

Frank Lichtenberg analyzed data from the 1996 MEPS to evaluate worth of newer drugs (28). He found that use of newer drugs, in comparison to use of older drugs resulted in significantly lower mortality, fewer work-loss days, and lower costs of all types of nondrug medical spending, especially hospitalizations. *Use of newer drugs resulted in a substantial net reduction in the total cost of treating a given condition.*

These findings are especially important because, in the new Medicare Part D benefit, Congress has placed the Prescription Drug Plans at risk only for the cost of pharmaceuticals. The PDPs, therefore, have no financial incentive to use newer drugs, or to direct drug therapy in ways that lower overall health care spending. Regulations and guidelines are critical to ensure that the PDPs do not impose policies that shift costs to other payers (such as Medicaid, Medicare Part A and Medicare Part B) and create obstacles to achieving optimal health outcomes for Medicare beneficiaries.

A second concern of ASCP is that the formulary, as a tool for medication cost-containment, is based on a flawed assumption. This assumption is that medications within the same therapeutic class have comparable effects and are interchangeable. This belief has been in force for decades, but recent research has demonstrated that this assumption was never really valid. In fact, medications within the same therapeutic class can have dramatically different effects on health outcomes.

A recent trial comparing rofecoxib to celecoxib has shown greater cardiovascular morbidity associated with rofecoxib. Simvastatin and atorvastatin were compared in another trial, showing significantly better health outcomes with atorvastatin. In the SSRI class, fluoxetine appears to have clear advantages in the pediatric population, with less likelihood of serious adverse effects.

The belief that drugs within the same class were comparable resulted from a lack of research and data to disprove the hypothesis. As this research and data becomes available, the hypothesis is clearly being disproven, calling into question the very philosophical basis of the formulary approach.

This leads to the third concern: the application of formularies as a tool for cost management in health care has virtually no credible research to support their use. Pearson and colleagues conducted a comprehensive review of the literature to review the effectiveness of strategies to improve the quality and efficiency of medication use in managed care organizations (29). The authors concluded:

> "Despite the substantial number of interventions to improve drug use in managed care, our understanding of the impacts of these interventions still is limited. Although PPOs and lightly managed HMOs play prominent roles in the US managed care industry, we found no studies conducted in those settings… There is a glaring lack of evidence concerning the effects of financial and formulary-related interventions. It is alarming to consider how little publicly available empirical evidence underlies the most common approaches used in managed care today."

An accompanying editorial in the same issue of the *American Journal of Managed Care* echoes the authors' concerns about the paucity of controlled studies to evaluate the cost and financial impact of commonly used managed care cost-control strategies. The editorial emphasizes the need for controlled evaluations of these strategies and calls for more well-designed research studies to be conducted (30).

7.3 Special Considerations for Dual Eligible and Frail Elderly Populations

Medications not included on a PDP formulary will require the use of an appeals process or grievance procedures to access. Formulary medications may also be subject to prior authorization or other barriers. These administrative procedures for access to nonformulary or restricted medications present four major problems for the dual eligible and frail elderly populations.

Dual eligible individuals have few financial resources. For most of these individuals, loss of access to *payment* for the medication by the PDP means loss of access to the *medication*. It is the same thing. It is not an understatement to say that Congress has delegated to the PDPs the authority to make life and death decisions for low-income individuals. With such authority, accountability (e.g.

guidelines, regulations, and stringent oversight) is needed to prevent harm to vulnerable populations and individuals.

These decisions on coverage of medications were previously made by state governments for the Medicaid population. Although states have begun to implement cost-containment tools in recent years, such as prior authorization, Medicaid recipients are rarely denied access to a medically necessary medication. Under Medicare Part D, low-income individuals have no similar assurance of access to medically necessary medications.

Because the PDPs have the ability to restrict Medicare beneficiaries to use of their formulary medications, the selection of medications included on the PDP formulary should be as wide as possible. To help ensure this outcome, the list of therapeutic categories and pharmacologic classes in the USP Model Guidelines should be as granular as possible. In addition, CMS review of plan formularies should be designed to assure access to medically necessary medications.

A second major problem with having few medications on the PDP formulary is the *delay* in access to needed and appropriate medications. The CMS draft regulations permit delays from 72 hours to 14 or more days in obtaining permission from PDPs to use medications not included on the PDP formulary. An individual of "normal" income may be able to pay out of pocket for the medications for a limited period of time, but the dual eligible and frail elderly populations often do not have such financial resources. In some cases, a delay of this magnitude could be life-threatening or could result in significant pain and suffering for the individual who must do without needed medication.

For low-income individuals who reside in nursing facilities or assisted living, such delays present another significant issue. These facilities are responsible for quality of care of the individuals they serve. State licensing agencies, and federal guidelines for nursing facilities, contain requirements that their residents receive needed medications in a timely manner. Who will be responsible to pay for these medications during the appeals process if the beneficiary is unable to pay? If the appeal is denied, who will pay for medically necessary medications for which the PDP refuses to pay?

New medications for nursing facility and assisted living residents are typically delivered within one to four hours of the medication order being written. Will PDPs have 24 hour per day, seven day per week staffing of their offices to provide prior authorization approvals or consent for use of nonformulary medications in emergency situations? If not, the formularies need to be as wide open and flexible as possible.

A third problem with a limited formulary for the dual eligible and frail elderly populations is the inability of a large proportion of these populations to navigate administrative procedures to access medications not included on the plan formulary. Approximately one fourth of individuals age 85 and over reside in nursing facilities. Many more reside in assisted living or are served by home health agencies. About 10% of those 65 and over, and 40% of persons age 85 and over, have dementia (31).

Because of cognitive and physical impairments, often limited education, and other obstacles that limit their ability to seek approval for use of nonformulary medications, these populations would be especially adversely impacted by a limited formulary offered by a PDP. Since these individuals frequently take eight or more medications, any limits on access to medication are almost certain to impact the vast majority. To prevent discouraging the enrollment of these individuals in Medicare Part D, a wide variety of medications is needed on the PDP formulary.

The need to pursue administrative procedures for access to nonformulary or restricted medications also creates significant challenges for the health professionals who care for the dual eligible and frail elderly populations. Geriatricians, physicians with a high proportion of elderly patients, and long-term care pharmacies will be especially burdened by these administrative hurdles. Nursing homes in rural areas already have difficulty getting physicians to serve their residents. Imposing greater requirements on these physicians to obtain needed medications for their patients will only exacerbate this problem of physician access.

If the choice of medications available on the formulary is limited to a small number, or are not the appropriate medications to use in these populations, physicians and patients will face substantial time involved in navigating administrative barriers to access.

Finally, the elderly and disabled are inherently susceptible to adverse selection by health plans because of their generally high costs. A review article by Huskamp (32) notes that extensive evidence exists to show that health plans restrict coverage of specialty mental health services in an attempt to avoid adverse selection. He notes:

> "Adverse selection is more likely to be an issue for drug classes that treat illnesses where treatment matching often involves trial and error. The reason is that once the patient finds a good treatment match, the patient and his or

> her clinician could be less willing to consider switching medications, and the patient could be more likely to seek a plan with generous coverage of these drugs. For example, a person with schizophrenia who responds well to Zyprexa, perhaps after unsuccessfully trying other antipsychotic medications, will be more likely to avoid a plan with a closed formulary that excludes coverage of Zyprexa, all else being equal.
>
> In the private insurance market, competitive pressures to avoid enrollees with higher expected spending could lead the market to provide an inefficiently low level of coverage by imposing tight formulary restrictions for psychotropics… The incentive exists for plans to limit coverage in this way."

Because psychotropic medications are widely used in the Medicare population, this category of medications is especially susceptible to the use of formularies to guide patient selection into Prescription Drug Plans. It is therefore especially important that psychotropic drug categories and classes be highly granular to prevent this adverse selection.

7.4 Pharmaceutical & Therapeutic Committee (P&T Committee)

CMS states its interpretation that the P&T Committee's decisions regarding the plan formulary should be binding on the plan, and requests comments on this interpretation. ASCP strongly supports this CMS interpretation. If the decision of the Committee is not binding on the plan, what would be the purpose of the review by these experts?

CMS also proposes requiring more than just one pharmacist and one physician on the committee who is independent and free of conflict. ASCP strongly supports this proposal as well. Since no maximum size for a P&T Committee is specified in the statute, designating a specific number of independent pharmacists and physicians may be inadequate. ASCP suggests designating a proportion of the P&T Committee in this regard, such as a simple majority.

CMS proposes that "at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals." ASCP recommends that CMS recognize the Certified Geriatric Pharmacist credential (33) as an appropriate way for a PDP to comply with the requirement that the pharmacist member of the P&T committee has this expertise.

7.5 CMS Oversight of PDP and MA-PD Formularies

As noted previously, USP has proposed a limited number of drug categories and classes (146) in their draft Model Guidelines. CMS has proposed that USP designated drug classes will have at least two drugs per class. The end result is that Medicare beneficiaries could have access to a very limited number of medications under Medicare Part D. For dual eligibles, in particular, this would be a very serious problem. A comprehensive review of all formularies proposed by PDPs and MA-PDs is, therefore, a critical function of CMS. Access to a wide variety of medications and dosage forms is extremely important in this population.

ASCP is very concerned that, with the broad categories and classes proposed for use by USP, a number of commonly used medications in the elderly may not be available under many of the PDP formularies. Some of the proposed drug classes have over 20 individual drugs. Providing only two medications in such broad classes would be extremely problematic.

Recommendation: ASCP urges CMS to reconsider the proposal to ensure access to only two drugs per therapeutic class. If the final USP classes approach the breadth in the current proposal, CMS may need to increase the number from two to something higher, to ensure that Medicare beneficiaries have access to needed medications.

The CMS proposed rule also would require that the drugs included in each therapeutic class or category include a variety of strengths and doses to the extent this is feasible.

Recommendation: ASCP urges CMS to include in this specification that the medications should also have a wide variety of dosage forms (e.g. liquids, injectables, topical patch, etc.) to the extent this is feasible.

7.6 Formulary Considerations for Dual Eligible Beneficiaries

Without access to an open formulary, CMS risks substantial discrimination against dual eligible beneficiaries, who formerly received prescription drug benefits under Medicaid. CMS has not addressed the discrepancy between the benefits that dual eligibles have under Medicaid, and the more limited potential benefits available to them under Part D.

Though State Medicaid programs are allowed to have formularies, federal statute limits the exclusion of drugs. (34) Under this policy, Medicaid is limited in terms of the drugs the State may exclude from coverage as follows:

> (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) ***only if***, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
>
> (D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5). (34)

As stated in this provision, State Medicaid programs are required to ensure that drugs excluded from formularies can be covered subject to prior authorization under Section 1927(d)(5). Federal statute mandates that prior authorization requests be decided upon within 24 hours, a 72-hour supply of medicine must be available in emergencies, and that the State must have in place a mechanism for the appeal of denial. (35) This standard ensures that Medicaid beneficiaries have access to drugs that are not on a State Medicaid plan formulary, and is particularly important for institutionalized beneficiaries with broad drug needs.

It is important to note that Medicaid beneficiaries are accustomed to the Medicaid standard for prescription coverage, and will experience the proposed Medicare Part D grievance and appeals processes proposed by CMS as a diminished benefit in comparison to Medicaid. As noted elsewhere in this document (section 14.0), ASCP has serious concerns about the CMS proposed grievance and appeals procedures.

We also are concerned about the transition period between Medicaid coverage for dual eligible residents of LTC facilities and the start of coverage under Medicare Part D benefits. In some states, Medicaid covers all medications including prescription drugs, over-the-counter medications, and infused drugs. Under MMA, however, states cannot pay for drugs defined by the MMA as covered Part D drugs through their Medicaid program, and states' ability to provide coverage with state funds may be limited. In addition, the MMA does not provide clarity on how existing Medicaid coverage for over-the-counter and infused drugs will be coordinated with Medicare Part D.

Recommendation: Special provisions are needed to ensure access to medically necessary medications by dual eligible beneficiaries. See also ASCP comments in sections 11,0, 12.0, and 13.0 of this document.

7.7 Formulary Considerations in Long-Term Care Facilities

ASCP strongly supports the use of open formularies in long-term care facilities. Long-term care pharmacies must be able to provide all medically necessary medications, including a wide variety of medications and dosage forms, to residents of long-term care facilities, to enable careful customization of drug therapy based on the medical needs of the individual. We do not see formularies imposed by PDPs as a viable option in long-term care. This position is based on the considerations explained below.

7.7.1 In the long-term care environment, facilities are legally responsible for providing medically necessary medications in a timely manner.

Nursing homes and intermediate care facilities for the mentally retarded (ICF/MRs) are subject to requirements of the CMS State Operations Manual requirements for their respective settings. These facilities are accountable for the quality of care provided to their residents, including a requirement for providing ordered medications in a timely manner. (36)

About two-thirds of nursing facility residents are dual eligible individuals. These persons have no cash with which to pay for medications. In recognition of this reality, Congress exempted nursing home residents from co-pays on their medications under Medicare Part D. If medications that are medically necessary for a dual eligible nursing home resident are excluded from a PDP formulary, the facility can not keep the resident in the facility without the medication. The likely result is transfer to the hospital, which would be far more expensive than covering the medication.

7.7.2 The proposed exceptions process for nonformulary medications is not feasible for long-term care residents.

The standard practice in long-term care pharmacy is to deliver newly ordered medications within one to four hours of being ordered. The vast majority of medications provided to nursing facility residents are paid for by Medicaid. Under Medicaid, there is a presumption that medically necessary medications will be covered. It is rare for Medicaid to deny coverage for a medication that the resident's physician believes to be medically necessary. Even if the long-term

care pharmacy must complete a prior authorization process, the medication is almost always paid for upon completion.

The Medicare Modernization Act did not provide this assurance for dual eligible beneficiaries. As a result, long-term care pharmacies can only be assured of getting paid for formulary medications. The emergency appeals provision requires that the pharmacy withhold dispensing the medication for up to 72 hours while awaiting a decision from the PDP on whether coverage will be provided. If the medication is dispensed during that time, the appeals process is delayed for at least two weeks, within which the nursing facility and pharmacy do not know if the medicine will be covered.

This situation is untenable for long-term care. Medications must be provided immediately upon ordering. Nursing facilities and pharmacies cannot wait for several weeks to find out if a medication will be paid for. Under Medicaid, the state must decide within 24 hours if the prior authorization is approved, or else the pharmacy may dispense a 72-hour supply that is automatically covered. Since medications are nearly always approved anyway, long-term care pharmacies routinely provide medications to long-term care residents as soon as they are ordered.

7.7.3 Nursing home residents lack the ability or resources to negotiate an exceptions process to gain access to needed medications.

Between 50 and 70 percent of nursing home residents have cognitive impairment, such as Alzheimer's disease. Others have physical infirmities that impede their ability to function. Few of these individuals have the physical and mental ability to negotiate complex appeals procedures or grievance processes to get permission for payment for needed nonformulary medications.

Many nursing home residents have no relatives nearby, or in a position to help them with this process. Nursing home staff have neither the time nor the expertise to assist residents with this process. Nor should it be the responsibility of the nursing home to navigate these administrative procedures.

The physicians who care for these individuals would be overwhelmed with paperwork and requests for assistance if formularies were imposed. Such requests would serve as a deterrent to physicians serving nursing home residents. Many nursing homes, especially in rural areas, already have difficulty attracting physicians to serve their residents. Such an administrative burden would make this situation much worse.

7.7.4 Requiring nursing homes to permit multiple formularies within their facilities from multiple PDPs would result in chaos, and increased potential for medication errors.

With regard to pharmaceutical services, nursing facilities operate in much the same way that a hospital does. If hospital staff and physicians were required to follow multiple formularies, and keep track of which patients were on which formulary each time a medication was ordered, the result would be chaos and an increase in medication errors. The number of different medications used, and the potential for mixing up medications with similar names, would make it much more difficult to keep drug regimens in line with the various formularies of the different PDPs.

One of the principles of quality improvement is that error reduction is improved when process variation is reduced. One of the keys to reducing errors and increasing efficiency, therefore, is to create an environment with consistency in as many areas as possible. Multiple formularies would create problems both for nursing facilities and for the long-term care pharmacies that serve them. This would be a sharp contrast to the situation that exists today.

7.7.5 Long-term care residents need access to a wide variety of medications and dosage forms. The imposition of formularies in this setting would create an overwhelming amount of paperwork and administrative burden for those who care for long-term care residents.

As noted in section 7.1, nursing home residents need individualized drug therapy due to wide differences among individuals in response to medications, prevalence of swallowing problems and feeding tubes, frequent need for intravenous therapy, and other factors. When a limited formulary is in place, the frequent need for access to nonformulary medications imposes a heavy administrative burden, and associated costs, to obtain access to needed and appropriate medications.

When the state of Michigan imposed a preferred drug list for Medicaid recipients, one long-term care pharmacy in that state had to hire five full-time equivalent employees just to process and track prior authorization forms for nursing home residents to obtain access to needed medications. The likelihood is that a formulary imposed by a PDP will be far worse with respect to administrative burden than any Medicaid program. This would create an untenable situation in long-term care.

7.7.6 Incompatibility of Hospital and PDP Formularies

About one-half of nursing home admissions come from the hospital, and nursing home residents often enter the hospital for acute treatment or exacerbations of chronic conditions. Hospitals have their own formularies, which are likely to be different from any of the formularies used by PDPs. If individuals are required to switch all their nonformulary medications to PDP covered medications immediately upon transfer, the risk of destabilizing the individual is significantly increased. A likely outcome is transfer back to the hospital.

When a frail elderly individual has four or five chronic conditions, and is taking eight or ten medications, the need to change several medications simultaneously because of formulary constraints is potentially a serious problem. If the individual displays a new adverse effect, tracing the source to the offending medication is more difficult when several changes occur at once. The ability of these individuals to adjust to several simultaneous medication changes is also diminished. In clinical management of the frail elderly, the general approach is to make changes slowly to allow the individual to adjust and to track the effects of individual changes.

The lack of ability to make gradual changes, imposed by the "all or nothing" nature of a formulary, is a significant impediment to use of the formulary approach in long-term care settings. Other opportunities for suddenly imposed formulary changes occur when:

- A PDP drops out of a market in a particular region, forcing its enrollees to change to a different plan
- An individual voluntarily changes to another PDP during an open enrollment period
- A PDP changes its formulary; this would require 30 days notice in the proposed rule, but this would not be adequate for transitioning many frail elderly individuals to different medications

Formulary changes by PDPs are especially problematic. With only 30 days notice required, and that done by web site posting, long-term care residents could have needed medications not covered until their next opportunity to change to a different PDP. Few nursing home residents use the internet. Physicians and long-term care pharmacies would need to invest substantial amounts of time changing patients to a covered medication, or else using the exceptions process to seek coverage for needed medications.

This same continuity of care issue is also a serious problem for the transition from Medicaid in December 2005 to Medicare Part D in January 2006 for the dual eligible population. If nursing home residents were to have this sudden change

imposed to PDP formularies, with no opportunity for gradual transition, the result could be a substantial adverse clinical impact. See section 12.0 of these comments for more discussion of this issue.

Boockvar and colleagues studied adverse events associated with transfer of individuals between hospitals and long-term care facilities. They found that transfers from hospital to nursing home resulted in an average of 1.4 medication alterations and transfers from nursing home to hospital resulted in 3.1 medication alterations per transfer. Adverse drug events associated with medication alterations occurred in 20% of the transfers and the overall risk of ADE per drug alteration was 4.4%. (37)

The authors note:

> " Few previous studies have looked systematically at the relationship between transitions in care location and ADEs… Our study suggests that alterations in medication prescribing are common during transfer between institutions and are a cause of ADEs. Clinicians may alter or discontinue medication use at the time of hospital or nursing home admission as a result of changes in a patient's clinical condition or to adhere to institutional formulary requirements."

This study should raise a red flag, demonstrating the need for more controlled studies on the impact of formulary restrictions, including the potential for adverse drug events associated with medication changes during patient transfers to other care settings. Until such studies are performed, it is clear that the widespread imposition of formulary requirements on nursing facility residents creates a high potential for harm in this vulnerable population. Prudence would dictate that such requirements should only be imposed if and when a way is found for this to be safely done.

7.7.7 Very little research exists to guide drug therapy decision making in frail elderly populations.

Most clinical research trials exclude individuals older than 75 years of age. As a result, evidence-based medicine and clinical practice guidelines are difficult to apply to the very old. In this realm, much of medicine is trial and error. When a medication, or combination of medicines, is found to be effective with minimal side effects, physicians are understandably reluctant to change therapy without clinical justification for doing so. Because of the concomitant number of chronic conditions and medications used, a change in one of the drugs may lead to the

need to change other drugs to maintain the proper balance and control for the individual.

In this environment, the imposition of arbitrary drug formularies creates the potential to wreak havoc on the ability of the physician to maintain stability in the fragile older adult.

7.7.8 Even less research exists to evaluate how cost-containment tools commonly used by the managed care industry may impact the frail elderly population.

The application of formularies as a tool for cost management in health care has virtually no credible research to support their use. This is especially true with respect to frail elderly individuals. Pearson and colleagues conducted a comprehensive review of the literature to review the effectiveness of strategies to improve the quality and efficiency of medication use in managed care organizations (29). The authors concluded:

> "Despite the substantial number of interventions to improve drug use in managed care, our understanding of the impacts of these interventions still is limited. Although PPOs and lightly managed HMOs play prominent roles in the US managed care industry, we found no studies conducted in those settings… There is a glaring lack of evidence concerning the effects of financial and formulary-related interventions. It is alarming to consider how little publicly available empirical evidence underlies the most common approaches used in managed care today."

An accompanying editorial in the same issue of the *American Journal of Managed Care* echoes the authors' concerns about the paucity of controlled studies to evaluate the cost and financial impact of commonly used managed care cost-control strategies. The editorial emphasizes the need for controlled evaluations of these strategies and calls for more well-designed research studies to be conducted (30).

The imposition of restrictive formularies in the long-term care population of frail elderly and disabled individuals would amount to a large-scale clinical experiment. And it would be conducted without well-designed plans to capture data on resulting health outcomes or total health care spending. It is doubtful that any Institutional Review Board would approve such an experiment, if it were to be proposed by researchers.

7.7.9 The use of formularies in long-term care settings creates a high potential for cost-shifting by PDPs to other health care payers.

Although this is an inherent problem with the use of formularies in Medicare Part D generally, long-term care settings offer particularly strong incentives for cost-shifting. This could be implemented in a number of ways:

- Restricting access to intravenous antibiotics and other parenteral therapies could require transferring the beneficiary to the emergency room or to hospital admission for therapy that could otherwise be performed in the nursing facility
- Restricting access to sustained release dosage forms could force long-term care nurses to administer shorter acting dosage forms multiple times per day, requiring substantially more nursing time and costs to the facility
- Providing preferential coverage to less expensive medications that require frequent blood tests for monitoring would increase costs of laboratory testing and physician visits for other payers, while reducing drug costs for the PDP
- Restricting access to medications with fewer drug interactions and adverse effects (often newer and more expensive) while allowing ready access to older medications with more adverse effects and drug interactions; this increases the risk of hospitalization, emergency room visits, and physician visits

Some of these strategies could also result in the need to move individuals from the assisted living or home environment into a nursing home, just to achieve adequate medication management for the individual. When access to once daily dosage forms is denied or restricted, management of the medication regimen becomes much more complex. In assisted living, staff members who are trained to administer medications may not be available 24 hours per day. If the assisted living residence can not meet the needs of the individual, discharge to a nursing facility may be necessary.

PDPs are economically motivated to implement these strategies to reduce drug spending, even though they may result in higher total health care costs and more risk to beneficiaries. This would not be in the best interests of Medicare beneficiaries or the overall federal contribution to health care costs.

Here is an example of how cost-shifting might occur:

> *Ms. Jones, an elderly nursing facility resident with Medicaid coverage, develops pneumonia. The physician orders ceftriaxone 1 gram to be administered intravenously every 24 hours for seven days. The standard of practice for treatment*

of pneumonia is to administer the first dose of medication within 4–8 hours; otherwise the risk of mortality increases significantly. Because the PDP requires prior authorization for this drug, and no time exists for administrative delays, the resident is transferred to the hospital for immediate treatment.

The result is that Medicaid must pay for the round trip ambulance transfer to the hospital, and pay a bed-hold fee to the nursing facility for the duration of the hospital stay. Medicare Part A pays for the hospitalization expense. The PDP saves money by avoiding the cost of providing the medication to the resident, but resulting costs for hospital treatment are far higher and borne by Medicaid and Medicare.

7.7.10 Managed care plans and pharmacy benefit managers have very little experience or expertise in providing a drug benefit to dual eligible or frail elderly populations.

Comments made by representatives of the managed care industry during deliberations over development of the USP Formulary Model Guidelines have been revealing and disturbing to those who are knowledgeable about the long-term care and frail elderly populations.

Consider this quote from a representative of the Academy of Managed Care Pharmacy (38):

> "Health plans already have formulary processes in place for their existing patient populations. Part of their decision making process with regard to whether or not to offer a pharmacy benefit to Medicare beneficiaries will be dependent on how compatible their current formulary system is with the proposed Model. Because their current practices address the multiple needs of their patient populations, there is no reason to adopt a different structure and approach for a Medicare drug benefit."

Comments such as this reveal a lack of understanding of the diversity of the Medicare population and the differences from the typically younger and healthier populations enrolled in managed care plans. In these same comments, the elderly are considered a "subpopulation."

Another comment from AMCP (38):

> "Other classes [in the draft USP Model Guidelines] may be inappropriate for an outpatient prescription drug benefit. For example, … classes addressing IV

> medications are not included on ambulatory formularies because of the need to be administered by a health care professional."

There is an apparent lack of awareness that the Medicare Part D benefit will apply to institutionalized individuals also, not just to "ambulatory" populations. In fact, home infusion therapy is a well-established mode of therapy even among ambulatory beneficiaries. A comment such as this is quite puzzling and disturbing.

The Pharmaceutical Care Management Association has been pushing for maximum flexibility and control and minimal oversight of the managed care industry to implement the Medicare Part D drug benefit. (39) This position is understandable, but CMS should ensure that the needs and interests of vulnerable Medicare beneficiaries are protected as Medicare Part D is implemented.

7.8 PDP Mid-Year Formulary Changes

CMS proposes to permit PDPs and MA-PDs to drop medications from their formularies in the middle of a plan year, even though the beneficiaries are locked into the plan through the end of the year. In fact, the list of covered medications is a primary consideration in choice of a drug plan by Medicare beneficiaries. Allowing plans to drop covered medications once the beneficiary signs up may force the individual to pay out of pocket for one or more necessary medications for the remainder of the year.

This controversial provision is similar to one that exists now with the Medicare prescription drug card program, where card sponsors can change or delete covered drugs on a weekly basis, while the beneficiary is locked into a particular card for the duration of the year. This has been widely cited as one of the concerns that led to lack of popularity of the Medicare drug card program. Since managed care plans typically have contracts with pharmaceutical manufacturers that are at least one year in duration, and because of widespread criticism of this provision in the drug card program, it is curious that CMS would include this provision in the proposed rules for Medicare Part D.

This provision is especially problematic for dual eligible individuals, who are likely to be unable to pay for needed medications out of pocket. These persons are also more likely to need assistance in using the exceptions process to obtain continued coverage of needed medications.

If CMS should choose to proceed with allowing PDPs to drop formulary medications in the middle of a plan year, 30 days notice would not be adequate for individuals in long-term care settings. If a commonly used medication were to be dropped, it could impact dozens or hundreds of residents served by a single long-term care pharmacy in nursing homes, ICF/MR, and assisted living settings. The logistics of contacting all the physicians involved and getting new medications ordered, or completing an exceptions process where needed, would be very complex and time-consuming.

Recommendation: ASCP recommends that PDP and MA-PD formulary time frames conform to the calendar year enrollment time frames for Medicare beneficiaries. If CMS should choose to permit plans to make mid-year formulary changes, ASCP suggests that individuals taking the medications at the time of formulary change be permitted to continue the medication with coverage until the end of the next open enrollment period.

7.9 Access to Covered Part D Drugs at Out-of-Network Pharmacies

ASCP concurs with CMS that long-term care pharmacies should be permitted to serve all residents of each of the long-term care facilities with which they contract. To the extent that a long-term care pharmacy is not included in the network of some PDPs in the region, providing services to these residents as an out-of-network provider is critical to achieving this goal.

8.0 PDP Plan Allowance

ASCP also agrees with CMS that, to the extent that it must operate as an out-of-network provider, the pharmacy should receive usual and customary (U&C) reimbursement. Historically, market forces have kept usual and customary fees charged by LTC pharmacies in check and have resulted in market efficiencies in the provision of services. We believe that market competition among LTC pharmacies will ensure the competitiveness of the usual and customary rate through negotiations with the contracted LTC facility, for example as it does currently with Medicare Part A. LTC facilities will seek to negotiate competitive prices for their residents, and will choose the LTC pharmacy that strikes the most effective balance between quality of service and cost.

8.1 Treatment of the Full Benefit Dual Eligibles

We are concerned that the proposed regulation does not account for the fact that full benefit dual eligible LTC residents and those with low incomes are not responsible for the difference between an out-of-network pharmacy's usual and

customary price for a covered Part D drug, and the plan allowance for the covered Part D drug under Section 423.124(b)(2). We believe that CMS must make explicit who will pay the cost differential between the out of network pharmacy price and the PDP plan reimbursement for full benefit dual eligibles and others with low incomes. As noted below, we believe the differential should be paid by the plan directly to the LTC pharmacy. The CMS payments to PDPs should recognize the differential cost between the usual and customary rate and the plan allowance, and therefore that plans should be directly responsible for covering the usual and customary rate. Otherwise, the most frail elderly, who are often also low-income, will be penalized by paying this higher cost.

The proposed regulation clearly outlines in Section 423.782 the agency's intent to provide coverage of dual eligibles' cost sharing under the new prescription drug benefit. If the final regulations reflect the current policy that enrollees are responsible for the differential cost between the usual and customary rate and the plan allowance, then we strongly encourage CMS to cover this differential for dual eligible and low-income beneficiaries the same as other cost-sharing. Otherwise, LTC pharmacies and/or nursing homes would be put in a situation where they were forced to collect this differential payment from full benefit dual eligible patients with no ability to pay, or from nursing homes who will simply bill the costs back to CMS or Medicaid through their independent reimbursement mechanisms. This would undermine the policy of allowing LTC pharmacies to bill out-of-network at the usual and customary rate to ensure that pharmacies are adequately paid to provide specialized services to LTC residents.

Therefore, we propose amendments to the proposed regulations that include a new subsection 4:

> **Section 423.782(a)**
> ***(4) Elimination of financial responsibility for the differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance as described in Sections 423.124(b)(1) and (b)(2).***

We recognize that CMS intends to treat low-income beneficiaries differently than full benefit dual eligible beneficiaries, in that low-income beneficiaries will remain responsible for a reduced co-pay. While we recognize that difference, we believe that the low-income subsidy for even these beneficiaries should include payment of any cost differentials for prescription drugs. For that reason, we also propose the following amendment:

> **Section 423.782(b):**

> ***(4) Elimination of financial responsibility for the differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance as described in Section 423.124(b)(2).***

In addition, and to make explicit that PD sponsors and MA plans must flow through those payments made to them by CMS pursuant to the low income subsidy program, we propose the following new subsection (7) to section 423.120(a), which clarifies that the PD sponsor or MA organization must provide any low-income subsidy funding through to the pharmacies.

> **Section 423.120(a):**
> ***(7) A PD sponsor or MA organization is required to pay the pharmacy the full plan allowance, as well as amounts referenced in Section 423.782.***

In addition, if CMS chooses to retain the policy that enrollees are responsible for this differential payment, we encourage CMS to retain its position that it count as a beneficiary incurred cost under Section 423.100.

Recommendations:

- The final rule should reflect that plans will be responsible for paying out-of-network pharmacies the usual and customary price.
- CMS should clarify in its final rule that full benefit dual eligibles and other low-income beneficiaries residing in long term care facilities have no cost-sharing for covered Part D drugs, whether or not they are on the formulary of the PDP or MA-PD plan.

8.2 Prompt Pay

ASCP is concerned that the proposed regulations do not reference or require plans to provide prompt payment to providers under Part D plans. We believe that payment to pharmacies for prescription drugs dispensed to enrolled Part D beneficiaries should be subject to prompt payment requirements comparable to provisions applicable to carriers under Section 1842(c) of the Social Security Act. Otherwise, plans will have the ability to deny payment of prescription drugs that should be covered by the plan, and force pharmacies to go through a costly appeals process in order to obtain payment. It is important to note that under the existing proposed regulations, pharmacies will not be allowed an expedited review if the drug is dispensed and the grievance is for payment only. Over time, this policy could force LTC pharmacies not to dispense necessary

prescription drugs until coverage is approved by the plan, potentially delaying care to patients.

Recommendation:

- **We recommend that CMS provide for prompt payment of pharmacy claims by PDP and MA-PD plans.**

We propose the following addition to Section 423.120(a):

(7) A PDP sponsor or MA organization must meet the requirements set forth at Section 1842(c) of the Social Security Act in providing payment to any pharmacy providing Part D covered drugs to enrolled beneficiaries that are eligible for coverage under the plan as a network or out of network provider, including dispensing fees and payment for services such as medication therapy management.

8.3 Disclosure of Cost of Generic Equivalent

ASCP strongly supports the proposed regulation waiving the requirement that information on differential prices between a covered Part D drug and its generic equivalent be made available to prescription drug plan and MA-PD plan enrollees at the point of sale when prescription drug plan enrollees obtain covered Part D drugs in long-term care pharmacies. We are pleased that CMS understands that LTC pharmacies generally provide drugs directly to the nursing facilities where the patient resides, not directly to the patient, under a medical benefit. We agree that it would be impracticable for LTC pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale.

CMS also requests comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies under Sec. 423.132(a). Not only must timing be considered, but also the recipient of such information. Over half of LTC residents have abnormal cognitive function, making disclosure information confusing and possibly leading to poor treatment decisions by the patient based on the disclosed information. (40) It is conceivable that the information could lead a patient to distrust the physicians, nurses and other caretakers in the facility simply because the patient did not have the cognitive ability to understand why the information was being provided and what it meant.

Section 423.132(c)(5) gives CMS the discretion to waive the public disclosure requirement in such circumstances as CMS deems compliance to be impracticable. Because of the nature of the sale and delivery processes that LTC

pharmacies use, ASCP requests that CMS waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies, rather than set a timeline for which disclosures must be made.

Recommendation:

- **CMS should waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies.**

We propose that CMS add to Section 423.132(c)(5):

> ***CMS waives the requirement under paragraph (a) of this section in the case of LTC pharmacies.***

9.0 Cost Effective Drug Utilization Management

In the preamble to the proposed rules, CMS states the following:

> "We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing and other tools to manage utilization."

ASCP recognizes the importance of the goal of containing drug costs under Medicare Part D. We also recognize that the managed care industry has widely used a variety of cost-containment tools to reduce drug spending. However, we believe that the application of these tools to the vulnerable population served by Medicare must be accompanied by safeguards and oversight from CMS to prevent adverse consequences from the use of these strategies.

A major concern with the use of these tools is the lack of research to demonstrate that the containment of drug costs is not associated with increases in total health care costs or adverse health consequences to vulnerable individuals.

Pearson and colleagues conducted a comprehensive review of the literature to review the effectiveness of strategies to improve the quality and efficiency of medication use in managed care organizations. (29) The authors concluded:

> "Despite the substantial number of interventions to improve drug use in managed care, our understanding of the impacts of these interventions still is limited. Although PPOs and lightly managed HMOs play prominent roles in the US managed care industry, we found no studies conducted in those settings… There is a glaring lack of evidence

> concerning the effects of financial and formulary-related interventions. It is alarming to consider how little publicly available empirical evidence underlies the most common approaches used in managed care today."

An accompanying editorial in the same issue of the *American Journal of Managed Care* echoes the authors' concerns about the paucity of controlled studies to evaluate the cost and financial impact of commonly used managed care cost-control strategies. The editorial emphasizes the need for controlled evaluations of these strategies and calls for more well-designed research studies to be conducted. (30)

Pearson et al. noted: "stepped-therapy protocols, which require patients to try older, lower-cost drugs in a therapeutic class before resorting to newer, higher-cost alternatives, are used by 76% [of HMOs]." Yet the Pearson literature review did not find one peer reviewed journal article that evaluated outcomes associated with this practice.

Step therapy was at issue in a widely reported Texas lawsuit that eventually went to the U.S. Supreme Court. (41) A physician ordered a COX-2 inhibitor medication for pain, but the insurance company refused to pay for it. The patient took naproxen and suffered a severe reaction requiring hospitalization. Since most Medicare beneficiaries are considered to be at high risk for gastrointestinal bleeding from traditional nonsteroidal anti-inflammatory drugs (NSAIDs), the use of step therapy with this class of drugs has high potential for harm in this population.

A recent study on tiered formularies involving over 20,000 patients was recently reported in the Archives of Internal Medicine. (42) The study evaluated the impact of three-tiered co-payment drug coverage and the use of NSAIDs. The authors found: "Three-tier formularies appear to reduce the use of COX-2 selective inhibitors among all patients with arthritis, even those at risk of experiencing gastrointestinal complications from using nonselective NSAIDs."

In the managed care plans studied by the authors, managed care enrollees who were at high risk for gastrointestinal complications were forced to pay higher amounts for access to the medications that were more clinically appropriate (safer) for them to use. In other words, everyone who used a COX-2 selective medication had to pay the highest co-pay for these drugs, even those who were at high risk of harm from use of the traditional NSAID medications.

The authors note that established risk factors that justify use of the COX-2 selective medications include: "age of 65 years or greater, history of peptic ulcer

disease or upper GI bleeding, concomitant use of oral corticosteroids or anticoagulants, and possibly smoking and alcohol consumption." Since nearly all Medicare beneficiaries meet one or more of these criteria, the use of tiered co-payments or co-insurance for this class of medications would result in Medicare beneficiaries having to pay the highest tier or suffer the adverse consequences of using the less appropriate traditional NSAIDs. If prior authorization were used for this class of medications for dual eligibles, the administrative burden on physicians and patients to get access to COX-2 inhibitor medications would be overwhelming.

A variation on the prior authorization requirement is the "fail first" requirement. 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.

These study findings highlight a fundamental flaw in the assumption underlying tiered co-payments: that patients can choose from among several drug therapy options in the management of their disease or condition. As seen in this NSAID example, a certain category of high-risk individuals really needs the COX-2 class of medicines to avoid a high risk of GI bleeding and other serious GI complications. For these individuals, choosing a lower cost medication is not a viable option. If they (and their physicians) do choose inappropriate medications in order to save money, the likely result is an increase in overall health spending to pay for treatment of drug therapy complications.

A recent survey of managed care enrollees evaluated consumer attitudes and factors related to prescription switching decisions in multi-tier co-payment drug benefit plans. Among the study findings was this observation by the authors:

> "Cost also was less likely to be an important factor for older plan members. This finding suggests that increasing the co-payment differential may not be effective in providing an incentive to switch for all plan members, particularly the elderly. Medicare + Choice plans [now Medicare Advantage] may need to use educational interventions and target physicians' prescribing habits to increase formulary compliance rather than rely on patient financial incentives."

In other words, the authors are saying that when tiered co-payment strategies are used with the Medicare population, the result is more likely to be cost-shifting to the beneficiary rather than increased compliance to the plan formulary. Thus, here is an example of a strategy that may be useful for some populations, but not necessarily useful or appropriate for Medicare beneficiaries.

Even the use of formularies in general lacks a research base to support their use. Our comments on formularies are found elsewhere in this document (section 7.0). In this section, we will just point out results of one recent survey of managed care enrollees, reported in the American Journal of Managed Care. (43) Almost half of survey respondents reported having been told that a prescribed medication was not covered by the plan formulary. In this situation:

- 53.6% reported that they paid extra for the nonformulary medication
- 26.0% switched to a formulary medication
- 13.0% did not get any medication
- 9.9% received permission from the plan to stay on the nonformulary medication
- 7.4% did not respond to the question

A 2002 Harris survey found that drug switching due to drug plan formulary restrictions can have a negative impact on the health of many older Americans. The study was sponsored by Project Patient Care, a nonprofit organization committed to improving patient care. The Harris organization conducted a telephone survey of adults age 50 and over who take prescription medications for at least one chronic condition; and primary and specialist healthcare providers who treat older adults. (44)

- 19% (an estimated 11 million people) of all Americans age 50 and older have had their medication switched due to formulary restrictions: 12% switched from a drug they were stable on to a drug that was either covered or less expensive under their health plan; 12% had to fill their prescription with a different drug that was either covered or less expensive under their health plan; and 8% received a prescription from their healthcare provider because the drug was either covered or was less expensive under their health plan.
- Many people who switch medications have negative health outcomes. Of the patients who were given a drug formulary substitution in the past year, 13% (an estimated 1.1 million people) report that the new drug was ineffective in treating their condition and 22% of patients (an estimated 1.9 million people) say they experienced side effects from the new medication.
- Many patients also have serious health problems from switching

> medications. For example, 18% of those who have more than minor side effects from drug formulary substitutions report having to visit an urgent care facility to treat their problem; 14% report having to visit an emergency room, and 11% state that they needed to be hospitalized.

Study results like these are not definitive, but do raise a red flag, indicating the urgent need for more research on the consequences of formulary use in populations of older adults.

ASCP has long been concerned about the inappropriate application of medication cost-containment strategies in vulnerable populations. One example is the requirement by some managed care programs that enrollees obtain certain medications in a higher dosage strength than they need, and then cut the tablets in half to save money for the managed care plans. Because the higher dosage strengths are approximately the same cost, the managed care plans can reduce their drug costs with this strategy. This strategy is particularly inappropriate in a population that includes many individuals with visual impairment, cognitive impairment, tremors from Parkinson's disease and other medical problems.

ASCP has a position statement opposing Mandatory Tablet-Splitting for Cost Containment. (45) ASCP has also released an issue paper on tablet splitting. (46)

Our second concern is that the Medicare population is more medically vulnerable than the general population typically served by managed care organizations. As a result, special care should be used in imposing these cost management strategies on this population. Just because the strategies have been used in a younger and healthier population does not mean that they are appropriate for the generally older and sicker population of Medicare beneficiaries.

When a pharmaceutical manufacturer requests permission from the FDA to market a new medication, the manufacturer is required to submit evidence that the drug is safe for use and effective for the intended purpose. CMS should apply the same criteria to a PDP that requests permission to use a cost-containment strategy for the Medicare Part D program. The PDP should produce evidence to show that this strategy will not produce adverse health outcomes for Medicare beneficiaries, and that the strategy will save money for the Medicare program rather than shifting costs from Part D to Parts A or B.

Just as prescribers use medications in combination, managed care plans also use cost-containment strategies in combination. Even in cases where each strategy

may be appropriate, combining strategies can lead to curtailed access to necessary medications and adverse health outcomes.

The Center for Studying Health System Change released a report in 2002 that focused on the use of cost-containment strategies by state Medicaid programs in non-elderly Medicaid recipients. The report found that state Medicaid programs use a variety of strategies to contain costs, including:

- Prescription co-payments
- Restricting the number of prescriptions per month
- Mandating the substitution of generic drugs for brand name drugs
- Requiring prior authorization for certain drugs
- Use of step therapy protocols that require physicians to try lower-cost drugs before prescribing more costly alternatives

The report also found that the more of these strategies that were applied, the greater the number of Medicaid recipients who did not get a prescription drug due to cost. Specifically:

- In states that used 0 or 1 cost-containment method, 15% of recipients did not get a prescription drug due to cost
- In states using 2 or 3 methods, 25% of recipients could not get a drug
- In states using 4 or 5 methods, 33% of recipients could not get a drug

Clearly, the application of multiple cost-containment strategies creates an increased risk that individuals will be denied access to medications. Before widespread imposition of combinations of cost-containment strategies on the vulnerable Medicare population, research and evidence is needed to show that beneficiaries will not be harmed by these combinations.

In view of the paucity of peer-reviewed literature in this area, CMS can provide a valuable public service by introducing some oversight to the managed care industry. Efforts by states to provide this oversight have been rebuffed by the courts, most notably with a recent U.S. Supreme Court decision. (41)

Recommendation: ASCP urges CMS to use special care in approving plans by PDPs for the application of cost-containment strategies for Medicare Part D. For each strategy proposed by the PDP, CMS should:

- Require plans to submit studies or data to show that the strategy will not produce adverse health outcomes in the Medicare population
- Require plans to monitor the implementation of any approved cost-containment strategies, to identify and evaluate adverse health outcomes or transfer of costs to other payers, including Medicaid and Medicare Parts A and B

- Require plans to submit regular reports to CMS on the results of this ongoing monitoring
- Intervene to stop or modify any cost-containment strategies that produce an adverse health impact on beneficiaries or increase total health care spending

Recommendation: CMS should develop a list of cost-containment strategies that are prohibited for use in Medicare beneficiaries. Mandatory tablet splitting, caps on the number of prescriptions that can be obtained per month, and "fail first" requirements are good examples of such strategies. In any event, the burden of proof should be on PDPs to show that proposed strategies are safe and effective in the Medicare population.

Recommendation: If a PDP proposes to use combinations of cost-containment strategies, CMS should obtain studies or data from the plan to show that the combination of cost-containment strategies will not produce adverse health outcomes in the Medicare population.

10.0 Quality Assurance

CMS is proposing to collect information or data on medication error rates. ASCP disagrees with this strategy. ASCP is a member of the National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP). (47) NCCMERP has adopted a position statement opposing the comparison of medication error rates. Differences in organization culture and attitudes toward collection and reporting of medication errors, along with differences in methodology used, make comparisons misleading and inaccurate. The NCCMERP statement, "Use of Medication Error Rates to Compare Health Care Organizations is of No Value" is on their web site. (48)

11.0 Medication Therapy Management Services

CMS is correct to note that medication therapy management (MTM) involves "targeted, direct patient care" and complements population based strategies that are employed in drug utilization management and quality assurance programs. CMS has listed a number of questions and issues relating to MTM services on which input is desired.

11.1 Summary of ASCP Recommendations on MTM Services

A characteristic feature of MTM services is a focus on the total patient. Whereas drug utilization review is focused on use of a particular drug, and disease management is focused on a single disease, MTM services focus on all the drugs and diseases related to a specific patient. This comprehensive approach is the best strategy to optimize therapeutic outcomes in the frail elderly population, which is characterized by multiple chronic conditions, high use of medications, and high drug costs.

The type and intensity of MTM services provided to an individual beneficiary should be determined by the needs of that individual. ASCP supports the CMS approach of ensuring that PDPs offer a range of MTM services to ensure that needs of diverse Medicare beneficiaries are met. As noted by CMS, "One beneficiary may require only a fifteen-minute phone consultation, while another would be better served by a one-hour in-person visit with the pharmacist." CMS should ensure that PDPs provide a wide range of MTM services, rather than limiting these services to exclusively telephone provision, for example.

ASCP also believes that is important for the pharmacist (or other health professional, if applicable) who provides MTM services have appropriate qualifications to deliver the level of services being provided. Since the MMA definition of "targeted beneficiaries" specifies a generally complex population, expertise in geriatrics or the care of the disabled would be especially important. In the area of geriatrics, the Commission for Certification in Geriatric Pharmacy provides a psychometrically valid certification examination in geriatric pharmacy. Individuals who successfully complete the examination are designated as Certified Geriatric Pharmacists (CGP).

The geriatric certification examination would be one way, but not necessarily the only way, for a pharmacist to demonstrate expertise in geriatrics. Pharmacists who have completed an accredited residency program in geriatrics, for example, should also have expertise in geriatric pharmacy.

Finally, ASCP strongly supports the use of Current Procedural Technology (CPT) codes for documentation and reporting of MTM services. These codes can be used to track the provision of these services and also to pay for the services when delivered by pharmacists who are not employees of the PDP. The Pharmacist Services Technical Advisory Coalition is developing and submitting CPT codes for this purpose at the present time, with the goal of having these codes ready for use by January 2006.

11.2 Medication-Related Problems

A fundamental purpose of MTM Services is to identify, resolve, and prevent MRPs. These MRPs prevent optimal outcomes from drug therapy. Eight types of medication-related problems (MRPs) have been identified by Hepler and Strand. (49) These medication-related problems are:

- Drug use without indication. The patient is taking a medication for no medically valid indication.
- Untreated indication. The patient has a medical problem that requires drug therapy but is not receiving a drug for that indication.
- Improper drug selection. The patient has a drug indication but is taking the wrong drug, or is taking a drug that is not the most appropriate for the special needs of the patient.
- Subtherapeutic dosage. The patient has a medical problem that is being treated with too little of the correct medication.
- Overdosage. The patient has a medical problem that is being treated with too much of the correct medication.
- Adverse drug reaction. The patient has a medical problem that is the result of an adverse drug reaction or adverse effect.
- Drug interaction. The patient has a medical problem that is the result of a drug-drug, drug-food, or drug-laboratory test interaction.
- Failure to receive medication. The patient has a medical problem that is the result of not receiving a medication due to economic, psychological, sociological, or pharmaceutical reasons.

11.3 Goals of Medication Therapy Management Services

MTM Services have the following purposes:

1. Ensure that Medicare beneficiaries are only taking medications that have a current and valid indication for use, reducing "polypharmacy"

   Older adults frequently continue to take medications even after the medical problem is resolved. They may also receive similar medications for the same problem from more than one prescriber, resulting in duplicate drug therapy.

2. Alert the prescriber when an individual has an apparent indication for drug therapy that is currently untreated.

   Pneumococcal vaccine is an example of a drug product that is indicated for nearly all older adults, but is widely underused.

3. Evaluate, and assist the prescriber, in monitoring whether the desired therapeutic outcomes are being achieved.

4. Evaluate the beneficiary for presence or high risk of adverse outcomes from medication use, including drug interactions, drug side effects and other adverse events such as falls, mental confusion, and delirium.

5. Monitor and encourage compliance or adherence to prescribed medications.

ASCP member Penny Shelton comments: "A huge gap in services today for seniors as it relates to medication management has to do with adherence. A home health agency will rarely provide services if medication adherence is the only health problem. I see many seniors who benefit from in-home evaluation, education and then ongoing pillbox fills/syringe fills, etc. Nonadherence is one of the most common reasons for referral to my services from physicians and social workers. My service has successfully delayed and in some cases prevented nursing home placement, which is a whole lot more expensive for Medicaid or Medicare than paying for syringe fills and pillbox fills and a quarterly evaluation."

6. Simplify and reduce overall costs of the drug regimen. MTM Services can reduce drug costs both for the payer and for the patient, by evaluating the overall drug regimen and exploring ways to achieve the same therapeutic objectives with lower cost alternatives. The pharmacist's broad knowledge of drug costs and PDP formulary and drug benefit design can be applied to work with high-cost patients to achieve these objectives. See Appendix B for case studies to illustrate this.

7. Detailed review of medications in patients who are experiencing adverse outcomes, such as falls or urinary incontinence. Many medications can cause or contribute to a variety of geriatric syndromes or conditions. A pharmacist with geriatric expertise can evaluate the drug therapy of these individuals and recommend drug regimen changes to reduce these problems.

8. Design and implement medication management strategies to prevent the beneficiary from having to move to more "restrictive" levels of care, such as helping the individual remain at home or in an assisted living setting instead of moving to a nursing home. This may include special packaging provided by the pharmacy at the time of dispensing.

11.4 Types of Medication Therapy Management Services

MTM Services are provided by a pharmacist who may or may not be associated with the pharmacy that dispenses medication to the patient. Some MTM Services are associated with the dispensing of a drug product, and are provided by the dispensing pharmacy.

Medication Therapy Management Services should be distinguished from the pharmacist services required by OBRA '90 and most state boards of pharmacy during the prescription dispensing process. The OBRA '90 pharmacist services are provided in conjunction with the dispensing of a single prescription, such as counseling patients on possible side effects or how to take the medication. MTM Services focus on the entire patient or on management of a disease, such as congestive heart failure. It is more comprehensive in scope.

The goals of MTM Services (listed above) provide an overview of the purposes of these services. The settings in which pharmacists provide these services include:

- A visit to the patient's home
- An office at the pharmacist's home or business setting
- Senior center or adult day service center
- Area Agency on Aging office
- Assisted living community
- A separate office within a community pharmacy setting
- Physician office or physician group practice

The services provided by these pharmacists include:

- Comprehensive review of the patient drug regimen to identify, resolve, and prevent MRPs; this includes review of over-the-counter and herbal or alternative medicine products, along with prescription drugs
- Evaluation of outcomes of drug therapy (e.g. whether pain medications are providing adequate relief) or recommendations for achieving optimal outcomes of drug therapy (e.g. recommending dose or medication change to enhance pain management)
- Evaluation of possible adverse effects of drug therapy (in the elderly, medication side-effects are often misinterpreted and treated with new medications)
- Evaluation of patient compliance or adherence to drug therapy, and patient counseling or education to improve adherence to drug therapy
- Collaboration with the prescriber(s) to provide feedback on drug therapy and assist in coordination of drug therapy

- Development and implementation of a medication management plan, in collaboration with the caregiver and others, to prevent the patient from having to move to a higher level of care (such as a nursing home)

Forty states now permit collaborative drug therapy management agreements between physicians and pharmacists. Pharmacists are often able to adjust dosages of medication or order needed laboratory tests for patients as part of these protocol arrangements. The services provided by pharmacists through such agreements should also qualify for compensation as part of MTM Services for Medicare beneficiaries.

An excellent example of these agreements involves monitoring of patients who take warfarin, a medication used to prevent blood clots. Warfarin must be dosed carefully and monitored closely to successfully prevent blood clots without causing serious bleeding as a side effect. Pharmacists often conduct these activities as part of anticoagulation clinics. Studies of pharmacists serving in anticoagulation clinics have shown excellent outcomes of care from these arrangements. (50-54)

The Medicare Modernization Act included special packaging as one of the possible services that could be provided as part of MTM. Special packaging is an important part of the pharmacy services provided to nursing facilities, assisted living, and certain other settings. Although special packaging could be paid as part of MTM services, ASCP believes that a more efficient way to reimburse for special packaging is to provide a higher level dispensing fee (Option 2—See section 4.0 of these comments) for long-term care pharmacies.

For more detailed information about the use of special packaging in long-term care settings, see ASCP's Issue Paper on this subject. (55)

11.5 Targeted Beneficiaries

The MMA specifies that the Medicare beneficiaries who are targeted to receive these MTM Services are "individuals who—
(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);
(II) are taking multiple covered part D drugs; and
(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary."

To ensure that MTM Services are provided to the targeted beneficiaries, two key strategies should be employed:

- The Prescription Drug Plans should use computer algorithms or protocols to identify individuals who meet the criteria, and refer them to be screened for receiving these services; and
- Physicians who provide care for Medicare beneficiaries should be able to refer targeted beneficiaries to receive MTM Services when the physician believes the individual could benefit from these services

Prescription Drug Plans, for example, should be able to identify individuals who are in poor compliance with drug therapy by tracking prescription refills. High-risk Medicare beneficiaries who are identified as not adhering to prescribed drug therapy would be prime candidates for referral for MTM Services.

High-risk ("targeted") Medicare beneficiaries are especially likely to be:

- Residents in assisted living
- Clients of home health agencies
- PACE (Program of All-inclusive Care for the Elderly) clients
- Clients of adult day service centers

Consultant pharmacists who serve these settings could be especially useful in providing MTM services to these individuals.

Other individuals involved in the care of the Medicare beneficiary may also be able to recognize a need for these services and alert the physician or Prescription Drug Plan about the need for these services. This may include geriatric care managers, social workers, home health nurses or other health professionals. The patient or caregiver may also be able to identify a need for these services.

11.6 Qualified Pharmacists

Not all pharmacists have the expertise to provide MTM Services to frail elderly individuals with multiple chronic conditions who take multiple medications. Few pharmacy schools require a course in geriatrics in the core curriculum. As a result, most pharmacists learn geriatrics after initial training and licensure as a pharmacist.

Pharmacists can learn geriatrics through completion of a geriatric residency or fellowship. The ASCP Research and Education Foundation also offers traineeships in various aspects of geriatrics. These are week-long intensive educational experiences. ASCP offers a variety of educational opportunities for pharmacists, including live educational programs at our Annual and Midyear meetings, and web-based education at www.geriatricpharmacyreview.com and www.scoup.net.

Many pharmacists also receive training from their employers and mentoring from experienced geriatric pharmacists. The nursing home environment is often the place where pharmacists learn basic principles of geriatrics.

The Commission for Certification in Geriatric Pharmacy offers a psychometrically valid international certification examination in geriatric pharmacy. Pharmacists who pass this examination become Certified Geriatric Pharmacists and have demonstrated their expertise in geriatric drug therapy principles and pharmaceutical care for older adults.

11.7 Payment for Medication Therapy Management Services

The MMA has appointed the Prescription Drug Plans as the payment intermediaries for the provision of MTM Services. The PDPs should establish a mechanism to provide payment to pharmacies and to individual pharmacists for MTM Services needed by the Medicare beneficiary. Payment for these services should be authorized when a need for the services is identified by either the PDP or the physician providing care for the beneficiary.

Payment formulas for MTM Services should be based on the time, clinical intensity, and resources required to deliver these services.

ASCP strongly supports the use of Current Procedural Technology (CPT) codes for documentation and reporting of MTM services. These codes can be used to track the provision of these services and also to pay for the services when delivered by pharmacists who are not employees of the PDP. The Pharmacist Services Technical Advisory Coalition is developing and submitting CPT codes for this purpose at the present time, with the goal of having these codes ready for use by January 2006.

11.8 Ambulatory versus Institutionalized Medicare Beneficiaries

In the ambulatory setting, MTM Services must be distinguished from the standard pharmacist services associated with dispensing of the drug product. These services are defined in state pharmacy practice acts and board of pharmacy regulations. At a minimum, most states chose to incorporate the OBRA '90 requirements into their standards of pharmacy practice. The pharmacist services that are already expected or required as part of prescription dispensing would not be considered part of MTM Services.

In the institutional setting (nursing homes), federal regulations require a monthly drug regimen review (DRR) by the pharmacist for all nursing home residents.

This DRR is the responsibility of the nursing facility. The DRR may be performed by:

- A pharmacist employee of the nursing facility
- An independent consultant pharmacist contracted by the nursing facility
- A consultant pharmacist employed by the provider pharmacy that contracts with the nursing facility

If contracted out, the consultant pharmacist services are paid by the nursing facility separately from the payment for provision of the drug product. ASCP recommends that separate agreements be used for provision of drug product services and consulting services. See ASCP's Statement on Separation of Providers and Consultants. (56)

Just as ambulatory MTM Services must be distinct from standard dispensing services, institutional MTM Services must be distinct from the legally mandated drug regimen review, which is the financial responsibility of the nursing facility. In addition to drug regimen review, consultant pharmacists also provide services to the nursing facility. These nursing facility services include:

- Assist in development of policies and procedures
- Ensure accountability of controlled substances
- Provide oversight and in-service education related to medication administration in the facility

These services provided to the nursing facility would also not be appropriate for patient specific billing as MTM Services. Pharmacists can provide advanced clinical services to patients, however. Examples of patient services provided by pharmacists that go beyond the drug regimen review include:

- Evaluation and management of residents receiving warfarin, providing recommendations on drug dosing and monitoring to the prescriber and nursing facility; or providing these services directly through a protocol with the prescriber.
- Consultation on residents with serious wounds or pressure sores, recommending wound care products and strategies to facilitate healing
- Evaluation and management of residents with Parkinson's disease, recommending or providing individualized dosing of appropriate medications to achieve optimal control of symptoms
- Consultation on residents with severe behavioral symptoms associated with Alzheimer's disease or other dementias, recommending strategies to reduce these symptoms and minimize adverse effects from drug therapy

The ASCP Research and Education Foundation (57) provides week-long intensive Traineeships to provide pharmacists with advanced training in a variety of clinical areas so that these services can be delivered.

11.9 Conclusion

Medication Therapy Management Services are designed to help ensure optimal outcomes from drug therapy, including adherence to drug therapy by the patient. CMS regulations to implement this section of the MMA should be designed to:

- Ensure that targeted beneficiaries are identified and offered these MTM services
- Ensure that targeted beneficiaries have access to MTM services
- Ensure that Prescription Drug Plans make these services available to targeted beneficiaries by providing adequate payment to pharmacists and pharmacies that provide these services
- Implement quality indicators that focus on achieving optimal outcomes from drug therapy

12.0 Transition of Dual Eligibles to Medicare Part D

On January 1, 2006, more than 6 million dual eligible individuals will lose their Medicaid drug benefit and transfer their drug coverage to Medicare Part D. These individuals, therefore, must be enrolled in a Medicare Part D plan prior to the end of 2005. CMS plans to permit dual eligible individuals to choose a Prescription Drug Plan or Medicare Advantage plan within their region beginning on November 15, 2005. Individuals who do not choose a plan voluntarily will be automatically enrolled through random assignment to a plan in their region. Dual eligible individuals will only be able to enroll in plans that are at or below the benchmark cost within their region. Thus, if there are three PDPs in the region, dual eligibles would be able to enroll only in the two lowest-cost plans.

It is expected that auto-enrollment would occur in early December, providing only a two-week window for dual eligibles to evaluate and enroll in a specific plan before being randomly assigned. Choosing from among multiple PDPs will be a complicated decision for these individuals. Critical factors to be evaluated include:

- Whether the individual's pharmacy is included in the PDP network
- Whether the individual's medications are covered by the PDP formulary
- Whether prior authorization or other restrictions apply to any of the formulary medications taken by the individual

- The complexity of the appeals process and grievance procedure used by the PDP

In regions where more than one plan is available to duals, the complexity of evaluating all the critical factors and selecting a plan will likely mean that few individuals will choose a plan during the brief time permitted. This is especially true for the dual eligible population, which has a high prevalence of disability, mental illness, cognitive impairment, and other barriers to decision-making.

The likely result of random assignment is that many individuals will no longer be able to get prescriptions filled at their customary pharmacy, forcing them to seek assistance in locating a participating pharmacy near their home. They are also likely to discover that one or more of their medications will no longer be covered by their drug program, as it was under Medicaid. Individuals will be forced to contact their physicians to obtain a prescription for a different medication, or seek assistance in applying for permission to continue their current medication.

When this scenario is multiplied by millions of individuals, it is clear that physicians will be overwhelmed by millions of requests for assistance with medication changes or appeals to continue existing medications. If all of these changes are expected to occur in the space of a few weeks, as currently proposed by CMS, then the expectation is wildly unrealistic.

It is essential that the transition of dual eligible individuals from Medicaid to Medicare Part D be substantially lengthened. ASCP would prefer that dual eligible individuals continue their Medicaid drug benefit until January 1, 2007 to permit more time for creation of the new drug benefit program and transitioning individuals into the new drug benefit.

ASCP is also concerned about the automatic enrollment of dual eligible individuals who reside in long-term care settings. If the pharmacy serving the long-term care facility is enrolled in only one of the available Prescription Drug Plans, all of the dual eligible individuals in that facility should be enrolled in the plan for which the long-term care pharmacy is included in that network. It would not make sense to auto-enroll dual eligibles into plans for which the long-term care pharmacy is not included in the network.

Recommendation: Dual eligible residents of long-term care facilities should only be auto-enrolled into PDPs in which the long-term care pharmacy serving that facility is included in the network.

Recommendation: If the Medicaid drug benefit for dual eligibles can not be prolonged past January 1, 2006, CMS must ensure that all dual eligibles are auto-enrolled by December 31, 2005 and that PDPs and MA-PDs offer an open formulary for all dual eligible individuals for a minimum of six months, through June 30, 2006, to ensure adequate time for physicians and patients to navigate administrative barriers and change medications to comply with formularies. This will permit dual eligible individuals to continue their existing medications while adequate time is permitted for a transition to the new drug benefit.

12.1 Special Enrollment Periods

Under the drug discount card program, a move to a nursing home was considered a change in residence allowing the enrollee to choose a new discount card plan with no penalty. (58) The proposed regulation does not specifically address this issue as it applies to LTC pharmacies under Part D. We are concerned that without a comparable special enrollment period for the Part D benefit, there would be considerable delay (until the next open enrollment period) in allowing the beneficiary to move to a PDP plan for which the LTC pharmacy serving that LTC facility is "in-network." In turn, this would cause the beneficiary (or CMS, in the case of full benefit dual eligibles) to incur a higher cost to the extent there is a differential between the PDP's covered plan cost and the U&C cost.

We believe that LTC residents will have an incentive to join the PDP plan that includes the LTC pharmacy in-network to avoid paying the differential between the usual and customary price, and the plan allowance. Impairing the ability of a timely change into that PDP plan would undermine the ability of an LTC pharmacy to negotiate to be in the network of a PDP or MA-PD plan. A special enrollment period comparable to the discount card program would increase choices for Medicare beneficiaries seeking the best plan for their needs, and allow the beneficiary (or CMS, in the case of full benefit dual eligibles,) to avoid additional costs until the next open enrollment period.

Therefore, ASCP proposes the following revision to Section 423.36(c)(7):

> **(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.** ***Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a long term care facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.***

Recommendation: Admission into a LTC facility should qualify as a "triggering event" for special enrollment into a PDP plan whose network includes the LTC pharmacy serving that facility, if any.

13.0 Disenrollment for Disruptive or Threatening Behavior

ASCP has 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. This is especially important for dual eligible individuals, who lack financial resources to pay out of pocket for medications if their drug benefit is involuntarily discontinued.

Behavioral symptoms associated with Alzheimer's disease are common among nursing home residents. For institutionalized individuals, a provision to permit disenrollment of individuals for the listed behaviors would be particularly inappropriate.

13.1 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 a non-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 to 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.

13.2 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.

13.3 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.

13.4 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 cognitive impairments that could manifest in disruptive behavior all but assures that where these regulations open the door, such discrimination will occur. Congress' clear concern in the conference report for assuring access to needed medications for individuals with mental illness argues for exercise of the greatest care in the development of these regulations to ensure that avenues for potential discrimination are barred. Absent such steps here, the disenrollment processes proposed in the NPRM will have a disproportionate impact on individuals with disabilities particularly those with mental illness and Alzheimer's, 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 CMS would 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.

13.5 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.

14.0 Grievances, Coverage Determinations, and Appeals

CMS proposed regulations in this area are highly complicated and fail to provide needed protections for Medicare beneficiaries. ***The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes.***

As noted in sections 7.7.2 and 7.7.3 of our comments, these requirements are especially inappropriate for long-term care residents, and we urge the use of open formularies for these individuals.

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.

14.1 Expedited Review

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.

14.2 Exceptions Process

CMS should develop a uniform exceptions process for use by all PDPs and MA-PDs when a prescriber needs to request permission to use a non-formulary medication. This uniform process will ensure that all Medicare beneficiaries have the same protections from undue administrative requirements, and will greatly reduce the administrative burden on physicians, who would only need to become familiar with one form and procedure instead of many. These protections will help ensure that Medicare beneficiaries have access to needed and appropriate medications, whether or not included on the formulary of a particular PDP.

14.3 "Fail First" Requirements

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.

One example of how this would apply relates to nonsteroidal anti-inflammatory drugs (NSAIDs). Some managed care plans have a requirement that an individual fail therapy with a traditional NSAID medication before a newer COX-2 inhibitor medication may be used. Since the benefits of these newer medications relate to safety, rather than effectiveness, such requirements have resulted in development of gastrointestinal ulcers, including serious GI bleeding. (41). Such requirements would be dangerous for the medically vulnerable populations of frail elderly, dual eligible, and long-term care individuals.

Recommendation: CMS should prohibit PDPs from employing "fail-first" strategies as a cost-containment tool under Medicare Part D.

14.4 Physician Requests for Nonformulary Medications

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 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 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 a nonformulary 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 also clearly state that dosage form requirements should be an important criterion for qualifying a medication for an exception process. For example, if the beneficiary has difficulty swallowing and needs a liquid dosage form, and the formulary medication is not available in a liquid, this should enable the patient to have access to the liquid dosage form of a nonformulary medication through the drug benefit.

14.5 Timeframes for Exceptions

We are deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is 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.

Recommendation: 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)).

15.0 Long-Term Care Pharmacy and the Special Needs of Long-Term Care Facilities

Nursing home and other LTC residents today have specialized drug therapy needs far different than the ambulatory Medicare beneficiary. To address those needs, over the past 25 years the LTC pharmacy industry has emerged to serve the unique needs of the nation's most frail elderly persons. We appreciate that CMS, in its proposed rule, has already recognized the fact that LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what a typical retail pharmacy provides today. Because LTC residents' needs, the services currently being provided by LTC pharmacy, and the resulting cost savings to health care delivery all factor into ASCP's comments to the proposed rules, we expand upon them below.

15.1 Drug Therapy Needs of LTC Residents—More Intense

Unlike the typical ambulatory senior, residents in LTC facilities usually are older, in poorer health, and in need of greater care. A 1999 study by Bernabei et al. described the typical LTC resident, as follows (40):

- mean age of residents is 83.1 years;
- 62% of residents were admitted to the LTC facility from an acute care hospital;
- over half of LTC residents had abnormal cognitive function, and only 17% were characterized as independent or required limited assistance in performing the activities of daily living;
- residents typically had three medical conditions, with 45% having four or more and 10% having more than six medical conditions. Typical diseases included cardiovascular clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents had dementia, and 20% were stroke victims;
- LTC residents were taking an average of 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% were on some type of cardiac medication, and approximately 40% were on an analgesic.

More recently, the 2000 National Medication Usage Study of 63,671 nursing home residents revealed an average of 8.07 routine medication orders per resident, with 41% receiving 9 or more routine medications per day. (59) The most commonly used drug classes were antidepressants (45%), analgesics (30%), antipsychotics (24%) and anxiolytics (11%). (52) The frequency of drug usage

does not reflect an overuse of medications, but rather the increased efficacy of today's more advanced medicines, and the significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses.

15.2 Drug Therapy Needs of LTC Residents—Different Therapies

Not only are elderly LTC residents on more medications, but they require different medications and different types of medications. More specifically, as a person ages the body processes drugs differently due to changing metabolism and typical decreases in kidney and liver function. (60) There has been extensive treatment in the literature describing the need for a different formulary for the elderly (5), and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in these frail elderly people. (61) While these specialized formularies are often not widely known outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

In addition to differing drug needs, LTC patients also often require specialized drug intake systems. One long-term care pharmacy company has estimated from their Minimum Data Set records of over 400,000 LTC residents that 9.3% of LTC patients cannot swallow and must be tube fed, and an additional 20.5% of residents have difficulty swallowing and must take their medications through capsules, liquids, injectables, or through pills that can be crushed. While LTC pharmacy today is equipped to handle and manage these specialized needs, the typical retail pharmacy or pharmacy benefit manager is not equipped to address these concerns, or properly manage the significant drug requirements of this specialized elderly population.

15.3 Drug Therapy Needs of LTC Residents—Enhanced Services

In light of the significant patient needs noted above, both standards of care and federal and state regulations have evolved to provide LTC residents with an enhanced set of services related to their prescription drugs not provided by retail pharmacy. These services include:

15.3.1 Unit Dose and Other Specialized Packaging

This packaging serves three important functions. First, the packaging allows for greater customization and quality control of the drugs and dosages to ensure that

medications are taken appropriately and without error. The special packaging improves the accuracy of medication administration in the LTC facility.

Second, the unit dose system provides a uniform and easily managed process for drug delivery through the central distribution point of the LTC nurse, who will actually deliver the drugs to the patient on any given day. The critical nature of this uniform distribution system throughout the facility cannot be overemphasized. LTC facility nurses face a significant challenge in distributing multiple drugs to dozens of patients each day. (62) The specialized drug packaging provided by LTC pharmacy today is a critical system in enhancing efficiency of drug administration from a nurse making delivery rounds.

The third critical reason for special packaging in long-term care is to ensure and promote accountability of controlled medications (e.g. morphine, alprazolam) in long-term care. The special packaging permits immediate recognition of the number of tablets or dosage forms of medication on hand. Since these medications are counted at each change of shift, the time and burden of counting pills from traditional pill bottles would be totally unworkable in long-term care.

15.3.2 Delivery of Medications

Unlike traditional community pharmacy, all residents of long-term care facilities need all medications delivered by the pharmacy. This is done because residents are unable to pick up their own medications. The LTC facility is accountable to regulatory authorities to ensure timely administration of medications to residents and needs consistency and reliability of delivery of new medications. Delivery by the pharmacy is also a security precaution. Having a representative of the resident pick up the medication introduces the potential for diversion or substitution of medications, especially for controlled drugs.

15.3.3 Emergency Services—"24/7"

Long-term care pharmacies provide emergency and after-hours dispensing of medications to meet the needs of the resident and facility. This includes weekends, night, and holidays when most retail pharmacies are closed. Emergency medications are also delivered by the pharmacy, just as routine medication orders are.

Long-term care pharmacies also provide "emergency kits" of medications with medications for use in medical emergencies (such as antidotes) or medications that may be urgently needed by a resident, such as pain medications.

15.3.4 Intravenous Therapy Services

Long-term care pharmacies usually provide intravenous therapy for LTC residents, such as IV antibiotics or IV hydration. Provision of these services in the LTC setting prevents the need for hospitalization of the resident and is much more cost-effective with respect to total health care costs.

15.3.5 Pharmacist Services—Pharmacy Provider

Long-term care pharmacies usually provide certain pharmacist services to the LTC facility, such as in-service programs on medication distribution procedures and pharmacy policies. The pharmacy may also provide reports to the facility on medications dispensed to facility residents or prepare forms for use, such as Medication Administration Record forms. The dispensing pharmacist also usually provides a prospective review of new medication orders to screen for potentially inappropriate drug use.

15.3.6 Pharmacist Services—Consultant Pharmacist

Long-term care facilities are served by a consultant pharmacist, who may be affiliated with the long-term care pharmacy provider of the facility or may be an independent consultant. Federal law requires a monthly drug regimen review to be performed by the consultant pharmacist on every nursing home resident. These reviews are conducted in the nursing facility and involve a comprehensive review of the drug regimen, laboratory test results, physician and nurse progress notes, and other records.

Consultant pharmacists also counsel patients, provide information and recommendations to prescribers and caregivers, present in-service educational programs, and oversee medication distribution services. LTC pharmacists also provide a wide range of other primary care services to seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment assessments and support. In this way, LTC pharmacy is the principal defense against medical errors and ensures the highest quality of patient care.

Critical for the provision of these important services is the need for the dispensing pharmacy and the consultant pharmacist to have a complete and accurate understanding of the patient's medical conditions, and, more importantly, current drug utilization. (62) Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than concurrent) basis is for there to be a

single dispensing pharmacy for any given patient. (63) Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate utilization of prescriptions.

The value of these screening services is significant. Bootman et al. estimated that consultant pharmacist intervention saves $3.6 billion (in 1997 dollars) in avoided medication-related problems. (64) Thus, any attempt to introduce alternative drug delivery systems into LTC facilities must be carefully examined against the backdrop of the savings that already exist as a result of the standards of care that LTC pharmacy already provides to these patients.

Bootman et al. explained their finding that medication-related problems in the LTC context ($4.6 billion with consultant pharmacists, as opposed to $8.2 billion without their services) were a third higher than those he had previously found in the ambulatory setting:

> First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for [drug related problems, or] DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the physiological effects of aging that alter the ability to metabolize certain drug products. Finally, another factor leading to the greater cost of drug-related morbidity and mortality is that once a DRP has occurred in the nursing home patient, there is a greater intensity of care required to treat the DRP. This could be the result of a more severe reaction experienced by the frail elderly or the higher costs of care that occur within the institutional setting.

15.4 Primary Payer of LTC Medications—Medicaid

The vast majority of LTC residents currently receive prescription drug benefits under Medicaid. A recently completed Lewin Group study on "Payer -Specific Financial Analysis of Nursing Facilities," published in March, 2002, indicated that 66% of LTC residents are Medicaid beneficiaries, 12% are Medicare beneficiaries (receiving specific Medicare Part A pharmacy benefits, for example, within their "first 100 days") and the remaining 22% receive insurance benefits or are "private pay" patients. These findings are consistent with both the National

Health Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for HealthCare Research and Quality. The National Health Expenses Chartbook also indicates that between 1987 and 1996 the number of LTC residents receiving prescription drugs outside of a Medicare or Medicaid benefit declined from 33.1% to 24.4%.

Data provided by LTC operators from approximately 3,000 facilities suggest that within six months of entering a LTC facility, approximately 80% of private pay patients become Medicaid eligible and that by the end of a year, 99% of those residents entering as "private pay" patients become Medicaid eligible. Thus, it is important for CMS to recognize that the vast majority of LTC residents receive Medicaid prescription drug benefits which include access to "medically necessary" prescription drugs. In addition, Medicaid provides for a 24 hour appeal determination and 72 hour dispensing, procedures which are less likely to result in adverse health incidents. A reduction in the benefits currently enjoyed by this population has the potential to result in increased adverse health incidents for this population of frail elderly institutionalized beneficiaries.

15.5 Federal Oversight of LTC Residents' Drug Therapy

LTC facilities are subject to federal statutory and regulatory requirements affecting the provision of drug therapy for their residents. Federal regulations require nursing homes to ensure that medication error rates are minimized and that residents do not receive unnecessary drugs. (65) LTC facilities meet this element of federal regulation by contracting with LTC pharmacies to provide prescription drugs and services to their residents. These services include consultations with physicians regarding drug regimens, 24 hour, 7 day per week deliveries, specialized packaging, and IV and infusion therapy services. Under this arrangement, beneficiaries receive their medication in a carefully controlled environment where safety can be assured, medication use monitored, and therapies changed to better reflect the needs of the resident.

15.6 Long-Term Care Pharmacy—Different from Retail Pharmacy

LTC pharmacy is different from the retail pharmacies that are likely to join PDP plans' networks, or those pharmacies contemplated by the MMA as serving the ambulatory Medicare population that will serve as the backbone of the PDP network. (66) There are three distinctions. First, retail offers other "items" for sale, and thus is not solely dependent upon appropriate drug reimbursement for its revenue. Second, LTC pharmacy's cost structure is higher due to the far greater suite of services it provides. Third, LTC pharmacy is far more dependent on the Medicare population as a customer base than retail pharmacy.

Addressing the structure of their respective facilities first, retail facilities provide a host of other items "for sale" such as food, beverages, candy, household items, and other "drug store" retail products, many of which carry a far higher profit than the prescription drugs sold at "the back of the store." Thus, retail pharmacies and pharmacy chains have an interest in providing prescription drugs to beneficiaries, if only to attract them into the stores so that other products can be sold. LTC pharmacy, in contrast, has no such "storefront" and has no such products for sale to its customers. Thus, the financial incentives that will attract a retail or traditional chain pharmacy serving ambulatory Medicare beneficiaries to enter into a PDP network, and the negotiating leverage the retail or chain pharmacy may have, is simply not present in the LTC context.

Second, pharmacies that serve institutional sites of care, such as nursing homes, have higher costs of doing business than other pharmacies. In particular, LTC pharmacies have high dispensing and related costs that are different from those of retail pharmacies serving ambulatory individuals in community settings. To quantify this phenomenon, in 2001 the Long Term Care Pharmacy Alliance commissioned the accounting firm of BDO Seidman to conduct a survey of its members' audited dispensing costs, consolidate the financial information, and issue a report on the costs of dispensing pharmaceuticals to residents in nursing homes and other LTC sites.

The BDO Seidman survey found (using 2001 audited data) that it costs the major national LTC pharmacy operators (who presumably, through economies of scale, maintain a lower cost structure than the smaller LTC pharmacy companies), on average, approximately $11.37 to dispense a prescription. (21) This figure does not include a return on equity or a profit margin, it simply reflects the costs of operating a LTC pharmacy. In contrast, the National Association of Chain Drug Stores (NACDS) estimated in 2000 that it costs a chain pharmacy, on average, $7.05 to dispense a prescription to a retail customer.

In reviewing the survey results, BDO Seidman found several reasons why the costs of dispensing prescriptions are higher for LTC pharmacies than they are for retail pharmacies. BDO Seidman attributed the higher costs to:

- the dispensing of drugs in specialized packaging systems, such as unit-dose packaging, that reduce the possibility of medication errors and are the standard of care in nursing homes;
- the need for round-the-clock delivery of critical and emergency medications to meet LTC regulatory requirements;

- the preparation and dispensing of intravenous medication solutions, a service that retail pharmacies typically do not provide;
- a high percentage of business reimbursed by Medicare and Medicaid, resulting in higher receivables, greater working capital requirements, and a higher percentage of bad debts than generally experienced in the retail setting; and
- the provision of considerable on-site support and consultation to nursing homes and other institutional provider-clients.

Third, beyond the distinct cost structures, retail pharmacies do not depend upon Medicare beneficiaries as a predominant source of revenue. Stated differently, retail pharmacies expect that a broad range of customers will enter their stores, including children, parents, and workers with prescription drug insurance. The flexibility in a retail pharmacy's customer base provides retail pharmacy a significant amount of discretion and leverage in choosing whether or not to enter into a PDP network if the PDP reimbursement is inappropriately low. In contrast, and as described above, the vast majority of LTC pharmacy's customer base are Medicare beneficiaries, and there is virtually no ability for LTC pharmacy to target a different customer base. Thus, by its very definition, LTC pharmacies can be "held hostage" to PDP reimbursement structures, simply for the reason that LTC pharmacy does not have the ability to shift its customer base and marketing efforts. ASCP urges CMS to take note of this significant market dynamic, which (beyond patient care needs, which also require this same solution) argues for allowing LTC pharmacies the flexibility of serving LTC residents as an out-of-network provider.

15.7 Electronic Prescribing

In long-term care environments, physicians and pharmacies serving the long-term care resident are both usually located off-site from the long-term care facility. This introduces an additional layer of complexity with respect to the adoption or use of electronic prescribing for residents of LTC facilities.

The typical pattern for new medication orders in long-term care is for the facility nurse to call the physician when the resident exhibits a new symptom or medical problem. The physician usually gives a verbal medication order to the nurse, who transcribes the order into the resident's medical record and then FAXes the order to the pharmacy. The pharmacy fills the medication order from the FAXed copy and sends the medication to the facility.

If the physician transmits a medication order to the pharmacy electronically, after giving the nurse a verbal order for the medication, medication ordering

involves two separate interactions with the physician. This introduces the potential for new medication errors. If the order sent by the physician to the pharmacy electronically is different from the verbal order given to the nurse, the medication sent by the pharmacy will not be consistent with the medication order written in the resident's record. Unless the discrepancy is clarified, a medication order will occur.

These discrepancies can easily happen if the physician is interrupted or delayed between the two interactions. The physician may recall the verbal medication order slightly differently from what was actually said, and give the pharmacy a different order (e.g. three times per day versus four times per day, or 20 mg versus 30 mg dosage strength). When these discrepancies occur, the physician must be contacted again to clarify the intent, and orders resubmitted. This increases the workload on the physician and other staff, and increases the risk of error.

For long-term care residents, prescribing is a three-way interaction, not the two-way interaction commonly used in community settings. For this reason, application of electronic prescribing in long-term care must recognize this reality and include the long-term care facility in the electronic interaction loop.

Recommendation: Before implementation in long-term care settings, electronic prescribing technology and procedures must be adapted to include the long-term care facility in medication transactions involving residents of the facility.

15.8 Summary of Recommendations Relating to Long-Term Care Pharmacy

ASCP offers the following recommendations to CMS regarding the provision of a Medicare Part D benefit to residents of long-term care facilities:

PDP-LTC Pharmacy Relationship:

- CMS should encourage, but not require, PDP plans to contract with LTC pharmacies.

- CMS also should explicitly preserve, and enhance, the language in proposed section 423.124 to specifically permit LTC residents to access LTC pharmacies as out-of-network providers.

- The final rule should explicitly state that fallback plans are subject to the requirements in Section 423.124 for out-of-network pharmacy access and payment.

- CMS should clarify in its final rule that full benefit dual eligibles and other low income beneficiaries have no cost-sharing for covered Part D drugs, whether or not they are on the formulary of the PDP or MA-PD plan.

- CMS should provide for prompt payment of pharmacy claims by PDP and MA-PD plans.

- Plans should not be allowed to presumptively include LTC pharmacies in their pharmacy networks based on pre-existing relationships outside the context of Part D.

Disclosure of Generic Equivalents:

- CMS should waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies.

Formulary:

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

- Beneficiaries residing in LTC facilities should have a presumption of access to all medically necessary drugs, regardless of a plan's formulary, and the LTC pharmacy should be permitted to dispense the drugs to these beneficiaries on an out-of-network basis, even if otherwise in-network for the beneficiary's PDP or MA-PD plan.

P & T Committee:

- CMS should require that the P&T Committee consider the special pharmacy needs of the frail elderly and institutionalized beneficiaries.

- CMS should maintain the requirement that the P&T Committee's decision be binding on the plan and require P&T Committee oversight of utilization controls.

Enrollment:

- In order to avoid gaps in coverage for full benefit dual eligibles between January 1, 2006 and June 1, 2006, CMS should postpone the

implementation of the Part D prescription drug benefit for dual eligibles until January 1, 2007. Alternatively, all dual eligibles must be auto-enrolled by December 31, 2005 and all PDPs should be required to provide an open formulary for all dual eligibles until June 30, 2006.

- CMS should auto-enroll dual eligibles in PDPs whose network includes the LTC pharmacy serving that facility, if any.

- Admission into a LTC facility should qualify as a "triggering event" for special enrollment into a PDP plan whose network includes the LTC pharmacy serving that facility, if any.

Dispensing Fees:

- CMS should provide for separate dispensing fees based on the complexity of dispensing the drug. ASCP recommends specifically that the dispensing fee for long-term care pharmacies should be either a separate dispensing fee added to that proposed in Option 1 for long-term care pharmacies, or an Option 2 dispensing fee, that incorporates the costs of specialized packaging, around-the-clock service and delivery, emergency services, and other considerations deemed appropriate by the Secretary. These services could each have a separate fee, resulting in a payment system that "layers" the appropriate fees for a prescription or medication order based on the services provided for that prescription.

Medication Therapy Management Program:

- CMS should add to Section 423.153(d)(2)(iv) "or are residents of LTC facilities" and require PDP sponsors and MA organizations offering MA-PD plans to disclose to CMS and others, upon request, the amount and portion of fees they expend for MTMP services to residents of LTC facilities.

- CMS should amend Section 423.153(d)(1)(iii) to specify that MTMP for residents of LTC facilities must be provided by pharmacists with specialized training or expertise in geriatric drug therapy in a LTC facility.

- CMS should establish a standard fee schedule for MTMP for LTC residents and require PDP plans to pay these fees in their contract arrangements with LTC pharmacies that are in-network and directly to LTC pharmacies that are out-of-network.

- CMS should convene an expert panel of pharmacists with specialized training or expertise in geriatric drug therapy in LTC and other related institutional settings to review the findings of CMS' Section 107(b) study and establish a set of activities that will constitute MTMP for LTC residents that will be well-integrated into the services currently provided by pharmacists in LTC facilities.

- CMS should establish a standard fee schedule for MTMP for LTC residents and require PDP plans to pay these fees in their contract arrangements with LTC pharmacies that are in-network and directly to LTC pharmacies that are out-of-network.

LTC Facility Defined:

- CMS should expand the definition of "long-term care facility" to include residents of congregate licensed living arrangements for the elderly that "assist with" or "manage" medication administration for its residents. These facilities include intermediate care facilities for the mentally retarded and hospice, as well as assisted living facilities and any facilities recognized by State law as eligible for payment under Sections 1915(c), 1616(e), and 1115.

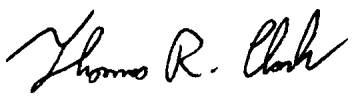
16.0 Conclusion

ASCP appreciates the diligent work of CMS to interpret and implement the provisions of the Medicare Modernization Act. We recognize the challenges that this entails, including the difficulty of balancing the needs of managed care organizations, and their desires for control and flexibility in administering the benefit, with the need for protection of vulnerable Medicare beneficiaries. We hope that our comments will prove to be useful to CMS in achieving the proper balance.

ASCP also appreciates this opportunity to provide comments to CMS, and we welcome the opportunity to answer any questions or engage in further dialog to explain or expand upon these comments.

Thank you.

Sincerely,



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Submitter : **Date & Time:** **10/04/2004 03:10:28**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-4068-P-904

Submitter : Mr. Patrick Finnerty **Date & Time:** 10/04/2004 03:10:44

Organization : Virginia Department of Medical Assistance Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The Virginia Department of Medical Assistance Services respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit regulations published in the Federal Register on August 3, 2004.

Issues 1-10

BACKGROUND

See attached document.

BENEFITS AND BENEFICIARY PROTECTIONS

See attached document.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

See attached document.

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

See attached document.

ELIGIBILITY, ELECTION, AND ENROLLMENT

See attached document.

GENERAL PROVISIONS

See attached document.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

See attached document.

PART D PROVISIONS AFFECTING PHYSICIAN SELF-REFERRAL, COST-BASED HMO, AND PACE REQUIREMENTS

See attached document.

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

See attached document.

REGULATORY IMPACT ANALYSIS

See attached document.

SPECIAL RULES FOR STATES

See attached document.

CMS-4068-P-904-Attach-1.doc

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Virginia Department of Medical Assistance Services (DMAS)
Comments on the Centers for Medicare and Medicaid Services' (CMS)
Medicare part D proposed regulations published in the
August 3, 2004 Federal Register (FR)

1. **Background, General Provisions and Impact Analysis.** DMAS is concerned with how the new requirements and changes required under part D will impact the agency's other initiatives and compliance efforts. For example, DMAS is concerned with how the changes required under part D will impact the its ability to meet the compliance requirements under HIPAA's Security Rule required by April 21, 2005. Medicaid Part D will require technical changes to the State's Medicaid Management Information System (MMIS), and will likely complicate the ability of states to reach this deadline. Further, other expected technical changes can be required in an expedited time frame relating to the Electronic Prescription program pilot expected as soon as January 1, 2006, and with the National Provider Identifier (NPI) standard required by May 23, 2007.

Furthermore, Medicare Part D, as detailed in this proposed rule, is required to abide by all Federal and State Laws regarding confidentiality and disclosure of medical records including all applicable HIPAA provisions. As State Medicaid plans are covered by HIPAA (45 CFR §160.103), there will be additional compliance responsibilities added to State Medicaid, including training, outreach to the provider community, business partners, and recipients.

The Privacy Rule Notice of Privacy Practice provisions will require amendments and distribution to all Medicaid recipients, not just dual eligible beneficiaries. Other modifications would be required to the Certificates of Coverage to include creditable time for receiving prescription drug benefits, revisions to all recipient handbooks plus other program materials.

Medicaid agencies will need to coordinate their pharmacy programs (and systems) with the PDP plans - for purposes of medication management programs, and will also need to educate beneficiaries on Medicare part D and how it will impact their Medicaid benefits.

Finally, in a NCVHS letter on the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) to Secretary Thompson on September 2, 2004, there were industry e-prescribing standard recommendations to be implemented through April 1, 2008. There appears to be insufficient time and more study needed on the administrative costs for State Medicaid programs, considering the technical and administrative costs anticipated over the long term. (FR pp. 46633, 46645, and 46670)

Comment: DMAS strongly urges CMS to acknowledge that these systems and compliance concerns will likely result due to the changes required by the Medicare part D program. Further, DMAS strongly urges CMS to provide clarification on precisely how CMS plans to address these concerns, and that CMS provide states with assurances that any adverse impacts related to the part D requirements will not adversely affect them

with respect to any financial or other penalties that could be imposed due to a failure to meet any particular deadline established prior to enactment of the MMA. Finally, it is unclear whether CMS reviewed and included the fiscal impact of such changes in the fiscal impact statement. DMAS requests that CMS clarify whether it included the estimated fiscal impact of these programmatic and administrative costs (including additional Part D information) in its fiscal impact estimate, and if not, that CMS provide the estimated fiscal impact.

2. **General Provisions.** In the proposed regulations, CMS requested comments regarding the advantages and disadvantages of requiring MA-PDs and PDPs to contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access to enrollees. (FR p. 46648)

Comment: DMAS currently pays home infusion services at "per diem" rates both for DME and Pharmacy supplies and services on a day rate basis, and also covers the ingredient cost (drugs) on a separate claim. Given the high quality and cost containment these services provide compared to the alternatives of increased hospital admissions, DMAS strongly suggests an appropriate payment methodology be developed along with inclusion of these services as a requirement of the PDP. Exclusion of theses services will lead to increased hospital days for patients and a lower quality of life.

3. **General Provisions.** The proposed regulations do not appear to adequately address the unique issues and needs related to persons in long-term care facilities. (FR p. 46661)

Comment: Among other things, DMAS recommends that CMS give special treatment or consideration to long-term care recipients with any type of swallowing problems with respect to developing the PDP formularies. Many elderly patients in long term care settings present with or develop dysphagia or require nourishment to be administered via naso gastric tube. Most time-released drugs are not conducive to this route of administration, thus the PDP's formulary should make exceptions for patients with these conditions. In addition, an effective drug utilization review program should be required.

4. **General Provisions.** 42 CFR §423.774 (c)(1) states that "appeals of eligibility determinations by States must be made in the same manner and frequency as the…appeals are made under the State plan." 42 CFR §423.774 (c)(2) states that "appeals of eligibility determinations…made by the Commissioner must be made in the manner specified by the Commissioner."

In the preamble, CMS invited comments on how to implement a process that would allow the two separate processes to produce the same outcome. (FR p. 46727, 46855)

Comment: DMAS believes strongly that this would best be achieved by having the Commissioner of Social Security Administration (Commissioner) handle all appeals. There is already a separate Medicaid appeals process that is administered by the States. Requiring the states to handle Medicare appeals would require an investment in additional staff and resources. This would impose an unfair burden on the states, because only one-half of these costs would be covered by the federal government. More importantly, it would be unfair to applicants and recipients of the Medicare program, because it would be extremely difficult, if not impossible, to ensure uniformity between two distinct appeals processes administered by two separate agencies. For these reasons, DMAS strongly opposes the requirement that the States handle appeals of low-income assistance eligibility determinations.

5. **General Provisions.** The proposed rules do not clearly define or list resources that will be included and excluded from the low-income eligibility resource test. Section 1613 of the Social Security Act (SSA) lists resource exclusions but does not define or list resources that are counted. (FR p. 46726)

Comment: If CMS expects the states to be able to make eligibility determinations and redeterminations, CMS needs to clearly identify which resources will be counted and those which will be disregarded for purposes of determining the low-income assistance eligibility. Further, the regulations should contain this information to give beneficiaries notice and to ensure that the counted/excluded resources are consistent with the legislation, consistently applied, and are not subsequently changed without further regulatory action.

6. **General Provisions and Impact Analysis.** In the preamble of the proposed regulations, CMS states that it is considering making States responsible for performing the automatic enrollment of dual eligibles into PDP plans. There appears to be no indication regarding what matching rate would be available for these additional costs to the states, and CMS does not appear to address the estimated fiscal impact of this potential requirement in the regulatory impact statement. (FR p. 46639)

Comment:

- *DMAS recommends that CMS should perform the auto-enrollment function.*
- *DMAS requests CMS provide the estimated fiscal impact to states and provide the federal financial participation rate if states were required to or opted to provide this function.*
- *Further, if states were mandated to perform this function, CMS should provide a full 100% federal match of all expenses related to this function.*
- *Finally, DMAS requests CMS clarify how the data connections would work if states were to perform this function, and, if not, how CMS envisions the functionality to accomplish this.*

7. **General Provisions.** CMS describes a part D eligible individual as an individual who is entitled to or enrolled in Medicare benefits under part A and or part B. This appears inconsistent with §1860D-1(a)(3)(A) of the SSA, as this section defines a "part D eligible individual" as an individual who is "entitled to benefits under part A or enrolled under part B." The definition of a part D eligible individual in the proposed regulations appears to be applied inconsistently throughout document. (FR pp. 46637 and 46810)

Comment: DMAS recommends that CMS conform this definition to the definition set forth in the SSA. Further, DMAS requests that CMS clarify whether part D eligible individuals are only those "entitled to" premium-free part A or are enrolled in part B, as seems to be implied in the language of §1860D-1(a)(3)(A) of the SSA. Therefore, if a Medicare beneficiary were enrolled in part A only, ineligible for the premium-free part A (had to pay the part A premium to enroll), presumably he would be ineligible for the part D benefit and, therefore, could only be eligible for Medicare part D by enrolling in Medicare part B. If the interpretation of "entitled to benefits under part A" does not mean entitled to premium-free part A, DMAS requests CMS to explain why such an interpretation is not inconsistent with CMS' interpretation of this language as applied to the Medicare-Approved Drug Discount Card program.

8. **General Provisions.** CMS discusses Special Enrollment Periods (SEP) for full-benefit dual eligibles described under 1935(c)(6) of the SSA – however, this section describes a full benefit dual eligible as those who have part D coverage through a Prescription Drug Plan (PDP) or Medicare Advantage prescription drug plan (MA-PD) and determined eligible for Medicaid. It is unclear why the SEP excludes those full-benefit dual eligibles not already enrolled in a part D plan, but applies to those already enrolled with part D coverage. (FR p. 46640)

Comment: DMAS recommends CMS clarify whether the SEP is intended to apply to all Medicare-Medicaid dual eligibles regardless of whether they have enrolled in a part D plan, or whether the SEP is to apply to those dual eligibles <u>without</u> current part D coverage.

9. **General Provisions and Impact Analysis.** In this section, CMS describes enrollee access to drugs from out-of-network pharmacies. An example given is that of an enrollee residing in a skilled nursing facility (SNF) that does not participate in the enrollee's Prescription Drug Plan (PDP) network. In this example, the SNF resident would be responsible for the difference in price from the usual PDP payment and pharmacy's price. It is unclear how this would work, especially with Medicaid and low-income assistance enrollees. For example, who would be responsible to pay the difference in price – since essentially all of the drugs provided by the SNF pharmacy would be out-of-network. (FR p. 46640)

Comment: DMAS strongly recommends that CMS clarify:

- *Who would be responsible for paying the difference in price in these situations (e.g., the recipient, the low-income assistance benefit or the nursing home);*
- *Because the pharmacy is assumed to be out-of-network in this example, how will the SNF, out-of-network pharmacy and enrollee know what the usual PDP payment is and how much the enrollee owes, and how will each of these entities be notified of any plan benefit changes;*
- *Because the pharmacy is out of network, how would the enrollee, SNF and pharmacy know what is on the PDP's formulary, how would each of these entities be notified of any changes, which of these parties would be responsible for submitting the coverage determination request if the needed drug is not on the plan formulary, and how would the out-of-network pharmacy get paid;*
- *If the low-income assistance does not pay for the difference in price because the pharmacy is out-of-network, what happens if the enrollee cannot pay the difference in price, what impact will this have on SNFs in general (please provide an estimated fiscal impact), and what is the pharmacy's or SNF's recourse if the enrollee does not/cannot pay the difference – for example, under the Medicaid program, an enrollee cannot be denied benefits for non-payment of a copayment, but as of January 1, 2006, this will no longer be considered a Medicaid benefit for the dual eligible population. Presumably, this policy would no longer apply to these services and CMS must clarify how this will affect the dual eligible population;*
- *If the enrollee is not a low-income assistance beneficiary and is responsible for paying the out-of-network costs, would these excess costs count towards their out-of-pocket threshold and count toward their Medicaid spend-down requirement. If yes, how would it be tracked – if no, this policy appears to have the effect of penalizing those individuals in nursing facilities; and*
- *Finally, did CMS consider how this would affect the reduction of patient pay amounts in its fiscal impact determinations.*

10. **General Provisions.** States will be required to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic re-determinations, and to notify CMS once they are made. (FR p. 46751)

Comment: DMAS opposes imposing this obligation on states due to increased administrative burdens, potential inconsistent results from states and the Social Security Administration performing eligibility determinations, and confusion among beneficiaries.

11. **General Provisions.** The proposed regulations would require states to begin accepting applications July 1, 2005, but does not impose a similar requirement on the Social Security Administration. (FR p. 46751)

Comment: As noted above, DMAS opposes the requirement that states make these determinations. In addition, DMAS recommends that CMS amend the regulations to impose the same time requirement on the Social Security Administration, and requests

CMS clarify why this timeframe was not imposed upon the Social Security Administration in the proposed regulations. By excluding the Social Security Administration from this requirement, it appears that this would increase the number of applications filed at the State versus the Social Security Administration, such that States would be responsible for making the bulk of the low-income eligibility determinations and redeterminations as well as handling appeals for the low-income assistance benefit.

12. **General Provisions.** CMS states that it worked with the Social Security Administration on a simplified application form and process for the low-income subsidy program and developed uniform criteria for determining resources, income, and family size. (FR p. 46751)

Comment: DMAS is concerned that States were not involved in development of the application form when they are required to be a partner in this effort, and strongly recommends that CMS provide states with an opportunity to provide comments on the development of this form.

13. **General Provisions.** The proposed regulations preclude states from using their resource rules when determining eligibility for low-income assistance benefit. This restriction will further complicate the eligibility process. States will be required to apply different rules regarding income and resources when determining an individual's eligibility as QMB for payment of Part A & B premiums and when determining eligibility for the low-income assistance benefit under Part D. The SSA gives the Secretary the option to allow states to use less restrictive methods. (FR p. 46725)

Comment: DMAS recommends that the Secretary exercise that option.

14. **General Provisions.** The proposed regulations establish a definition for determining "Family size." The proposed definition is different from that used by SSI and Medicaid, and will add yet another level of complication to the low-income assistance eligibility determination process because of inconsistencies between the rules and definitions used. (FR p. 46726)

Comment: DMAS recommends that CMS conform its definition of family size to the definition used by SSI and Medicaid.

15. **General Provisions.** The proposed regulations consider "liquid resources" to be those that can be converted to cash within 20-days. (FR p. 46726)

Comment: DMAS recommends that CMS clarify what assets and property are subject to this definition, and how a State is to determine what resources can be converted within 20-days, and how to determine the value of those resources for purposes of evaluating

low-income assistance eligibility. Further, DMAS requests CMS explain how it selected the "20-day" timeframe.

16. **General Provisions.** The premium subsidy amount is equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region. (FR p. 46728)

Comment: DMAS requests that CMS specify what types of data interfaces CMS envisions so that states will know the coverage details, and requests clarification of how states will know what each PDP covers.

17. **General Provisions.** The proposed regulations provide that states will not provide assistance for "covered part D drugs." It is unclear how state Medicaid agencies will know what part D drugs are covered for each recipient. Additionally, keeping track of this could be logistically impossible if PDP plans can change their formularies and optional drug coverage frequently. (FR p. 46638)

Comment: DMAS requests that CMS specify what types of data interfaces CMS envisions so that states will know the coverage details, and requests clarification of how states will know what each PDP covers.

18. **General Provisions.** If beneficiaries move between Part D coverage and Medicaid, how will beneficiaries be affected by formulary differences? Prior authorizations, co-payments, etc. may apply based on Medicaid versus other plan coverage. This may cause confusion with beneficiaries and more administrative work for providers. (FR pp. 46634, 46659 - 46661)

Comment: DMAS requests that CMS clarify how they will educate Medicare part D enrollees on the program, the requirements and their responsibilities.

19. **General Provisions.** CMS requested comments on whether ICF/MRs should be included in the definition of long-term care facility. (FR p. 46648)

Comment: In Virginia, the ICF/MRs that are state facilities contract with long-term care pharmacies, while those ICF/MRs that are privately owned may only contract with local pharmacies. Including all ICF/MRs in the definition of "long-term care facility" for part D may hamper access to part D drugs for residents in privately owned ICF/MRs. Therefore, DMAS recommends CMS modify this definition to include ICF/MRs to the extent needed to address the distinct licensure or credentialing requirements of the facility. Further, DMAS recommends that CMS include residents of all ICF/MRs in its definition of institutionalized individual for purposes of the low-income assistance benefit

(regardless of whether such ICF/MR falls under the definition of long-term care facility), as these persons are considered institutionalized individuals under Medicaid, and should be able to access the full low-income assistance benefits afforded to institutionalized low-income assistance beneficiaries.

20. **General Provisions.** How do these regulations affect pre-PACE programs? In the regulations, CMS addresses how the Medicare part D program will affect PACE program, but does not address how it will impact states that do not have a PACE program, but only have a pre-PACE program. (FR p. 46753)

Comment: DMAS recommends that CMS clarify how part D will affect pre-PACE.

21. **General Provisions.** In the case of an individual who is eligible for part D and also eligible for full Medicaid benefits, medical assistance is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. The provision of Part D covered drugs is no longer considered a benefit under the Medicaid program for full benefit dual eligibles, even if such individuals have not enrolled in a Part D plan. Therefore, no payment should be made under Medicaid for covered Part D prescription drugs for full benefit dual eligibles. (See also § 423.906(b)). If Medicare-Medicaid enrolled recipients disenroll from the Part-D coverage for any reason, this will leave the states in an impossible position. States will face the impossible choice of denying drug coverage, resulting in potential adverse health affects and increased health care costs, or providing drug coverage with state funds only. This forced option will have significant negative effects and will compromise the health of patients and increase total healthcare expenses for both Medicare and Medicaid programs by increasing medical expenditures through hospitalization. (FR p. 46751)

Comment: DMAS recommends that CMS develop a re-enrollment option that requires the recipient to re-enroll in Medicare part-D and not to (essentially) force the state to cover the drug costs with state-only funds. In the alternative, DMAS recommends that CMS allow states to claim federal matching for drug costs related to individuals who voluntarily chose to opt-out of Medicare part D or reduce their clawback payment proportionately.

22. **General Provisions.** Eligibility Determinations. If state Medicaid agencies will be required to make low-income assistance eligibility determinations, they will have access to other information regarding the applicant's income and resources (e.g., through IRS files). How will the state's Medicaid eligibility process be changed if they are required to make initial eligibility determinations for part D low-income subsidies and have access to additional information on an applicant's income and resources? (FR p. 46751)

Comment: DMAS requests that *CMS to clarify how states can/must use this information in its Medicaid eligibility determination process.*

23. **General Provisions.** Section 42 CFR 423.44(d) is referenced in the discussion regarding allowing PDPs to disenroll individuals who fail to pay premiums or whose behavior is disruptive. It is unclear how these individuals who are prohibited from re-enrolling in a PDP will access benefits under part D. (FR pp. 46751 and 46642).

Comment: DMAS recommends that CMS clarify how these individuals will access benefits under part D and who pays for the medications for these individuals.

24. **General Provisions.** In the preamble, CMS states that the Buy-in file will be replicated by Medicaid state agencies to accommodate the part D program. Buy-in is extremely complex and labor-intensive from a data-maintenance point of view. (FR p. 46752)

Comment: DMAS recommends the removal of the requirement.

25. **General Provisions.** Provision of income levels. Meeting this requirement will require us to establish and populate a new data field. (FR p. 46751)

Comment: DMAS recommends the removal of this requirement.

26. **General Provisions.** The requirements for file sharing and other third-party payor coordination activities are not detailed. DMAS uses HMS to do data matches with other payors including Medicaid recipients covered by Medicare. (FR p. 46702)

Comment: DMAS strongly urges CMS to clarify how the part D plans will coordinate payment information for third-party payor purposes as well as for Medicaid agencies to provide wrap-around coverage. For example, what sorts of data interfaces does CMS envision so that states will know the coverage details? Medicaid state agencies will need to know how one goes about finding out which drugs are covered. How frequent would the updates be? Is it something that could be folded into the Blue Book update? How will this be handled; TPL, or by another third party vendor?

27. **General Provisions.** In the preamble, CMS solicited comments on how ADAP programs can effectively coordinate with the Medicare part D and low-income assistance benefit. CMS further stated that any monies expended by ADAP programs to pay for the premium or cost-sharing obligations of Medicare part D enrollees would not count towards these beneficiaries' annual out-of-pocket thresholds. The distinction that CMS

appears to be making is that, since ADAP programs are federally funded, these funds cannot be used to help meet the out-of-pocket threshold. (FR p. 46651)

Comment: DMAS believes that, to the extent the state agency administering an ADAP or similar program pays for these beneficiary costs with state funds, these expenditures can be counted towards the beneficiaries out-of-pocket threshold. This seems to be consistent with the MMA's permitting payments made by state SPAPs to count towards the beneficiary's out-of-pocket threshold. Further, any state or locally funded programs that provide pharmacy coverage to certain populations (such as programs that provide free medications to persons suffering from mental health conditions to prevent institutionalization) and that choose to pay the beneficiary's Medicare part D cost-sharing obligations, should also be counted towards the beneficiary's annual out-of-pocket threshold. Finally, DMAS requests that CMS amend the regulations to clearly provide for this option.

28. **General Provisions.** In accordance with section 1860D-1(b)(1)(C) of the Act, CMS is seeking to establish a process to automatically enroll a full benefit dual-eligible individual (as defined under section 1935(c)(6) of the Act) who has failed to enroll in a PDP or MA-PD plan by either the end of the individual's initial enrollment period or upon becoming dual eligible after his/her initial enrollment period. For full benefit dual eligibles, this time frame runs from November 15, 2005, to May 15, 2006. As written, it could be interpreted that a full benefit dual eligible individual who does not actively enroll in a plan will only be automatically enrolled after May 15, 2006. In this case, such dual eligibles who have not enrolled prior to January 1, 2006 would not receive Part D coverage until they are either automatically enrolled in May or they actively enroll in a plan. DMAS believes that the auto-enrollment process, for those who do not select a plan during their designated enrollment period, may present significant difficulties. As of January 1, 2006, these individuals will have neither access to Medicaid pharmacy benefits or coverage under Medicare part D. This will leave a significant period of time where the individual will be without any outpatient drug coverage. (FR pp. 46638 - 46639)

Comment: CMS must develop a process by which all full-benefit dual eligibles are enrolled with a Medicare part D plan on January 1, 2006. Otherwise, this will result in these beneficiaries lacking any form of prescription drug coverage, and, as stated previously, will leave the states in an impossible position. States will face the untenable choice of denying drug coverage, resulting in potential adverse health affects and increased health care costs, or providing drug coverage with state funds only. This forced option will have significant negative effects and will compromise the health of patients and increase total healthcare expenses for both Medicare and Medicaid programs by increasing medical expenditures through hospitalization.

29. **Impact Analysis.** CMS specifically states that it did not include states' estimated costs for conducting low-income eligibility determinations in determining the "net

savings" to states under the part D program. Additionally, CMS stated that it will update this estimate once the operational processes for eligibility are more fully developed. (FR pp. 46784-46786)

Comment: DMAS requests CMS revise its net savings to include these costs (including costs associated with appeals and redeterminations) in the "net savings" calculation and requests clarification regarding whether an estimate of associated implementation (start-up) costs that states will incur prior to 2006 (e.g., systems changes) are included in the estimated fiscal impact.

30. **Impact Analysis.** It appears that CMS did not consider possible indirect costs to states, such as possible reduction in negotiating power to obtain supplemental rebates (impact on states' PDL programs). (FR pp. 46785-46786)

Comment: DMAS requests CMS clarify whether it factored in any indirect costs in its state fiscal impact estimate, and if so, please specifically identify which factors CMS did consider and the estimated fiscal impact of each of these factors.

31. **Impact Analysis.** Estimated administrative costs related to the Medicare part D program. States will need to provide extensive and complex training to educate staff on this new program and how it affects the programs that they administer. Medicaid agencies will need to coordinate their pharmacy programs (and systems) with the PDP plans - for purposes of medication management programs, and will also need to educate beneficiaries on Medicare part D and how it will impact their Medicaid benefits. The estimated budgetary impact does not appear to include these associated costs. (FR pp. 46784-6)

Comment: DMAS requests that CMS clarify whether it factored in these administrative costs in its state fiscal impact estimate, and if so, please specifically identify which factors CMS considered and what is the estimated fiscal impact for each of these factors.

32. **Regulations.** Cost-Sharing Subsidy: Institutionalized individuals will have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans. The definition of institutionalized individuals is the same as the definition set forth in §1902(q)(1)(B): "institutionalized individual or couple" means an individual or married couple: (i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and (ii) who is or are determined to be eligible for medical assistance under the State plan." Under this definition, it appears that Medicaid home and community-based waiver recipients would not be included in the definition of institutionalized individuals, and therefore, would have some form of cost-sharing. (FR pp. 46854 – 46855)

Comment: DMAS recommends that CMS change this definition to include Medicaid home and community-based waiver recipients in the definition of institutionalized individuals, especially because these Medicaid waiver programs are alternatives to institutional placement.

33. **Regulations.** Administration of subsidy program. It is unclear how the subsidy program would be administered so that it would effectively coordinate with state Medicaid agencies. According to the proposed regulations, eligibility determinations will become effective beginning with the first day of the month in which the individual applies. (See §423.774 (b)). How will CMS notify PDPs of an enrollee's eligibility for the subsidy and how will the beneficiary receive those benefits retroactively? (FR p. 46856)

Comment: DMAS requests that CMS clarify how the subsidy benefit will be coordinated with the PDP plans, how beneficiaries will receive subsidy benefits retroactively, and how CMS will ensure that this does not negatively impact beneficiary access to services.

34. **Regulations.** Calculation of the State Contribution of the Drug Benefit Costs. The formula for calculating the per capita drug cost for each Medicaid program uses CY 2003 as base year data for the state and will use one inflation factor for all state Medicaid programs to grow the cost to calendar year 2006. This formula does not allow the factoring of cost savings initiatives implemented by the states between CY 2003 and 2006 nor does it give the states a mechanism for adjusting their base year calculation if there was an anomaly in the 2003 data. Furthermore, since the total state cost will be based largely on the number of enrollees in the future years and it is estimated that the number of dual eligibles may increase substantially as a result of outreach and enrollment efforts for the Medicare part D program this initiative may actually result in a significant cost increase to the state Medicaid programs as opposed to the fiscal relief that this initiative was originally envisioned to achieve. (FR p. 46862)

Comment: DMAS strongly recommends that CMS develop a system whereby states can appeal for modifications to the initial cost calculations and requests CMS devise a mechanism to limit states' liabilities if this initiative results in substantial increases in enrollment of dual eligibles.

35. **Regulations.** 42 CFR §423.906 states that "regular Federal matching applies to the eligibility determination and notification activities specified in 42 CFR §423.904(a) and (b)." It is noted that the state may incur other administrative costs in addition to these enumerated costs (e.g., the cost of administering appeals, if the State is required to do so). DMAS seeks assurance that regular Federal matching applies to all expenses incurred in the State's administration of this program, and not only to those specified in 42 CFR §423.904(a) and (b). (FR p. 46862)

Comment: DMAS recommends CMS clarify that all expenses incurred in the states' administration of this program be subject to, at a minimum, the regular federal matching rate.

36. **Regulations.** 42 CFR §423.774 does not make it clear whether individuals who appeal the termination, reduction, or suspension of services will be entitled to receive continued services during the appeal process.

A Medicaid recipient who appeals an adverse action involving the termination, suspension, or reduction of services, prior to the effective date of the action, is entitled to the continuation of services during the appeal process. Because this is a part of the Medicaid appeals process, presumably this provision would apply equally to appeals of low-income assistance eligibility. (FR p. 46855)

Comment: CMS must clarify whether this provision would apply to appeals of low-income assistance eligibility determinations when those appeals are conducted by state Medicaid agencies. Further, because these regulations do not make clear whether Medicare appellants will also receive the continuation of services when the appeal is conducted by the Commissioner, DMAS strongly recommends CMS clarify what a Medicare beneficiary's rights are while an appeal is pending if an appeal is filed with the Commissioner and when an appeal is filed at the state Medicaid agency.

This issue should also be viewed as an example of why DMAS is opposed to the proposed system allowing appeals to be handled by two separate agencies. Differences in appeals processes and differences in the interpretation of the part D regulations would likely lead to disparate appeal processes. As stated in Comment #4, DMAS strongly recommends that all appeals be handled by the Commissioner.

37. The Medicare Part D legislation allows for pharmacy coverage through managed care plans with the potential for closed formularies or similar pharmacy benefit management programs. Under the Medicaid program, it is virtually impossible for a Medicaid agency to provide a pharmacy benefit through the use of a closed formulary. Further, Virginia has not included the Medicare-Medicaid dual eligible population in its 1915(b) managed care programs, and Virginia did not implement its preferred drug list until after calendar year 2003 (the base period for the "clawback" calculation). As a result, the clawback calculation for Virginia will be based on cost data for a pharmacy benefit package that is likely to be more generous than the benefit package that the Medicare-Medicaid dual eligible population will receive under the Part D program.

Comment: Because these factors do not appear to be factored into the clawback calculation, the percentage that DMAS will be paying through the clawback will likely be disproportionately higher than the estimated 90% of Medicare part D program costs (phased-down thereafter). DMAS strongly urges CMS to adjust the clawback calculation

to reflect the savings that Medicare part D will likely recognize through the use of closed formularies and managed care plans.

38. CMS has stated that it intends to allow states to act only as an intake center for the Medicare part D low-income assistance applications – whereby Medicare beneficiaries can submit an application for the low-income assistance benefit at the Medicaid agency, and Medicaid agencies would only be responsible for forwarding these applications to the Commissioner. The Commissioner would then make the low-income determinations.

Comments: DMAS recommends CMS amend the regulations to: (i) reflect this option, (ii) clarify whether the state Medicaid agencies would still be required to screen these applicants for Medicare cost savings programs and Medicaid eligibility, (iii) confirm that if states would be required to perform these screens, that all necessary beneficiary information needed to make these determinations would be on the Medicare part D low-income assistance application, and (iv) clarify that if the states were required to act only as an intake center for the Medicare part D low-income assistance applications, that any and all administrative costs associated therewith would still be eligible for the federal match.

CMS-4068-P-905

Submitter : Ms. Carol Baizer **Date & Time:** 10/04/2004 03:10:38

Organization : ILRC

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

It is essential for medicare recipients who are people with disabilities returning to the workforce that the new medicare regulations and formularies do not pose a barrier to joining the workforce. A version of Medicare where presciption drug coverage becomes prohibitive will work as a disincentive for people with disabilities to seek employment.

CMS-4068-P-906

Submitter : Stacy Dixon **Date & Time:** 10/04/2004 03:10:54

Organization : Susanville Indian Rancheria

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-4068-P-906-Attach-1.pdf

CMS-4068-P-906-Attach-2.rtf

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September 29, 2004

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

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

Dear Administrator:

On behalf of the **Susanville Indian Rancheria**, I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

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

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

Sincerely yours,

Stacy Dixon/hjb

Stacy Dixon
Tribal Chairman

Attachment -- Part D Comments

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

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part D's implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part D does not result in inadvertent and unintended harm to that system.

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

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

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

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

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

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

In order to fully comprehend the potential adverse impact Part D implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian tribes.[1] Pursuant to statutory directive,[2] this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); **pharmacy operations**; an extensive (but underfunded) contract health services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights[3] reveals a number of alarming statistics such as:

- AI/ANs have the highest prevalence of Type II diabetes *in the world*, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.

[1] *See, e.g.*, 25 U.S.C. § 1601.
[2] 42 U.S.C. § 2001.
[3] U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

- The cardiovascular disease rate among AI/ANs is two times greater than the general population.
- AI/ANs are 770% more likely to die from alcoholism.
- Tuberculosis deaths are 650% higher among AI/ANs than the general population.
- AI/AN life expectancy is 71 years, five years less than the general U.S. population.
- The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
- The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

- The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
- Indian tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
- In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report[4], the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.[5]

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

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

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

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Pharmacy Services for Dual Eligibles

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963[6] and 30,544[7] individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918.[8] We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between **$23.8 million**[9] **and $53.6 million**.[10] It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

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

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[6] This number represents 85 percent of the three-year total of active users.
[7] This is the number of active users, defined as at least one visit in the past three years.
[8] From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.
[9] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
[10] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

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

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

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

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

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

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

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

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

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

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit *all* Medicare beneficiaries, does not produce the opposite result for *Indian* Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

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

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

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

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

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

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

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

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

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

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

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

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) *Assuring pharmacy access*.

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

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

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

Insert the following new subparagraph (iv):

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

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

(A) Acknowledge the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.

(B) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.

(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq*. and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.

(D) Recognize that I/T/Us are non-taxable entities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for **AI/AN dual eligibles drug costs ranges between $23.8 million[15] and $53.6 million.[16]** It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract

[15] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.

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

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

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

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

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

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

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

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

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

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

***

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

[17] Washington State Administrative Code provides a precedent and contains sample language for this provision. **WAC 284-43-200 Network adequacy.** "(7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility."

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

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

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

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

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

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

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

Section 423.124(a) ***

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

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

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

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

Option 3: Special Endorsements with Wrap-Around Payment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(4) **Pharmacy network contracting requirements**. In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage –
(i) Must contract with any pharmacy that meets the prescription drug plan's or MA-PD plan's terms and conditions;
(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA-PD plan's network; *and*

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

FORMULARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL
Comments regarding Section 423.286 Rules regarding premiums.

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

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

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

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

WAIVER OF COST SHARING
Comments on Background at 46651 and Section 423.120(a)(4)

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

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

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

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

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

CREDITABLE COVERAGE

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

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

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

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

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

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

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

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

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

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

ELIGIBILITY AND ENROLLMENT

Comments regarding Section 423.48: Information about Part D.

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

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

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

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

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

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

2. Definitions.

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

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

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

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

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

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

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

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

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

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

3. Description of Provider.

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

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

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

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

4. Co-pays, deductibles.

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

5. Persons eligible for services of Provider.

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

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

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

6. Applicability of other Federal laws.

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

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

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

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

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

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

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

7. Non-taxable entity.

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

8. Insurance and indemnification.

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

9. Employee license.

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

10. Provider eligibility for payments.

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

11. Re-Enrollment Period.

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

12. Dispute Resolution.

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

13. Governing Law.

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

14. Pharmacy/Dispensary Participation.

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

15. Acquisition of Pharmaceuticals.

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

16. Formulary.

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

17. Transitional Assistance Claims.

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

18. Payment Rate.

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

19. Information, Outreach, and Enrollment Materials.

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

20. Hours of Service.

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

CMS-4068-P-907

Submitter : Ms. Brenda Solheim **Date & Time:** 10/04/2004 03:10:23

Organization : Ms. Brenda Solheim

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please See Attached File From the Disability Community

CMS-4068-P-908

Submitter : Jean Hemphill **Date & Time:** 10/04/2004 03:10:08

Organization : Church Alliance

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached Comment Letter

CMS-4068-P-908-Attach-1.doc

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October 4, 2004

Via E-mail

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

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

Ladies and Gentlemen:

This letter responds to the request of the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS") for comments regarding the proposed Medicare Prescription Drug Benefit regulations, 42 C.F.R. Parts 403, 411 and 423 (the "Proposed Medicare Part D Regulations"). We are commenting on behalf of the Church Alliance, which is a coalition of the leaders of more than thirty denominational programs that provide benefit programs for ministers and lay employees of churches, synagogues and related organizations, including retiree medical with prescription drug benefits. The prescription drug benefit programs provided by denominations in the Church Alliance cover in excess of 50,000 retirees.

As an initial matter, we wish to express our appreciation for the efforts of CMS in preserving flexibility in the Proposed Medicare Part D Regulations to encourage employers to continue offering retiree prescription drug benefits. Through the auspices of the Church Benefits Association, the denominational church plans formed a coalition to work together to hold down the rapidly increasing costs of prescription drug benefits for both their active and retiree medical plans. The coalition has studied the Proposed Medicare Part D Regulations and is concerned that, without the relief requested herein, the denominations may be forced to end their retiree medical plan prescription drug coverage.

The key concern, as explained more fully below, is that the unique nature of church plans may make the Federal subsidy unavailable to church plans. It is very important to make the Federal subsidy available to as many church plans as possible to encourage the continued availability of church plan retiree prescription drug benefits. In time, church organizations providing prescription drug benefits may coordinate such coverage with Medicare Part D by adopting a so-called "wrap-around" plan, or they may offer such coverage through a prescription drug plan ("PDP") sponsor. We believe, however, that it will take some time for these alternatives to become available to church organizations in the marketplace.

I. Background of the Church Alliance

The Church Alliance coalition includes the leaders of most mainline Protestant Churches (*e.g.*, Lutheran, Presbyterian, Episcopal, Southern Baptist, American Baptist, United Methodist, United Church of Christ) and Jewish Movements (Reformed and Conservative). It also includes the Christian Brothers, who provide benefits to many Catholic organizations (especially parochial schools).

The Church Alliance was formed in the mid-1970's when Congress was considering the Employee Retirement Income Security Act of 1974 ("ERISA"),[1] the first comprehensive Federal legislation regarding employee benefits. The Church Alliance was a subgroup of denominations from a larger group called (at the time) the Church Pensions Conference. The Conference, now called the Church Benefits Association, has been meeting annually for over eighty years to share information about church benefit plans. The Church Alliance consists of those church benefit groups who wanted to work together to influence public policy as it relates to employee benefit plans of churches and synagogues.

II. Church Plans

Most major religious denominations in the United States have longstanding employee benefit programs for their clergy and lay workers, some of which date back to the 1700's. Many of these "church plans" were established by the denominational governing body or assembly to be administered on a denomination-wide basis by a separately incorporated organization or board of the church, subject to denominational law and polity. The denominations designed and funded their respective church plans to provide consistent benefits for their church workers throughout their careers with the denomination, regardless of the congregation served, and in retirement.

To conform to the fundamental constitutional principles of separation of church and state, church plans, as defined in both ERISA and the Internal Revenue Code of 1986, as amended ("IRC"), are exempt from ERISA and are subject to numerous special rules and

[1] 29 U.S.C. § 1001 *et seq.*

exemptions under the IRC and other Federal statutes. These special rules address the varying employment relationships between ministers and their churches, dioceses or conferences, which are defined by the polity of each denomination and reflect the reluctance of Congress and the judiciary to interfere with the internal affairs of church governance. In addition, Congress in developing public policy, and the judiciary in interpreting that public policy, traditionally have attempted to achieve neutrality, rather than favoring one polity over another.

While non-electing church plans do not have the benefit of ERISA preemption from state law, church plans are exempt from certain state laws which might have an impact on benefits matters. The Church Plan Parity and Entanglement Prevention Act of 1992[2] ("CPPEPA") provides that a church plan is deemed to be a plan sponsored by a single employer, notwithstanding that fact that it may provide benefits to the clergy and lay workers of several thousand separate congregations within the denomination. Accordingly, the CPPEPA exempts church plans from state insurance laws relating to licensing and solvency, and prevents church plans from being treated as multiple employer welfare arrangements, or MEWAs.[3]

One unique aspect of many church plans is the manner in which such plans are funded. Church plans are funded through various sources, depending on the denomination and its ability to mandate the actions of the congregations and church organizations. For the most part, the congregations remit dues to the church benefit board to cover the cost of the participation of their employees in the church plans. However, many of the church plans have unique funding formulas or subsidy arrangements designed to lessen the financial burden for the smaller congregations.

Nearly all of the denominational plans require some type of subscription payment or contribution from retirees for retiree medical and prescription drug coverage. Church employers typically are not asked to fund retiree coverage because the retiree has served a number of congregations during the course of his or her career. In many cases, a minister's last service is of brief tenure or is a phased retirement service on less than a full-time basis for a small congregation. These final ministries are extremely important to the staffing of the smaller congregations, particularly in rural areas. If the final church were required to fund the entire cost of the retiree medical and prescription drug coverage, no church would call an elderly minister. The denominations fund a portion of the retiree medical and prescription drug coverage through various sources, including contributions from congregations, and in some cases, national church organizations. These funds subsidize the cost of the retiree medical and prescription drug coverage and reduce the required contribution of the retiree. In addition, the church benefit boards strive to pay a pension benefit to retirees that will cover the cost of the retiree's share of the retiree medical and prescription drug coverage.

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[2] Pub. L. No. 106-244 (July 10, 2000).

[3] *See* 29 U.S.C. § 1144(b)(6) for the ERISA rules applicable to MEWAs.

III. Comments on the Proposed Medicare Part D Regulations

A. The "gross value" test should be used to determine actuarial equivalence, provided that Federal subsidy payments are used exclusively to reduce the cost of the retiree medical plan.

Section 423.884 of the Proposed Medicare Part D Regulation provides that, to be eligible for the Federal subsidy payable to sponsors of qualified retiree prescription drug benefit plans, a plan sponsor must provide CMS with "an attestation that the actuarial value of the retiree prescription drug coverage under the plan is at least actuarial equivalent to the actuarial value of the standard prescription drug coverage under Part D." The Proposed Medicare Part D Regulations do not contain a definition of actuarial equivalence, but the regulatory preamble sets forth a detailed discussion regarding possible approaches to defining actuarial equivalence.

In the preamble, CMS outlines three basic alternatives for defining actuarial equivalence. The first is the "gross value" test whereby the gross value of the prescription drug coverage offered by the plan sponsor must be at least equal to the gross value of the standard Part D benefit, without regard to the financing of the benefit package. The second is a modified gross value test, whereby actuarial equivalence would be determined on a gross value basis, but the Federal subsidy payment made to the sponsor would be limited to the portion of the prescription drug coverage actually funded by the sponsor. The third is a two-prong gross value and net value test. Under the net value prong, the overall value of the prescription drug coverage offered by the plan sponsor would be reduced by the value of the portion of coverage funded by retirees, and then compared to the value of the standard Part D benefit. Several different variants of the net value prong are discussed in the preamble.

In crafting a definition of actuarial equivalence, CMS identifies in the preamble the four Part D policy objectives articulated by Congress – maximizing the number of retirees retaining employer-based coverage through the Federal subsidy, avoiding windfalls, minimizing administrative burdens for CMS and not exceeding budget estimates. CMS also lists a fifth policy objective, which is to enhance the prescription drug coverage offered to retirees. CMS has expressed its concern that the gross value test could create windfalls to plan sponsors who finance all or a substantial portion of their retiree prescription drug coverage through retiree contributions.

The Church Alliance believes, based on its preliminary analysis, that most church plans will qualify for the Federal subsidy under the gross value test. However, if CMS ultimately defines actuarial equivalence by reference to the net value test, most church plans will be unable to satisfy the actuarial equivalence requirement, and therefore will fail to qualify for the Federal subsidy. As noted above, most church plans require substantial retiree contributions towards the cost of prescription drug coverage. In many cases, retirees finance in excess of 50% of the cost of coverage. Additionally, some church plans would be unable to administer the net value test because they do not receive data regarding the extent to which retirees are contributing. In certain denominations, the church plan invoices the last employing congregation

for the retiree health subscription costs, and the individual congregation determines what amount, if any, the retiree is obligated to contribute. The church plan has no record of the cost allocation between the congregation and the retiree.

Congress clearly intended the Federal subsidy to be available to church plans by specifically referencing church plans in the definition of "group health plan" which, in turn, is used to define "employment-based retiree health coverage."[4] Defining actuarial equivalence in a manner that would preclude most church plans from receiving the Federal subsidy would not be consistent with four of the five Congressional and CMS policy objectives identified in the preamble. If church plans are not able to use the subsidy to reduce costs, the less expensive Part D coverage will cause retirees to drop the denomination-sponsored coverage. Those who do not drop denomination coverage voluntarily ultimately may be forced to the standard Part D benefit due to cost increases. The transfer of thousands of retirees from church plans to Part D will result in increased administrative burdens for CMS and will adversely impact Federal budget estimates. Finally, the cost constraints for the denominations, which will be exacerbated by their ineligibility for the Federal subsidy, will prevent the coverage offered by church plans from being further enhanced. From the church plan prospective, the cost of prescription drug coverage for active church employees will rise due to the decrease in volume purchasing upon the loss of retirees.

Given the stated policy objectives and the unique nature of church plans, we suggest that CMS allow church plans the option of using the gross value test to determine actuarial equivalence. In an effort to address the CMS concern that the gross value test will result in windfalls for church plan sponsors,[5] we suggest that use of the gross value test be paired with a requirement that all Federal subsidies for retiree prescription drug coverage received by the denominations be used to reduce the cost of such coverage. To assist in the enforcement of this requirement (thereby minimizing the administrative burdens on CMS), CMS could require that Federal subsidy payments be held in a trust created by the church plan sponsor and subject to an exclusive purpose rule, similar to the exclusive purpose rule set forth in Section 403(c)(1) of ERISA (which itself is derived from the common law of trusts).[6] Accordingly, the Federal subsidy payments would not inure to the benefit of church plan sponsors, and would be used for the exclusive purposes of providing retiree medical benefits and defraying the reasonable expenses of church plan administration.

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4 1860D-22(c)(3)(C) ; 42 U.S.C. § 1395w-132(c)(3)(C).

5 Of course, as non-profit entities, church plan sponsors will not benefit from the non-taxable nature of the Federal subsidy. Accordingly, church plan sponsors are already less likely than for-profit employers to receive a windfall.

6 29 U.S.C. § 1103(c)(1).

In addition to the foregoing, CMS could require these church plans that receive data on retiree contributions to use the Federal subsidy payments, on a proportional basis, to reduce contributions made by the church and the retirees towards the cost of retiree prescription drug coverage. For those church plans that do not receive retiree contribution data, CMS could require the Federal subsidy payments to be allocated between the church organization and the retirees in a fair and equitable manner. All Federal subsidy payments would be held in trust in the manner described above. The approach we propose will be simpler than the combination of a gross value and a net value test and will be useful to all churches that sponsor retiree medical plans. Importantly, this approach satisfies all of the objectives stated by CMS and will help many churches preserve pharmacy benefits for their retirees.

If the denominations fail to qualify for the Federal subsidy, they will be unable to offset the costs of providing retiree prescription drug coverage, which means they will not be able to reduce the retiree's share of such costs. Starting in 2006, relatively healthy retirees likely would drop the denominational prescription drug coverage in favor of the less expensive Part D coverage offered through PDPs. Those retirees with chronic conditions and significant annual drug expenses who have a need for the more comprehensive drug coverage offered by the denominations would be more inclined to stay in the church-subsidized denominational plans, causing adverse selection and accelerating the upward cost spiral. Ultimately, the increased costs of providing retiree prescription drug coverage most likely would force denominations to drop retiree coverage altogether.

The Church Benefits Association prescription drug purchasing coalition has discussed the Proposed Medicare Part D Regulations with its pharmacy benefit managers ("PBMs") and its third-party medical plan administrators, and has been advised that some of these vendors may not be in a position to offer PDP or other alternatives to church plans as of January 1, 2006. The denominations may be able to transition to these alternatives in the future, but at least for an initial period, it appears that the denominations likely will have to maintain their own retiree prescription drug benefit programs, or no programs at all. The availability of the Federal subsidy to church plans is the determining factor. Thus, in the event that CMS elects to use something other than the gross value test in determining actuarial equivalence, we suggest that there be a transition period of at least five years during which time the qualifying church plans would be eligible for the Federal subsidy. This is particularly important due to the lead time required for some denominations to make design or benefit changes to their church plans. In some cases, a church plan may not be amended or terminated without approval of the denominational assembly and such body may not meet more frequently than biennially or quadrennially.

B. The Federal subsidy should be paid to qualifying employers on a monthly basis; rebates should offset the Federal subsidy when paid.

Section 423.888 of the Proposed Medicare Part D Regulations provides, by cross reference, that the Federal subsidy will be paid to eligible plan sponsors in accordance with the

rules that govern subsidy payments to PDPs. The provisions suggest that the Federal subsidy will be paid to eligible plan sponsors on a monthly basis.

The preamble contains a more detailed discussion regarding the approach proposed by CMS with respect to the timing of Federal subsidy payments, as well as alternatives that CMS is considering. Under the primary proposal, a plan sponsor would certify to CMS the actual retiree gross drug spending for a month by the fifteenth day of the following month. CMS would pay the Federal subsidy for the month to the plan sponsor by the end of the following month (*i.e.*, approximately 15 days after the certification due date). Within 45 days of the end of the calendar year, the plan sponsor would submit a final reconciliation for the year, and would pay or receive any adjusted subsidy amounts. Thereafter, any rebates received by the plan sponsor attributable to the closed year would serve to offset any Federal subsidy payments due in the month the rebate is received.

The Church Alliance generally supports the CMS primary proposal for monthly subsidy payments, as described above and in the preamble. From a financial standpoint, advance or contemporaneous Federal subsidy payments would allow denominations to implement cost-sharing adjustments as quickly as possible. However, the denominations recognize that the need for contemporaneous data and/or estimates of future costs would present significant administrative burdens for church plans. After conducting preliminary discussions with their PBMs, the Church Alliance members feel that the approach involving monthly subsidy payments with a year-end reconciliation and future rebate adjustments, as proposed by CMS, is the most desirable approach.

C. CMS should encourage the establishment of one or more national PDPs.

The Proposed Medicare Part D Regulations establish a detailed application and approval process for prospective PDP sponsors. Under Section 423.112, a PDP must cover at least one PDP region. The proposed rule suggests that CMS would be willing to consider approval for multi-regional or even national PDPs.

We support the creation of national PDPs, and we ask that CMS continue its efforts to encourage the creation of PDPs on a national basis. As noted above, each denominational church plan covers active and retired employees in multiple congregations which are located throughout the United States. The use of multiple regional PDPs, each of which would cover only a small portion of the covered retirees, most likely would prove to be administratively and financially impractical for a church plan.

D. Employers should only be required to file an actuarial certification once every five years, unless there is an interim material change in the retiree prescription drug coverage.

Section 423.884(a) of the Proposed Medicare Part D Regulations provides that a plan sponsor seeking the Federal subsidy is required to provide CMS with a certification that its

plan is at least actuarially equivalent in value to the standard Part D benefit. The certification must be made at least 90 days prior to the beginning of each year. Certifications also are required at least 90 days prior to the implementation of a material change to the retiree prescription drug coverage. The preamble indicates that a material change is one that potentially causes a plan to no longer meet the actuarial equivalence test.

As indicated above, church plans have been accorded special treatment under existing laws relating to employee benefits in recognition of the constitutional principles of separation of church and state. In particular, church plans generally are exempt from the reporting and disclosure requirements of Title I of ERISA.[7] Unlike employee benefits plans sponsored by private employers, church plans are not required to, and in fact do not, file Form 5500 annual tax returns or any other Federal, state or local tax returns. While the major denominations use actuarial services for internal purposes, there is no current legal requirement for a church plan to have an actuarial certification or report prepared or filed with any governmental agency.

We recognize that CMS has an interest in ensuring that a recipient of a Federal subsidy payment maintains a plan that is in compliance with the actuarial equivalence requirement. In light of this interest and the unique nature of church plans, we suggest that CMS require sponsors of church plans to maintain an actuarial certification available for auditors but it would not be required to file the certification more than once every 5 years, except in the event that there is a material change in the plan.

[7] *Id*. § 1003(b)(2).

We thank you for the opportunity to comment on the Proposed Medicare Part D Regulations. We would be pleased to discuss our comments with you at your convenience.

Sincerely yours,

/s/
Jean C. Hemphill

JCH/p

cc: Church Alliance Steering Committee
Members of the CBA Health Benefits Committee
David A. Starr, Esq.

Submitter : Ms. Debra Ness **Date & Time:** 10/04/2004 03:10:10

Organization : National Partnership for Women

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Section 423.505.
Prescription drug claims paid history is one of the most valuable sources of timely data available to state Medicaid agencies for purposes of both quality assurance initiatives in programs (such as home and community based care) for their chronically ill beneficiaries and for combating fraud and abuse on the part of beneficiaries, pharmacies, or prescribers. When the full benefit dual eligibles begin to get their drugs through the new Medicare Part D program, that valuable data will disappear. In order to avoid that outcome, states should have the option to enter into data exchange agreements with the PDP and MA-PD plans so that they can receive the drug claims data on a regular, and timely, basis. This should not pose a significant burden on the drug plans, as they are already required, under the statute and under 423.329(b)(3) of the proposed rule, to make available claims paid history linked to the individual beneficiary. We recommend subsection (a)(8) be amended to include this additional requirement.

BENEFITS AND BENEFICIARY PROTECTIONS

Section 423.128.
This section lays out the information a PDP or MA-PD plan must make available to prospective enrollees. Subsection (b) lists the information that must be supplied; subsection (c) describes information that must be made available 'upon request' by the potential enrollee. One of the optional items, described at (c)(3), is information about the number and disposition of grievances and reconsiderations. We believe consumers should not have to ask for this information, but should have it readily available to inform their choice. We recommend this language be moved into the mandatory information list in subsection (b).

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

Section 423.156.

This section implements the statutory requirement that CMS conduct consumer satisfaction surveys of PDP and MA-PD enrollees similar to those it conducts of Medicare beneficiaries enrolled in managed care plans. In the preamble to the proposed rules (Federal Register p. 46670) CMS states its plans to work with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey tool and implementation plan similar to the CAHPS survey now used for managed care entities and a similar tool near implementation for hospital care (HCAHPS). We fully support this requirement and the plan to use a CAHPS-like tool. The National Partnership has been a member of the stakeholder group that worked with CMS and AHRQ on the HCAHPS survey tool, and we would be pleased to offer our assistance in connection with the pharmacy consumer satisfaction instrument as well.

Because it will take time to develop and implement the survey, however, we have some suggestions for interim measures CMS could use to measure consumer satisfaction. All of the suggestions are drawn from the experience of purchasers contracting with pharmacy plans. They are:

- The percentage of customer service calls answered by a live voice within a given period of time and the percentage of customer service calls that are abandoned (calls terminated while on hold or prior to speaking with a person). An automated call director system can be programmed to track both. Common standards are an average of 30 seconds or less for access to a live voice and a maximum of 3% abandonment rate.

- The percentage of time the plan's on-line claims processing system is available to access a patient drug profile for purposes of avoiding inappropriate drug interactions and controlling potential abuse (such as altered prescriptions or early refills). The standard is generally 99% or better

of the time the system is regularly scheduled to be available. Some purchaser contracts incorporate a standard for system response to participating pharmacies as well.

- If a plan offers drug dispensing by mail, the percentage of orders (measured in business days) filled within a given time between the time the order is received and the time the drug is deposited with the U.S. Postal Service or other carrier. A two day requirement (excluding the day of receipt) is often used, with a standard of an average of 95% or better.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Subpart B: Enrollment

Section 423.38.
This section establishes the effective date of a Medicare beneficiary's enrollment in a PDP as the first day of the calendar month following the month in which the enrollment occurs. An exception to this effective date will be made for enrollment or changes in enrollment made during a special enrollment period 'specified in 423.36(a)(3)'; in these cases, the individual's effective date will be determined by CMS in a manner that 'is consistent with protecting the continuity of health benefits coverage.' The special enrollment period specified in 423.36(a)(3) is the one that parallels the Part B enrollment rules and applies only to individuals first eligible to enroll in a Part D plan on or after March 2006.

Further on in 423.36, however, at subsection (c), a number of special enrollment periods are outlined, designed to cover a variety of situations in which an individual seeks enrollment or a change in enrollment outside of the normal initial or annual election period. The situations covered include 1) those due to loss of prior creditable coverage, moving to another PDP region, etc. or 2) those where the individual is a full benefit Medicare/Medicaid dual eligible.

We recommend the cross reference in 423.38(c) be changed in the final rule from 423.36(a) to 423.36(c). This would permit the Part D plan coverage to begin sooner than the first day of the next month for all who enroll or make changes during a special enrollment period and would avoid having these beneficiaries denied prompt access to necessary prescription drugs.

While the issue is not expressly addressed in this section, we are also concerned about the 'intermittently' eligible full benefit dual beneficiary: namely, the individual who spends down to Medicaid income eligibility by paying out of pocket for medical care. A segment of this population will be eligible for full Medicaid coverage for a time, ineligible due to income for a subsequent short time (due to tiny fluctuations in income or medical condition), and then back on the Medicaid rolls again. We understand that some states, with regard to the QMB program, pay the monthly Part B premium with 100% state funds in order to avoid interruption in Part B benefits. If feasible, we recommend that states be offered the option to do the same with respect to Part D. We believe that offering states this option would provide the strongest protections for this vulnerable population and would best ensure their continuity of benefits.

Section 423.48.
This brief section describes the information that CMS must make available to current and prospective enrollees in order to make an informed choice of a Part D plan. It is critical that all the performance measurement results, whether interim measures suggested below or the CAHPS information that will be available in later years, be publicly reported and readily accessible to the public, not just Medicare beneficiaries. This publicly reported data will be invaluable to a variety of stakeholders, including plan managers, purchasers, and caregivers, to enable informed decision making, the identification and dissemination of best practices, and the setting of performance improvement targets.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

The National Partnership shares the concerns being expressed by many consumer organizations that the coverage exceptions and appeals processes are going to be cumbersome and confusing to Medicare beneficiaries. We are especially concerned about those beneficiaries, such as Medicaid and Medicare Savings Program enrollees, who have very limited incomes and are on drug regimens that cannot be interrupted without serious

consequences for their health and safety. This includes persons on chemotherapy or psychotropic medications, or those in HIV/AIDS treatment programs. Costs of some of the new 'wonder' drugs on which their lives depend can be thousands of dollars a month.

Because these beneficiaries qualify for a state Medicaid program, they currently have access to the drugs they need. On January 1, 2006, however, federal matching funds will no longer be available to states for drugs covered under the new Medicare Part D. It is likely some of the plans available to these dual eligibles will not automatically include their particular drug in its formulary, and the beneficiary, or his physician, will have to use the exception process. Under the proposed rule, even the expedited exception process can take up to 17 days. Section 423.578 (c) of this part would entitle a plan enrollee to coverage of up to 1 month?s supply (or more) of the prescription drug that is the subject of the request, but, as we read the language, only if the request is a result of the sponsor's removing a drug from its formulary.

This section should be broadened to include situations in which: (1) the enrollee had had prescription drug coverage under a state Medicaid program immediately prior to enrolling in the PDP or MA-PD plan; and (2) the plan formulary does not include a drug s/he had been taking, and for which the Medicaid program had been paying, at the time Medicare coverage begins.

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

The National Partnership fully supports, and commends, the Department, for proposing to use a broader definition of family size than is used for the Supplemental Security Income program. The proposed definition includes not only the individual and spouse but also any family members living with them who depend upon them for 50% or more of financial support. This definition will encompass the thousands of seniors who are raising their grandchildren or nieces and nephews and are already stretching their limited incomes to meet those expenses.

We also fully support the proposed definition of 'resources.' It will greatly simplify the application process and reduce the administrative burden for the applicant, the agency staff and the community volunteers helping them.

We are very pleased that the Secretary has chosen to exercise his discretion with regard to deeming all enrollees in a Medicare Savings Program (MSP) automatically eligible for the full subsidy. The Secretary?s decision means that MSP enrollees will have to fill out only one form - enrollment in a Part D plan - rather than separately completing both a subsidy application form and a plan choice. As we know already from our experience with the discount card credit program, reaching this population and persuading them to act is very challenging. The fewer barriers we have, the more effective the outreach will be.

CMS-4068-P-909-Attach-1.doc

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CMS-4068-P-910

Submitter : Dr. rodney tubbs **Date & Time:** 10/04/2004 03:10:07

Organization : tennessee pharmacist assocation

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

all pharmacist and pharmacy's should be able to fill all prescription

ELIGIBILITY, ELECTION, AND ENROLLMENT

all pharmacist should be able to participate in the filling of all medicare prescriptions and the payment level should be the same with no incentives to the patient to get prescriptions at specific pharmacys or mail order institutions

CMS-4068-P-911

Submitter : Mr. Dustin May **Date & Time:** 10/04/2004 03:10:53

Organization : American Society of Transplant Surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Comments to General Provisions are Attached.

CMS-4068-P-911-Attach-1.doc

October 4, 2004

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

RE: Comments to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 Proposed Rule

CMS File Code: CMS-4089-P

The following are comments submitted by the American Society of Transplant Surgeons (ASTS) on the proposed regulation implementing the Medicare Prescription Drug Benefit. ASTS is an organization comprised of almost 1000 transplant surgeons and physicians dedicated to promoting and encouraging education and research with respect to organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

ASTS would like to thank CMS for taking on the arduous, yet important task of setting forth proposed regulations implementing the largest set of modifications to the Medicare program, including a new outpatient prescription drug benefit. Perhaps the single most important issue relating to the MMA that we as transplant surgeons are concerned about is that of ensuring comprehensive coverage for immunosuppressive drugs for all Medicare beneficiaries who are transplant recipients. Rejection of an organ as a result of non-compliance with immunosuppressive therapy is costly to both patients and the Medicare program, especially considering the 85,000 Americans waiting for an organ transplant. Preventing rejection through immunosuppressive therapy is one step that ameliorates needless organ rejection and provides to all Americans the hope for a full life as a result of transplantation. ASTS hopes that CMS will incorporate our recommendations so that we can preserve the “gift of life” for all Medicare recipients.

Summary

ASTS would like to work with CMS to ensure that all transplant recipients receive access to comprehensive immunosuppressive coverage, including those who will be newly eligible for

coverage under Part D. As a result, g*aps in immunosuppressive coverage, where a transplant recipient is ineligible for Part B immunosuppressive coverage, should be eliminated through implementation of the Part D prescription drug benefit*. The Part D benefit, as ASTS will recommend below, should provide access to all medically necessary immunosuppressive drugs so as to prevent organ rejection, unnecessary acute care, possible retransplantation, costly dialysis, not to mention pain, suffering, and at worst, death.

Discussion of Immunosuppressive Therapy and its Role in the Medicare Program

Immunosuppressive drugs are a critical component of post-transplant medical care. They prevent immune response that could cause rejection of a transplanted organ. Prevention of rejection reduces acute and outpatient care costs and, in the case of kidney transplants, hemodialysis. For instance, according to the recently published *United State Renal Data Service Annual Cost Report for 2004*, the cost of hemodialysis to the Medicare program, on average, was $54,006 per beneficiary in 2002.[1] Maintenance of a kidney transplant with immunosuppressive drugs, alternatively, cost the Medicare program, on average, $18,394 per beneficiary in 2002.[2]

Unfortunately, in our experience, one of the principal causes of acute rejection is completely preventable: non-compliance with a medication regimen due to the inability to afford the high cost of immunosuppressive drugs.

Recent advances in transplant science and immunosuppressive therapy allow transplant patients to live longer, independent lives and are cost-effective to the Medicare program. Congress and CMS recognized this fact by creating, at first, a limited outpatient Medicare Part B immunosuppressive drug benefit.[3] Subsequently, realizing the benefit to patients and the Medicare program overall, *Congress increased the scope of the immunosuppressive benefit* to cover all Medicare eligible individuals who had their transplant originally covered by the Medicare program for the *duration of their enrollment in Medicare*—thus ensuring the long-term success of that transplant and preventing additional, expensive acute care costs such as retransplantation or hemodialysis.

As recognized in the preamble to the MMA Title I proposed regulation,[4] Medicare Part B does not cover immunosuppressive drugs for beneficiaries who did not have their transplant covered by the Medicare program. For example, a 60-year old non-disabled patient who receives a heart transplant that is covered by employer-sponsored group health insurance would not be eligible for Medicare immunosuppressive coverage upon reaching age 65 because the transplant was not covered by Medicare. Such individuals are currently required to pay out-of-pocket for their immunosuppressive drugs.

In fact, one of the determinations used to establish eligibility for a transplant is the ability to pay for immunosuppressive drugs. If Medicare is not paying for the transplant, beneficiaries must demonstrate ability to pay for these expensive drugs for the rest of their lives. As a result

[1] USRDS ACR 2004, http://www.usrds.org/2004/pdf/B_precis_04.pdf, Page 18.
[2] Id.
[3] Immunosuppressive coverage was initially limited to 36 months of coverage for all transplants.
[4] See 69 Fed.Reg. 46632, 46647 (Aug. 3, 2004).

of new Part D coverage, though, some previously rejected transplant candidates will at last be eligible for transplantation—but only if beneficiaries are guaranteed access to medically necessary immunosuppressive drugs.

Discussion of Transplant-Related Immunosuppressive Coverage under Part D

Medicare beneficiaries who have received a transplant that was not covered by Medicare will be eligible for coverage of their outpatient immunosuppressive drugs through a Medicare Part D PDP or MA-PD. There are a substantial number of transplant-recipient Medicare beneficiaries who will be subject to receiving their coverage through Part D. Clearly the unique circumstances that sparked the creation of Part B coverage should also be considered when implementing Part D coverage.

ASTS believes that Part B immunosuppressive coverage, which provides access to all medically necessary immunosuppressive drugs, should be standard of coverage to which all Part D plans should attain. As a result, ASTS believes that there are a number of methods that CMS should undertake to fill gaps in immunosuppressive coverage, ensure compliance, and prevent unnecessary medical care as a result of acute rejection. They are as follows:

I. Ensuring Access to all Immunosuppressive Drugs in a Formulary-Driven Environment

ASTS has grave concerns with respect to the potential use of formularies by PDPs and their potential to restrict access to medically necessary immunosuppressive drugs for transplant recipients enrolled in Part D. Because of the sensitive nature of immunosuppressive drug regimens, it is absolutely essential that transplant recipients receiving coverage for immunosuppressive drugs through Part D have access to the same range of medications available to those receiving coverage through Part B.

As stated in the preamble of the proposed regulations, you "are soliciting comments concerning any drugs that may require specific guidance with regard to their coverage under Part D…"[5] Any restriction on choice for immunosuppressive drugs can mean the difference between a healthy life for a beneficiary with a transplant or an episode of acute rejection.

Medicare Part B currently covers all medically necessary transplant immunosuppressive drugs.[6] (See footnote for list of all drugs currently covered by Part B.) To the extent that PDPs utilize formularies to reduce costs, it is essential that CMS establish a process whereby beneficiaries can get access to any of these critical drugs without burdensome appeals or additional cost-sharing, i.e. highest tier copayment for an alternative coverage PDP plan. *We*

[5] Id.

[6] Part B coverage for immunosuppressive drugs includes the following specifically labeled immunosuppressive drugs that the FDA has identified and approved for marketing*:* Sandimmune®, Neoral®, Gengraf™ (cyclosporine), Imuran® (azathioprine); Atgam® (antithymocyte globulin); Orthoclone® (OKT3, muromonab-CD3); Prograf® (tacrolimus), Cellcept® (mycophenolate mofetil), Zenapax® (Daclizumab), Cytoxan® (Cyclophosphamide), Rapamune® (Sirolimus), Methotrexate, Prednisone, Prednisolone.

suggest that CMS establish regulations that require PDP sponsors to provide direct access to all immunosuppressive drugs for beneficiaries who are recipients of an organ or tissue transplant.

ASTS made comments to the United States Pharmacopeia outlining pharmacologic classes that would be necessary to ensure access to medically necessary, transplant related immunosuppressive drugs. Our recommendations to the USP, which are paraphrased below, outline a model formulary that should allow PDPs the greatest flexibility to negotiate discounts while simultaneously providing access to all medically necessary transplant-related immunosuppressive drugs. Our recommendations for an "Immune Suppressants" therapeutic category and related pharmacologic classes encompass all outpatient, transplant-specific immunosuppressive drugs. *To the extent that CMS reviews and approves PDP formularies, we strongly recommend that CMS establish a transplant-specific review process for all PDP formularies that ensures immediate, low-cost access to all immunosuppressive drugs for transplant recipients.*

II. ASTS's Discussion of USP Draft Model Guidelines

USP's proposed therapeutic category of "Immunological Agents," its pharmacologic classes, and recommended subdivisions do not explicitly account for transplant-related immunosuppressive therapy nor specify a distinct therapeutic category, pharmacologic class, or, most alarmingly, a distinct immunosuppressive subdivision that incorporates major transplant-specific drugs[7]. The guidelines propose a broad "Immunologic Agents" therapeutic category that is specified as follows:

Therapeutic Category	Pharmacologic Class	Recommended Subdivisions
Immunological Agents	**Immune Stimulants**	*Toxoids*
		Vaccines
		Immune Stimulants, Other
	Immune Suppressants	*Interleukin Inhibitors*
		TNF Inhibitors
		Immune Suppressants, Other
	Immunological Agents, Other	*Immunoglobulins*

USP's proposed "Immune Suppressants" pharmacologic class would essentially combine immunosuppressive asthma, rheumatoid arthritis, dermatologic, and cancer drugs into the same class as transplant-related immunosuppressive drugs. Under the Medicare statute, a minimum of two drugs are required per pharmacologic class. The current structure of the Model Guidelines would almost certainly restrict access to immunosuppressive drugs for transplant recipients

[7] Calcineurin inhibitors, such as cyclosporine and tacrolimus, are not included in the Model Guidelines even though they are the backbone of many post-transplant immunosuppressive drug regimens. Although they are often prescribed for conditions such as psoriasis, it is nevertheless essential that therapeutic category include a pharmacologic class that specifically denotes coverage for these essential drugs.

because the pharmacologic class is simply too broad. Even requiring two drugs per recommended subdivision would not guarantee access.

Because there are many other less costly drugs within the proposed "Immune Suppressant" class, there is little incentive—let alone requirement—for PDPs to include even one transplant-specific immunosuppressive drug. The possibility exists, therefore, that PDPs will not cover medically necessary immunosuppressive drugs. Transplant-related immunosuppressive drugs are likely to be utilized at a much lower volume than other drugs in the same pharmacologic class.

To ameliorate these concerns, ASTS recommended to the USP that a new "Immune Suppressants" therapeutic category be created that incorporates the following pharmacologic classes[8]:

Therapeutic Category	Pharmacologic Classes	Examples
Immune Suppressants	**Interleukin Inhibitors**	Interleukin-2 Receptor Antagonists
	Calcineurin inhibitors	Cyclosporine, Tacrolimus
	Antiproliferative Agents	Azathioprine Mycophenolate Sirolimus
	Antilymphocyte Antibodies	Antithymocyte Globulin Muromonab CD-3
	TNF Inhibitors	Infliximab Adalimumab
	Immune Suppressants, Other	

This proposed therapeutic category is more closely related to what many clinicians are accustomed to seeing. It also provides PDPs the flexibility to design a formulary that promotes cost effectiveness while at the same time providing access to key transplant-related immunosuppressive drugs.

III. Role of Medication Therapy Management Programs in Part D Immunosuppressive Drug Coverage

ASTS is concerned that there is little incentive for PDPs to provide comprehensive access to immunosuppressive drugs or institute programs that monitor their usage. *Since PDPs are not required to manage acute care risk and pay acute care claims, they have no actuarial incentive to cover expensive, low volume transplant-related immunosuppressive drugs.* Additionally, PDPs are not required by statute to monitor compliance with immunosuppressive drug regimens through medication therapy management programs (MTMPs). Without an incentive (or requirement) to take steps to prevent acute rejection, the costs for non-compliance, as we

[8] This proposed table does not take into account other immunosuppressive pharmacologic classes that are not related to transplantation, though clearly some drugs in these classes have non-transplant indications.

discussed earlier, are far greater to the Medicare FFS program than the cost of the drugs themselves.

According to the proposed MTMP rule, CMS is soliciting comments on the following:

> "As provided under 423.153(d)(2), 'targeted beneficiaries' would be plan enrollees who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that we determine. We invite comments on how we should provide guidance to drug plans in defining 'multiple chronic diseases' and 'multiple Part D drugs' for the purposes of determining which Part D enrollees would qualify for MTMP services, or whether such determinations are best left to the plans as part of their benefit design."

Being a transplant recipient is often the result of one or more chronic conditions, such as Chronic Kidney Disease. Though some transplant recipients may not have "multiple" chronic conditions or take multiple Part D covered drugs (some immunosuppressive regimens can be less than three drugs), clearly transplant recipients often require close monitoring of their condition and medication management in order to prevent rejection episodes or recurrence of their chronic conditions.

Because transplant recipients would clearly benefit from MTMPs and because PDP plans do not bear risk for non-compliance with immunosuppressive regimens, we recommend that ***CMS not defer to plans to decide which beneficiaries meet the qualifications*** *for inclusion in a MTMP. We recommend that CMS publish—in regulation—that transplant recipients enrolled in Part D and who are receiving their immunosuppressive drugs through Part D plans be required to enroll such beneficiaries in MTMP programs unless the beneficiary and his or her physician state, in writing, an intention to opt out of such a program,.*

Since ASTS does not directly represent pharmacists specially trained in the field of transplantation, we cannot comment directly on the technical details of specific programs best suited to transplant recipients. However, we do work routinely with such pharmacists and suggest that you contact the following individuals:

David Quan, Pharm.D, a transplant pharmacist at the University of California, San Francisco School of Pharmacy and a consulting editor of the "Textbook of Therapeutics - Drug and Disease Management" can be contacted at (415) 353-1462 or dquan@itsa.ucsf.edu. Additionally, Gwen McNatt, MS, RN, CNN, CFNP, Manager, Solid Organ Transplant at Northwestern Memorial Hospital can be contacted at (312) 695-1705 or gmcnatt@nmh.org.

IV. Discussion of "Least Costly Alternative" and Generic Substitution

As required by the statute and proposed regulation, ASTS is concerned that the requirement for pharmacists to disclose the lowest priced alternative drug at the time of sale could be extremely problematic for certain transplant recipients.

Three critical dose immunosuppressive drugs, Sandimmune®, Neoral® and Gengraf™ are different formulations of cyclosporine. Cyclosporine is commonly used in immunosuppressive regimens in combination with corticosteroids such as prednisone. Though these drugs are clinically substitutable, *they should never be substituted without physician supervision and careful monitoring of the active ingredient's bioavailability*.

Sandimmune®, Neoral® and Gengraf™ are not bioequaivalent,[9] are absorbed at different rates by patients with difference types of transplants,[10] have a very narrow therapeutic index,[11] and patients switching from one formulation to another must be closely monitored. As a result of these factors, these drugs should ***not*** be automatically substituted by a pharmacist in accordance with a utilization management program, upon patient consent, or under any other circumstances without notification to and consultation with the prescribing physician.

We have encountered patients who have experienced acute allograft rejection as a result of automatic substitution performed without the consent of the prescribing physician.

ASTS recognizes Congressional intent and the desire of PDP plans to reduce costs by promoting generic drugs. As health care professionals concerned about rising health care costs, we could not agree more. However, efforts to craft this disclosure provision in such a way that could promote the automatic substitution (or upon patient consent) of therapeutic and bioequivalent drugs could lead to this potentially deadly substitution. To the extent that CMS provides guidance to PDP plans, pharmacies, and consumers on which drugs are subject to this provision, we strongly urge CMS to alert MTMP programs and pharmacies to this issue. We anticipate that because Sandimmune®, Neoral® and Gengraf™ are AB2-rated drugs that pharmacists may not perform due diligence and may promote substitution based on a patient's or plan's desire to lower costs.

V. Part D Transplant Recipients Data Not Available for Risk Adjustment

ASTS is not aware of any specific data on exactly how many beneficiaries would be subject the "gap" in immunosuppressive coverage. As a result, we are unable to provide information to CMS that could assist with risk adjustment calculations. We would anticipate that following the enrollment period in late 2005, though, that PDPs could request accurate data from PDPs' MTMP programs that would enroll beneficiaries based on their high cost and special medication needs.

Therefore, we suggest that CMS partner with organizations, such as ASTS, to commission a study that would ascertain the full picture of immunosuppressive coverage. As a result, CMS could adequately design a risk adjustment methodology that would not unfairly penalize plans for providing access to immunosuppressive drugs and incentivize them to provide fair and adequate coverage.

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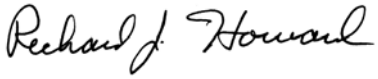
[9] FDA Orange Book, Sandimmune®, Neoral® and Gengraf™ Product labels.
[10] Physicians' Desk Reference, 2004.
[11] Id. Narrow therapeutic index is defined as less than a two-fold difference between a median lethal dose and the median effective dose, less than a two fold difference between minimum toxic concentration and minimum effective concentrations, and requires careful titration and patient monitoring.

Conclusion

ASTS would like to thank CMS for their efforts to craft these complex regulations in a way that specifically accounts for the challenges associated with health care for transplant recipients. If ASTS can be of any further assistance in development of a final rule, please do not hesitate to contact Rebecca Burke, Regulatory Counsel to ASTS at 202-466-6550 or via e-mail at rebecca.burke@ppsv.com.

Sincerely,



Richard Howard, M.D., Ph.D.
President

CMS-4068-P-912

Submitter : Ms. Vilas Rajanna **Date & Time:** 10/04/2004 03:10:34

Organization : Ms. Vilas Rajanna

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

CMS-4068-P-912-Attach-1.doc

October 4, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Beneficiary Access to Community Retail Pharmacies

I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than "on average" in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Multiple Dispensing Fees Needed

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

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

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

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

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

Proposed Regulation Creates Networks Smaller than TRICARE:

The proposed regulation also allows plans to create "preferred" pharmacies and "non-preferred" pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one "preferred" pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only "preferred" pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require

plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered 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.

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.

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Vilas Rajanna

CMS-4068-P-913

Submitter : Mr. Charles Mollien **Date & Time:** 10/04/2004 03:10:29

Organization : APhA Academy of Student Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam,

I want to first thank you for allowing me to submit my comments on the proposed regulation to implement the Medicare prescription drug benefit. As a student pharmacist, the regulations you release are going to have a major impact on my entire career and I truly hope you consider the fact that the pharmacist is the right healthcare professional to implement MTM services. With are intenses education, we are the medication experts because we spend years in the classroom studying every aspect of medication - no other professional can say the same.

In Subpart C: Benefits & Beneficiary Protections, you need to consider a revision so that the pharmacy access standard is at a local level (ie. TRICARE pharmacy access requirements). If you use a plan's "overall service" how will we be able to ensure that all benficiaries are going to have convienent access to a local pharmacy? There are thousands of pharmacists throughout the United States and it is fair to say that the most identifiable to the public who will be reciving these services are those in the community setting. All pharmacists receive the same level of training, do not limit any of the MTM services to be provided by a pharmacist that specializes in a particular area or there will be no way our patients are going to be able to get the services they deserve. This would severely limit the number of pharmacists able to provide service when all of them are quailifed because we all have been through the intense training it takes to graduate pharmacy school and pass our boards to practice. I would hate for regulations to allow companies establish "preferred networks." In America, this is not good healthcare. People need to be able to choose what PHARMACIST they want to consult with for MTM - not the individual they MUST see in a preferred network or in fact not even be a pharmacist the network selects. I appreciate that CMS recognizes the pharmacist as the one to provide these services, but do not allow for companies to make the final decision, give this to pharmacists who can be found in all parts of the country, rural and urban. Please make it clear in the regulations that ALL PHARMACIES are able to provide their services to our patients.

Again, I appreciate the ability to express my comments to you. I truly hope you see the value of the pharmacist and that you too know your pharmacist on a personal level. Get to know their name and talk to your pharmacist, you'll see what I'm talking about when I say we are the medication experts. I hope that you see this importance and will make it very clear that CMS wants these services to be offered by pharmacists - and not just some, but all pharmacists.

Thank you again for your time,

Charles Mollien
2688 Royal Vista Dr NW Apt 102
Grand Rapids, MI 49544
(616) 262-1663

CMS-4068-P-914

Submitter : Mr. Vilas Rajanna **Date & Time:** 10/04/2004 03:10:02

Organization : Mr. Vilas Rajanna

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

CMS-4068-P-914-Attach-1.doc

October 4, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Beneficiary Access to Community Retail Pharmacies

I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than "on average" in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Multiple Dispensing Fees Needed

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

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

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

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

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

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The proposed regulation also allows plans to create "preferred" pharmacies and "non-preferred" pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one "preferred" pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only "preferred" pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require

plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered 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.

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.

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Vilas Rajanna

Submitter : Mr. Timothy Robertson **Date & Time:** 10/04/2004 03:10:11

Organization : Ukrop's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for taking my comment. I am a community pharmacist located in a grocery store setting. I am ready and willing to take a greater role in the care of medicare beneficiaries. In order for me to be able to do this, CMS needs to look very closely at the comments coming from pharmacists. Please do not overlook to ability of the community pharmacist to improve the health and well being of an enormous number of medicare beneficiaries.
Thank you.
Tim Robertson

Issues 1-10

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

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.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

? I want to be able to serve my patients. To do that, CMS should revise the pharmacy access standard to require plans to meet the TRICARE requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the access standard on a local level is the only way

to ensure that all beneficiaries have convenient access to a local pharmacy.
? 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
? 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.

? 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.

CMS-4068-P-915-Attach-1.pdf

CMS-4068-P-915-Attach-1.pdf

CMS-4068-P-915-Attach-1.pdf

Medication Therapy Management Services
Definition and Program Criteria

Original: 4-May-04 (APhA MTM Services Working Group)
Last Revised: 7-Jul-04 (Pharmacy Profession Stakeholders)
Approved: 27-Jul-04 (by 11 Supporting Organizations)

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.

CMS-4068-P-916

Submitter : Mr. Vince Cukrov **Date & Time:** 10/04/2004 03:10:01

Organization : Mr. Vince Cukrov

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

People with HIV/AIDS risk life-threatening illness if drug plans are allowed to limit the number of HIV drugs covered. Drug plans must carry all the drugs people with HIV/AIDS need.

Because restricted access to needed HIV/AIDS medications could lead to drug resistance or severe medical complications, Medicare should treat people with HIV/AIDS as a "special needs population" and require drug plans to offer them an "open formulary."

Individuals eligible for both Medicaid and Medicare (know as "dual-eligibles") may get fewer benefits under Medicare than they now receive in Medicaid. CMS should ensure that new benefits are of equal or greater quality than those provided by Medicaid.

With the law cutting off Medicaid drug benefits for dual-eligibles on December 31, 2005, but not automatically enrolling them in the new Medicare drug program, dual-eligibles will be at risk for interruptions in drug coverage. Dual-eligibles with HIV/AIDS cannot risk a gap in coverage during the transition from Medicaid to Medicare, which would severely compromise their health.

The draft grievance and appeals process is inadequate and must be enhanced to provide greater protections for Medicare recipients. Grievance and appeal processes must be effective and easy-to-access, and must include the right to get an emergency supply of medications while an appeal is under way.

Proposed rules allow drug plans access to the names and medical histories of Medicare recipients in order to aid their marketing and enrollment strategies. Drug plans should not violate the privacy of people with HIV/AIDS and other Medicare beneficiaries.

Thank you for allowing me to provide my input to this very important issue.

Submitter : Dr. Paul Volberding **Date & Time:** 10/04/2004 03:10:46

Organization : HIV Medicine Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached document and contact Christine Lubinski or Andrea Weddle at the HIVMA office with questions at 703.299.1215.

CMS-4068-P-917-Attach-1.doc

CMS-4068-P-917-Attach-2.doc

hivma
hiv medicine association

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

I am writing on behalf of the HIV Medicine Association (HIVMA) and its more than 2,600 HIV clinician members who devote their careers to the prevention, care and treatment of HIV disease. As an organization, we co-author guidelines on prevention and treatment of HIV with the federal government and just released guidelines on the primary care management of HIV disease. In addition, several members of our Board of Directors including myself are on the federal panel that develops and maintains the *Guidelines for the Use of Antiretroviral Agents in HIV Adults and Adolescents.*

More than 80,000 Medicare beneficiaries are people living with HIV disease. At least 60,000 of these beneficiaries are dually eligible for Medicaid and will be required to enroll in the new Medicare drug benefit in January 2006. We are particularly concerned about our dual eligible patients. These patients by virtue of qualifying as dual eligibles are our sickest patients and have very limited resources available, if any, to supplement an inadequate prescription drug coverage policy.

The comments and recommendations that follow reflect our collective expertise as HIV clinicians and researchers. We urge CMS to grant them serious consideration as HIV is a complex disease that requires special expertise and significant patient management experience for successful treatment outcomes. Discoveries in drug therapies are responsible for reducing mortality due to HIV disease by 60 to 80 percent and transforming it from a terminal to a serious but chronic condition. Failure to provide meaningful and affordable access to prescription drugs for Medicare beneficiaries with AIDS through Medicare Part D will result in some of our sickest patients being unable to access life-saving drug therapies.

PEOPLE LIVING WITH HIV/AIDS ARE A SPECIAL POPULATION THAT REQUIRE SPECIAL TREATMENT AND UNRESTRICTED ACCESS TO MEDICALLY NECESSARY DRUGS.

We strongly support the CMS recommendation to designate “special populations” unrestricted access to drugs through “open formularies.” We recommend that people with

AIDS be designated as a special population to ensure access to all of the drugs that are medically necessary to treat the disease and related co-morbidities.

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 AIDS having access to all anti-HIV drugs available to suppress the virus. If drug plans fail to cover all anti-HIV drugs at the lowest cost-sharing tier, it is extremely unlikely that our patients will have the resources to obtain these life-saving drug therapies. 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.

Many of our Medicare patients have serious co-morbid conditions such as hepatitis C, depression, heart disease, diabetes, and liver disease. Treatment for co-morbid conditions requires that we have access to the medications that most effectively treat the condition in conjunction with anti-HIV regimens. Failure to effectively treat comorbid conditions negatively 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.

Special Populations also Require Special Protections with Regards to Cost Containment Measures.

We appreciate the acknowledgment by CMS that certain populations may be discriminated against and adversely affected by cost containment measures implemented by prescription drug plans. We strongly encourage CMS to learn from the experience of Medicaid programs that have tried to balance containing costs with maintaining access to 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 recommend that CMS prevent discrimination against Medicare beneficiaries with AIDS regarding cost-sharing by requiring prescription drug plans to place HIV-related medications on the lowest cost-sharing tier. Medicare beneficiaries with AIDS, especially lower-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-

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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. AIDS Behev. 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.

related medication, or a non-HIV drug, the drug should be available at the lowest cost-sharing tier. We encourage CMS to grant serious consideration to the numerous studies that demonstrate that even modest levels of cost sharing result in low-income individuals and people with chronic illnesses being deprived of medically necessary prescription drugs.[3]

IN THE ABSENCE OF THE ESTABLISHMENT OF AN OPEN FORMULA FOR AIDS, IT IS CRITICAL THAT CMS ADOPT OTHER SPECIAL FORMULARY PROVISIONS FOR MEDICARE BENEFICIARIES WITH AIDS.

§423.120(B)(1) Formulary Policies Must Meet the Clinical Needs of Medicare Beneficiaries with AIDS.

We strongly recommend that drug plans be required to defer to the Public Health Service guidelines for the treatment of HIV disease and related opportunistic infections and be required to cover all drugs referenced in the guidelines. The enormous variation in drug resistance[4], drug tolerance and toxicity,[5] drug interactions, co-morbid conditions[6], and virulence of the HIV strain requires that clinicians have access to all of the drug therapies available to treat HIV disease. The current provision that "recommends" that Pharmaceutical & Therapeutic (P&T) Committees refer to the guidelines is not sufficient for ensuring that all of the prescription drug plans cover all of the drugs required for successful treatment of HIV disease.

We also strongly support CMS' recommendations to require greater independence and increased specialty representation on the P&T Committees. Specifically, we encourage CMS to adopt the provisions below in the final rule.

- Formulary decisions made by P&T Committees must be binding. If P&T Committees are not granted the authority to make binding decisions than their rigorous evaluations would be rendered meaningless if not accepted by the prescription drug plans.

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[3] 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.

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

[5] 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.

[6] 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.

- A majority of P&T Committee members must be independent and free of conflict with respect to the prescription drug plan sponsor and the prescription drug plan to ensure that recommendations by independent members are not ignored or outvoted.
- P&T Committees should be required to have contractual relationships with medical specialists who are not directly represented on the P&T committee. Furthermore, they should be required to have a contractual relationship with an HIV experienced clinician to advise them on all HIV-related issues.

Require Coverage for Drugs Prescribed for Off-Label Purposes without Placing Undue Burden On Clinicians.

We strongly recommend strengthening the language regarding coverage of drugs for off-label uses. We feel it is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label uses that are standard practice in the medical community. For HIV disease, as with many complex conditions, actual clinical use frequently runs ahead of label indications as practicing 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 strongly that 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.

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 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 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 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. 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. It is absolutely critical that Medicare beneficiaries with 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.

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."

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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 AIDS without any drug coverage for a period of weeks or even months.

§423.30(D)(1)Dual Eligibles Must Not Be Limited To The "Average Cost Plan."

We understand that the federal premium subsidy for the dual eligible population will be limited to the premium for the average cost plan in their area. Our patients who are dual eligibles have extensive prescription drug needs and minimal or no resources to pay for them. It is imperative that they 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.

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Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under the Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. People with HIV/AIDS depend on a daily regimen of multiple medications (most of which are branded drugs). Beneficiaries with AIDS depend on as many as 10 prescriptions monthly. Even minimal co-payments create a financial burden for individuals who are left to choose between paying for medications and meeting other basic needs such as food and housing. Dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a prescription drug for failure to pay cost sharing.

§423.782(A)(Iv) And §423.782(B)(2) Low-Income Individuals Should Not Be Denied Medications For Failure To Pay Co-Payments.

We are concerned that low-income Medicare beneficiaries between 100% and 150% of the federal poverty level face cost-sharing requirements in the proposed regulations that could prevent them from filling medically necessary prescriptions. Individuals between 100% and 135% of the federal poverty level must pay $2 for generics and $5 for brand-name drugs. Individuals between 135% and 150% are required to pay a 15% co-insurance for their drugs. HIV medications are some of the most expensive drugs on the market. This requirement will impose a significant financial barrier for thousands of beneficiaries with AIDS who will be unable to pay the required level of cost sharing. 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.

THE MEDICARE PART D BENEFIT SHOULD HAVE A BETTER SYSTEM FOR BENEFICIARIES AND THEIR PHYSICIANS TO CHALLENGE PLAN DECISIONS AND RESOLVE DRUG COVERAGE DISPUTES.

Beneficiaries with AIDS Should be Granted Expedited Appeals and Must be Given Emergency Supplies of Medicine Pending the Appeal Decision.

Grievances and appeals are always a last resort, and engaging in these processes is very challenging for beneficiaries. Because of the critical need persons with AIDS have for continuity of care, especially continuous use of medications, these beneficiaries must have access to an expedited appeals process. Furthermore, it is vital that the beneficiary be granted an emergency supply of medication during the appeals process, so that grave medical harm is not an outcome of the process itself. 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. 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. The final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal**.**

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Finally, there seems to be little rationale to bar a medical provider from filing an appeal on behalf of a beneficiary, when the appeals process moves outside the plan. One can clearly argue that the involvement and support of the physician at this stage in the process is critically important to the beneficiary. A cynical reading of this provision would suggest that the goal is to discourage beneficiaries from filing appeals once their appeal has been denied by the plan. Unfortunately, beneficiaries with AIDS do not have the luxury of discontinuing their efforts to secure medically necessary and potentially life-saving medications. We strongly urge CMS to allow medical providers to file appeals on behalf of their Medicare patients during every stage of the appeals process.

WE ARE CONCERNED BY A NUMBER OF OTHER ISSUES RAISED IN THE PROPOSED RULE.

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We are very concerned that the regulations specifically exclude state-appropriated dollars spent by AIDS Drug Assistance Programs (ADAP) from counting as “incurred” or “true-of-pocket” costs. It is discriminatory and unacceptable to not recognize state dollars spent on AIDS drugs through ADAP while recognizing state dollars spent by State

Pharmaceutical Assistance Programs' (SPAPs) on behalf of Medicare beneficiaries. 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. ADAP plays a critical role as a payer of last resort for our patients who are uninsured or under-insured. Many ADAPs are already struggling to meet the needs of their residents who without them do not have access to AIDS therapies. Failure of CMS to recognize funds that ADAPs spend on prescriptions drugs for Medicare beneficiaries will contribute to the growing numbers of people on waiting lists and individuals who face restricted access to anti-HIV drugs.

§423.50 Strict Guidelines Must Be Applied to the Release of Individual Identifying Information to Prescription Drug Plans.

We have grave concerns regarding the provision in the MMA law that allows the Secretary to disclose personal identifying information to prescription drug plans for the purpose of outreach and marketing activities. Disclosure of personal information is particularly unacceptable for Medicare beneficiaries with AIDS who face significant discrimination in many communities. We strongly disagree with the provision in the MMA that allows the Secretary to disclose this information and feel that mass marketing activities through venues such as community health and senior centers provide more appropriate mechanisms for drug plans to facilitate enrollment and outreach.

If personal identifiable information is provided to drug plans for these purposes, we recommend that strict rules be applied. Personal information should not be provided without beneficiary consent. Personal identifiable information disclosed must be limited to a 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. Finally, we urge you to grant serious consideration to consumer groups that are offering more detailed comments on these provisions.

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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." Behaviors that resemble any of these descriptions can result from drug interactions or diminished mental capacity, which are beyond the control of the beneficiary. Ironically, the provision could result in drug plans leaving beneficiaries without access to drug coverage when they need it most. Without clear definitions of these terms, plans can designate enrollees to be disruptive as a way to disenroll a high cost beneficiary or to sidestep responding to legitimate criticism and claims. We strongly recommend that CMS remove this provision from the final regulations. At a minimum, if the provision is not removed we strongly recommend that CMS clearly state definitions and standards that explicitly exclude behaviors associated with mental illness or cognitive

impairment. Furthermore, a special enrollment period should be required to allow beneficiaries who are involuntarily disenrolled to reenroll in another plan. Any late fee that may apply should also be waived.

In conclusion, we urge you in the strongest possible terms to designate beneficiaries with AIDS as a special population as a way to ensure that the new drug benefit meets their needs. In the absence of such special provisions, we fear many of our patients will essentially be worse off under this new program—with diminished prescription drug coverage, breaches in continuity of care, and increased financial hardship. Our first obligation as physicians is to do no harm. We respectfully urge you to do everything you can, through final regulations and recommendations for changes in law, to ensure that beneficiaries with AIDS are not harmed by this ill-considered legislation. Please contact Christine Lubinski or Andrea Weddle at the HIVMA office at 703.299.1215 with questions regarding these comments.

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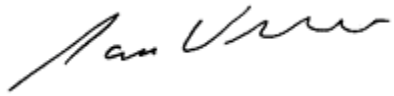

Paul Volberding, MD
Chairman
HIVMA Board of Directors

hivma
hiv medicine association

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

I am writing on behalf of the HIV Medicine Association (HIVMA) and its more than 2,600 HIV clinician members who devote their careers to the prevention, care and treatment of HIV disease. As an organization, we co-author guidelines on prevention and treatment of HIV with the federal government and just released guidelines on the primary care management of HIV disease. In addition, several members of our Board of Directors including myself are on the federal panel that develops and maintains the *Guidelines for the Use of Antiretroviral Agents in HIV Adults and Adolescents.*

More than 80,000 Medicare beneficiaries are people living with HIV disease. At least 60,000 of these beneficiaries are dually eligible for Medicaid and will be required to enroll in the new Medicare drug benefit in January 2006. We are particularly concerned about our dual eligible patients. These patients by virtue of qualifying as dual eligibles are our sickest patients and have very limited resources available, if any, to supplement an inadequate prescription drug coverage policy.

The comments and recommendations that follow reflect our collective expertise as HIV clinicians and researchers. We urge CMS to grant them serious consideration as HIV is a complex disease that requires special expertise and significant patient management experience for successful treatment outcomes. Discoveries in drug therapies are responsible for reducing mortality due to HIV disease by 60 to 80 percent and transforming it from a terminal to a serious but chronic condition. Failure to provide meaningful and affordable access to prescription drugs for Medicare beneficiaries with AIDS through Medicare Part D will result in some of our sickest patients being unable to access life-saving drug therapies.

PEOPLE LIVING WITH HIV/AIDS ARE A SPECIAL POPULATION THAT REQUIRE SPECIAL TREATMENT AND UNRESTRICTED ACCESS TO MEDICALLY NECESSARY DRUGS.

We strongly support the CMS recommendation to designate “special populations” unrestricted access to drugs through “open formularies.” We recommend that people with

AIDS be designated as a special population to ensure access to all of the drugs that are medically necessary to treat the disease and related co-morbidities.

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 AIDS having access to all anti-HIV drugs available to suppress the virus. If drug plans fail to cover all anti-HIV drugs at the lowest cost-sharing tier, it is extremely unlikely that our patients will have the resources to obtain these life-saving drug therapies. 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.

Many of our Medicare patients have serious co-morbid conditions such as hepatitis C, depression, heart disease, diabetes, and liver disease. Treatment for co-morbid conditions requires that we have access to the medications that most effectively treat the condition in conjunction with anti-HIV regimens. Failure to effectively treat comorbid conditions negatively 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.

Special Populations also Require Special Protections with Regards to Cost Containment Measures.

We appreciate the acknowledgment by CMS that certain populations may be discriminated against and adversely affected by cost containment measures implemented by prescription drug plans. We strongly encourage CMS to learn from the experience of Medicaid programs that have tried to balance containing costs with maintaining access to 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 recommend that CMS prevent discrimination against Medicare beneficiaries with AIDS regarding cost-sharing by requiring prescription drug plans to place HIV-related medications on the lowest cost-sharing tier. Medicare beneficiaries with AIDS, especially lower-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-

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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. AIDS Behev. 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.

related medication, or a non-HIV drug, the drug should be available at the lowest cost-sharing tier. We encourage CMS to grant serious consideration to the numerous studies that demonstrate that even modest levels of cost sharing result in low-income individuals and people with chronic illnesses being deprived of medically necessary prescription drugs.[3]

IN THE ABSENCE OF THE ESTABLISHMENT OF AN OPEN FORMULA FOR AIDS, IT IS CRITICAL THAT CMS ADOPT OTHER SPECIAL FORMULARY PROVISIONS FOR MEDICARE BENEFICIARIES WITH AIDS.

§423.120(B)(1) Formulary Policies Must Meet the Clinical Needs of Medicare Beneficiaries with AIDS.

We strongly recommend that drug plans be required to defer to the Public Health Service guidelines for the treatment of HIV disease and related opportunistic infections and be required to cover all drugs referenced in the guidelines. The enormous variation in drug resistance[4], drug tolerance and toxicity,[5] drug interactions, co-morbid conditions[6], and virulence of the HIV strain requires that clinicians have access to all of the drug therapies available to treat HIV disease. The current provision that "recommends" that Pharmaceutical & Therapeutic (P&T) Committees refer to the guidelines is not sufficient for ensuring that all of the prescription drug plans cover all of the drugs required for successful treatment of HIV disease.

We also strongly support CMS' recommendations to require greater independence and increased specialty representation on the P&T Committees. Specifically, we encourage CMS to adopt the provisions below in the final rule.

- Formulary decisions made by P&T Committees must be binding. If P&T Committees are not granted the authority to make binding decisions than their rigorous evaluations would be rendered meaningless if not accepted by the prescription drug plans.

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[3] 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.

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

[5] 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.

[6] 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.

- A majority of P&T Committee members must be independent and free of conflict with respect to the prescription drug plan sponsor and the prescription drug plan to ensure that recommendations by independent members are not ignored or outvoted.
- P&T Committees should be required to have contractual relationships with medical specialists who are not directly represented on the P&T committee. Furthermore, they should be required to have a contractual relationship with an HIV experienced clinician to advise them on all HIV-related issues.

Require Coverage for Drugs Prescribed for Off-Label Purposes without Placing Undue Burden On Clinicians.

We strongly recommend strengthening the language regarding coverage of drugs for off-label uses. We feel it is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label uses that are standard practice in the medical community. For HIV disease, as with many complex conditions, actual clinical use frequently runs ahead of label indications as practicing 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 strongly that 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.

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 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 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 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.

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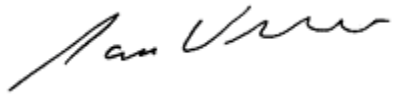

Paul Volberding, MD
Chairman
HIVMA Board of Directors

CMS-4068-P-918

Submitter : Ms. Eva Dech **Date & Time:** 10/04/2004 03:10:23

Organization : Westchester Indepentent Living Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have
Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, these 7 million people with disabilities the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into nursing homes and mental institutions to get needed medications that have become unaffordable in the community, contrary to the Olmstead and the Freedom initiative supported by CMS.

Having personally worked with colleagues with the National Council on Disability in 1994 ? 1996 to develop the Ticket to Work/Work Incentives Improvement Act, and having advocated for its passage through Congress, and gone to Washington to watch our dreams and hard work signed into law just days before the millennium, I am personally appalled that the Part D Program, touted as a benefit, could, as it is written, negate our ten years of hard work.

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

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

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

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

Thank you for your consideration of my views.

Yours sincerely,

Eva Dech
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White Plains, NY 10601
(914)682-3926
edech@wilc.org

Submitter : Mrs. Betty Ripley **Date & Time:** 10/04/2004 03:10:46

Organization : Concerned consumer

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I have a friend with a son who has a mental problem and if unable to get a job. If the coverage of his drugs are not extended, it will cause a undo burden on his parents. I urge you to continue this covered program for his prescriptions.

CMS-4068-P-920

Submitter : Ms. Lorraine Tarnove **Date & Time:** 10/04/2004 03:10:39

Organization : American Medical Directors Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

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Please see the attached comments.

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

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

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

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

CMS-4068-P-921

Submitter : Ms. Christine Lubinski **Date & Time:** 10/04/2004 03:10:01

Organization : HIV Medicare and Medicaid Work Group

Category : Consumer Group

Issue Areas/Comments

GENERAL

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Please contact Christine Lubinski at 703.299.1215 with questions regarding the attached document.

CMS-4068-P-921-Attach-1.doc

October 4, 2004

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

RE: File Code CMS-4068-P

Comments on Draft Medicare Part D Regulations- Part II

Section 422.52—Specialized MA plans for special needs beneficiaries including beneficiaries with HIV/AIDS

We are writing to respond to the call of CMS for comments on Medicare Advantage plans for special needs beneficiaries generally, and in regard to plans developed for Medicare beneficiaries with HIV/AIDS specifically.

We are a collection of national and state HIV/AIDS organizations representing persons with HIV/AIDS, providers of services to persons with HIV/AIDS and agencies that administer programs for this population. While we have submitted detailed comments on Draft Medicare Part D Regulations- Part I, we are limiting our comments on Part II to these provisions. From our vantage point, Medicare managed care plans have not provided beneficiaries with HIV/AIDS a positive alternative to the fee-for-service program. Despite the substantial federal funding granted to these programs, its history has been characterized by sudden program closings, increases in premiums and reductions in benefits. Nevertheless, the potential for managed care plans developed specifically for the HIV/AIDS population could aid people living with HIV/AIDS in getting the services they need, so we offer our comments.

We support the development of specialized Medicare Advantage plans to serve so-called "special needs" beneficiaries, and beneficiaries with HIV/AIDS would clearly constitute such a group. A program designed to address the unique needs of persons with HIV/AIDS would clearly be a welcome option for HIV/AIDS beneficiaries. However, such plans must provide access to HIV experienced providers, and to the array of services and referrals vital to meeting the complex medical needs of persons living with this infectious disease. Finally, a critical factor to the success of "special needs" plans will be reimbursement levels that support the delivery of these comprehensive services.

Currently Medicare Advantage (MA) plans do not serve as an ideal option for most beneficiaries with AIDS for a variety of reasons. First, there is a dearth of MA plans in many jurisdictions with a large number of AIDS cases. For example, there is not one MA plan currently operating in the District of Columbia— a jurisdiction with the heaviest concentration of AIDS cases in the country. Second, persons with AIDS are strongly committed to the physicians who provide their care and research has demonstrated a

direct correlation between HIV physician experience and patient morbidity and mortality. Many of these physicians do not participate in MA plans. Third, few current MA plans provide the amount and complement of services that Medicare beneficiaries with HIV/AIDS require. Frequently MA plan members with HIV/AIDS rely on Ryan White funded services, especially prescription drug services under the AIDS Drug Assistance Program (ADAP). They qualify for Ryan White services on the basis of being underinsured. HIV/AIDS Medicare Advantage plans will be valuable to this beneficiary population only if the program offers services in the amount, duration and scope necessary to meet the myriad medical needs of this population.

An HIV/AIDS special needs plan must provide a network of experienced HIV physicians and other health professionals. Without a strong network of experts, beneficiaries will not make this choice, or will likely receive substandard care. Such a plan must provide comprehensive benefits, including the full complement of medications necessary to effectively treat HIV and common co-morbid conditions such as hepatitis B and C, chronic mental illness, alcoholism and drug addiction. Patients must also have access to the range of medications necessary to treat conditions associated with HIV treatment such as neuropathy and hyperlipidemia. Plans must also provide comprehensive mental health and substance abuse treatment services, case management to coordinate care and to support treatment adherence, and home and community-based services. The plan must also have the capacity to provide referrals to community-based agencies to respond to non-medical needs that have a direct bearing on health outcomes, such as housing assistance, child care and other support services. Plans must also provide prevention services to individuals in care to reduce further transmission of HIV/AIDS. Finally, capitation payments for such plans must be fully risk-adjusted to encourage health plans to develop special plans for persons with HIV/AIDS and to discourage plans from rationing care to contain costs. We appreciate the effort CMS is making to phase-in risk adjustment, but like the end-state renal disease (ESRD) population, treating HIV disease requires 100 percent risk adjustment now.

There is precedent for HIV special needs plans in the Medicaid program. The state of New York is currently implementing HIV special needs plans for the Medicaid population with HIV/AIDS, with plans required to provide a comprehensive list of services with HIV experienced providers financed by risk adjusted capitation. The website of the New York State Department of Health provides detail on the so-called HIV SNPS-- http://www.health.state.ny.us/nysdoh/hivaids/snps/index.htm.

In 1999, the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) provided financial support to the George Washington University School of Public Health and Health Services, Center for Health Services Research and Policy to develop managed care purchasing specifications to address issues in the primary and secondary prevention and medical management of HIV/AIDS and HIV-related conditions. We refer you to these specifications for details about consumer protections, coverage determinations as well as benefits—http://www.gwumc.edu/sphhs/healthpolicy.

We believe the creation of MA special needs plans could provide an important therapeutic option to a number of Medicare subpopulations, including beneficiaries suffering from chronic and persistent mental illnesses. The George Washington University School of Public Health and Health Services has also developed purchasing specifications for this population. In most cases, the services, provider and reimbursement requirements outlined here for HIV/AIDS MA plans are also appropriate for plans providing services to beneficiaries with diabetes or chronic mental illnesses. It would certainly be appropriate to allow health plans to limit enrollment to a particular population for which the plan is specifically designed. It is critical, however, that such plans offer comprehensive services provided by well-trained providers and be adequately financed if they are to transcend the current inadequacies of Medicare Advantage plans for beneficiaries with significant medical needs. While the availability of such plans will not compensate for the many deficiencies of the Medicare prescription drug plans (PDP) as currently envisioned in law and in proposed regulations, such plans do hold the promise of serving as a viable managed care plan alternative to the PDP for Medicare populations with serious chronic and life-threatening medical conditions, including dual-eligibles who are required to enroll in Medicare Part D and will in most cases be limited in their plan choices.

If you have any questions or comments, please contact Christine Lubinski at clubinski@idosociety.org or call 703-299-1215

Respectfully submitted,

Steering Committee of the HIV Medicare and Medicaid Working Group[1]

Organizations listed.

AIDS Foundation of Chicago, Chicago, IL
The AIDS Institute, Washington, DC
American Academy of HIV Medicine, Los Angeles, CA
Gay Men's Health Crisis, New York, NY
HIV Medicine Association, Alexandria, VA
Housing Works, Inc., New York, NY
National Alliance of State and Territorial AIDS Directors, Washington, DC
Project Inform, San Francisco, CA
Treatment Access Expansion Project, Washington, DC

[1] The HIV Medicare and Medicaid Work Group is a national coalition of more than 75 organizations that represent community-based AIDS service organizations, HIV medical providers, advocates and people living with HIV/AIDS.

CMS-4068-P-922

Submitter : Julie Scofield **Date & Time:** 10/04/2004 03:10:45

Organization : NASTAD

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

CMS-4068-P-922-Attach-1.pdf

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

On behalf of the National Alliance of State and Territorial AIDS Directors (NASTAD), an organization representing the public health officials that administer state HIV/AIDS care and treatment programs, I appreciate the opportunity to comment on the proposed regulations entitled, "42 CFR Parts 403, 411, 417 and 423 Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule," 69 FR 46632. NASTAD is extremely concerned that the implementation of the Medicare Part D prescription drug benefit ensures a comprehensive benefit for people living with HIV/AIDS.

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. NASTAD strongly urges CMS to publish a final rule that ensures that Medicare beneficiaries living with HIV/AIDS at all income levels have affordable access to all HIV-related 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. 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 regulations for the Part D prescription drug benefit.

We feel the two issues highlighted below warrant special and serious consideration because of their potential impact on Medicare beneficiaries living with HIV/AIDS accessing daily life-sustaining treatments.

- **Designate people living with AIDS as a "special population"**

  NASTAD strongly recommends that CMS designate people living with HIV/AIDS as a "special populations" and require drug plans to exempt these populations from formulary restrictions and granting them special protections from cost-sharing requirements and other

cost-containment measures that may impede access to prescription drugs. Please see our comments on page 6 for details on this recommendation.

- **Delay Implementation of the prescription drug benefit for Dual Eligibles**

  NASTAD is very concerned that the current proposed timeframe which begins enrollment on November 15, 2005 will not ensure that the nearly 60,000 dual eligibles living 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 no breach in drug coverage will occur 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 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 the collective experience of state AIDS directors and program staff, 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 that best fits their medical needs. 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.

SUBPART B—ELIGIBILITY AND ENROLLMENT

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

The federal premium subsidy for the dual eligible population will be limited to the premium for the average cost plan in their area. The restriction could leave dual eligibles without meaningful access to the full range of prescription drug plans in their area. 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.

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

NASTAD is 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 recommend the removal of this provision but at a minimum 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)

State AIDS Directors have significant concerns regarding the provision in the MMA statute that allows the Secretary to disclose individual 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. While we understand that sharing of this 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, including distribution of materials at community health or senior centers.

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

1. Individual identifying 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. Individual identifying 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.
3. If the Secretary decides to disclose individual identifiable information, Medicare beneficiaries must have the option to opt-out of having their information disclosed. We instead 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.

Finally, it is important to reiterate in the final rule that if the Secretary discloses identifiable information that use of the information is strictly limited to marketing and enrollment activities.

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. We disagree with CMS' suggestion that it could be beneficial for prescription drug plans to be allowed to market other services such as financial services to beneficiaries. 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.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

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

While NASTAD appreciate the opportunity to weigh-in on possible coordination between AIDS Drug Assistance Programs (ADAPs) and private Part D plans, we are deeply troubled by the 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 gaps left by other federal programs, including Medicaid and Medicare. We strongly recommend that the final rule count cost-sharing subsidies from ADAPs as incurred costs for beneficiaries.

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 would 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 the pressure on ADAPs fiscal viability because such funds cannot count toward the catastrophic limit and the benefit itself may be too limited to respond to all 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 commences, ADAPs may have several roles to play. While we understand that CMS is hopeful that all prescription drug plans (PDPs) will include all necessary HIV-related drugs on their formularies, it is not required. Therefore, even individuals who benefit from the low-income protections included in the benefit may find themselves turning to ADAPs to receive the remaining necessary medications. 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% FPL. These individuals will most likely need assistance with drug costs incurred within the "donut-hole." Not allowing ADAP expenses spent on premiums, deductibles, cost-shares or the amount spent filling in the donut hole to be used toward incurred costs could result in people living with HIV/AIDS falling 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 toward "incurred costs" runs counter to CMS' apparent understanding of the circumstances of individuals living with HIV/AIDS.

NASTAD is very concerned that the regulation also disallows state-appropriated dollars spent by ADAPs to be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS while at the same time allowing state dollars to be used for State Pharmaceutical Assistance Programs' (SPAPs) expenditures on behalf of a beneficiary. Under the proposed regulations, SPAPs are allowed to wrap-around in a way that all costs spent on the behalf of a beneficiary count as incurred costs. States should have the flexibility to provide prescription drugs to a variety of populations, including people living with HIV/AIDS, with the state dollars appropriated. It is inexcusable to exempt people living with HIV/AIDS from receiving this type of assistance from their state, while allowing people with other medical conditions to benefit from the use of state dollars. Ironically, persons with AIDS who live in states with SPAPs and who are eligible for assistance will have SPAP costs count toward incurred costs, while those who rely on ADAP will not.

States recognize the importance of providing prescription drugs to individuals living with HIV/AIDS. In the majority of states, ADAPs operate through 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. NASTAD feels 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.

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 mandatory *and* negotiated 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, 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 PDPs is, under the proposed rule, 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 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, 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 this proposed rule, 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.

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 we are not prepared to comment on the details of any such collaboration.

PEOPLE LIVING WITH HIV/AIDS ARE A SPECIAL POPULATION THAT REQUIRE SPECIAL TREATMENT AND ACCESS TO AN OPEN FORMULARY (§423.120)

NASTAD strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with 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.

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 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.

SPECIAL PROVISIONS AND PROTECTIONS FOR SPECIAL POPULATIONS ARE NECESSARY TO PROTECT AGAINST DISCRIMINATORY COST CONTAINMENT MEASURES (§423.120)

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. NASTAD 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. [1]

We also 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 be unable 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.

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

NASTAD strongly supports the 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. If the P&T Committees are not granted the authority to make binding decisions, 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.

One independent physician and one independent pharmacist are inadequate to ensure a formulary that is based on medical evidence rather than cost. NASTAD recommends 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 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.

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[1] 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.

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. 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.

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

NASTAD strongly recommends strengthening the language regarding coverage of drugs for off-label use. It is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label 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 yet an indicated use of the drug.

NASTAD also feels 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.

NASTAD also strongly recommends that prescription drug plans be required to add new categories or classes of anti-HIV therapies upon approval by the Food and Drug Administration. 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. We also recommend extending the period of time that is required for drug plans to notify affected enrollees and other parties in writing 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.

NASTAD strongly recommends that CMS require drug plans to proactively provide detailed information on their 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 the prescription drugs they cover, cost sharing associated with the respective drug, and any special cost containment rules that apply to the drug. 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.

NASTAD objects 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 get sick when away from home or because an in-network pharmacy is closed.

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 (§423.560)

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. The appeals process as described in Subpart M does not provide dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes.

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, 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).

THE FINAL RULE MUST PROVIDE FOR AN EMERGENCY SUPPLY OF DRUGS PENDING THE RESOLUTION OF AN EXCEPTION REQUEST OR AN APPEAL (§423.578(c)(2))

NASTAD finds it extremely troubling that the proposed rule 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). 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.

Our concern regarding treatment interruptions are heightened due to the absence of adequate protections that ensure that individuals can receive a timely resolution of an appeal, and the 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. 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. 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.

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

The provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with HIV/AIDS and other persons with serious and complex conditions receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. NASTAD appreciates 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.

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 pay to $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. 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 Federal Poverty Level (PFL) face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. 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. Low-income Medicare beneficiaries should not be denied medications for failure to pay co-payments.

Again, thank you for the opportunity to comment on these important regulations on the Medicare Part D prescription drug benefit. Please contact me if you need further clarification of any recommendations NASTAD has put forward.

Sincerely,

Julie M. Scofield
Executive Director

Submitter : Mrs. Geri Jennings **Date & Time:** 10/04/2004 03:10:51

Organization : Yakima dialysis (DaVita)

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

Please include prescription water soluble vitamins for Dialysis patients in the prescription drug benefit. Dialysis patients lose water soluble vitamins during their tx. Deficiencies of these vitamins can lead to hyperhomocysteinemia a cardiac risk factor and anemia (decreased red blood cell production.

CMS-4068-P-924

Submitter : Ms. Lorraine Tarnove **Date & Time:** 10/04/2004 03:10:58

Organization : American Medical Directors Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comments.

CMS-4068-P-924-Attach-1.doc

A national organization of long term care physicians committed to quality care

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October 4, 2004

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

Re: Medicare Prescription Drug Benefit; 69 Fed. Reg. 4663 (Aug. 3, 2004); File Code CMS-4068-P

Dear Administrator McClellan:

The American Medical Directors Association (AMDA) appreciates the opportunity to comment to the Centers for Medicare and Medicaid Services on this important proposed regulation. AMDA represents more than 7,000 medical directors, attending physicians, and others who practice in nursing homes. AMDA physicians see an average of 100 nursing facility patients per month per member (approximately 8.5 million visits in 2000 or 42 percent of the total number of nursing facility visits that year). AMDA physicians also care for patients in other venues in the long term care continuum, which includes home health care, assisted living settings, hospice and other sites of care for the frail elderly. Our comments on this proposed regulation reflect that experience, as well as the commitment to provide the best quality of care to our patients.

Formulary Development and Use - §423.120(b)(2)

CMS has proposed that each Medicare Part D drug plan sponsor would be required to develop their own formularies and offer a minimum of two drugs per class, according to guidelines of the United States Pharmacopoeia (USP). The development of formularies for drug plan sponsors is of critical importance to AMDA and its members. Long term care patients have special needs for access to a wide array of medications, and a drug benefit that does not allow such access will be detrimental to these patients.

AMDA strongly urges CMS to allow an open formulary for Part D enrollees in long term care facilities. Long term care patients have complex care and pharmaceutical needs that are distinct from the ambulatory population. Those needs must be examined and addressed, or the Medicare drug benefit will not be successful in long term care facilities, and will, in fact, pose great harm to patients' overall health status.

According to a recent article,[1] the average over 85 year old takes 8 to 10 prescription drugs. While the 65 year old and up population only comprises 13 percent of the population (as of 1995), they account for 30 percent of the nation's prescriptions.[2] Typically the nursing facility population today has 6 to 10 active medical problems and 9 or more prescription drugs.

The physiologic effects of aging (e.g., loss of reserve functional capacity of key organs such as liver and kidneys, deterioration of homeostatic control, etc,) and the subsequent impact on drug pharmacokinetics and pharmacodynamics result in increased sensitivity to the effects of some medications. Coupled frequently with multiple drug therapies and multiple comorbidities, this leads to increased risk of side effects, adverse reactions, and interactions. [3] For these patients, selecting an appropriate therapeutic agent requires careful consideration of drug side effects, and specifically the capacity of the drug to cause or worsen geriatric conditions such as falls, urinary incontinence, mental confusion, delirium, drug contraindications with co-morbid conditions, kidney and liver function of the patient, drug interactions, and a number of other factors. Thus these patients require a broader range of medications to be available.

In addition, long term care patients require a wide variety of drugs in multiple forms (pills, liquid, solutabs, injectibles, patch, immediate release, extended release, etc.) and doses.

The frail condition of many long term care patients requires immediate access to appropriate medications. Delays in medication must be avoided in this vulnerable population in whom appropriate drug therapy may be the most effective type of therapeutic intervention available[4] that can tremendously improve quality of life and probably reduce health care costs.[5] [6] An open formulary for long term care patients is particularly needed because the lengthy grievance process proposed in the regulation is

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[1] Tune, LE. Anticholinegergic effects of medications in elderly patients. J Clin Psychiatry 2001:62 (suppl. 21)

[2] Salom, I L., Davis, K. Prescribing for older patients: how to avoid toxic drug reactions. Geriatrics 1995; 50:37-40.

[3] Turnhein, K. Drug treatment in the elderly. pharmacokinetic and pharmacodynamic considerations. In: Mallareky, G. editor. Auckland. Drug treatment considerations in the elderly. ADIS International; 1999. 35-59.

[4] Abrams, WB, Beers, MH. Clinical pharmacology in an aging population. Clin Pharmaco Ther 1998; 63(3):281-4.

[5] Prisant, LM, Moser M. Hypertension in the elderly: can we improve results of therapy? Arch Inter Med 200; 160(3): 283-9

[6] Genazzini AR, Gambacciani M. Hormone replacement therapy: the perspectives for the 21st century. Maturitas. 1999 May 31; 31(1): 11-17.

not an appropriate remedy for resolving disputes over the medical needs of these fragile patients.

Broad flexibility in prescribing for long term care patients is also important because drug therapy for these patients is as much art as science. It is often difficult to stabilize these fragile patients, and physicians often need to make multiple adjustments in the medication regimen to achieve therapeutic results.

Most clinical research trials exclude individuals over 75 years of age, and clinical guidelines that were developed for other populations are sometimes difficult to apply to long term care patients. The result, again, is that multiple adjustments are often needed to stabilize long term care patients, and physicians need the flexibility of prescribing "off-label" drug use.

We believe that these unique needs justify the adoption of an open formulary for long term care patients.

An open formulary for long term care patients is particularly necessary because CMS has not completed a required assessment of long term care pharmacy services in nursing facilities. That study should inform the regulatory process, and absent its findings, long term care patients need to continue to have the greatest possible access to a wide array of drugs.

Long term care patients in diverse care settings have similar needs. AMDA also encourages an open formulary for Part D enrollees who have been deemed eligible for nursing facility level care (i.e., individuals covered under home and community-based (HCBS) waivers and individuals in Programs of All-Inclusive Care for the Elderly (PACE)).

At a minimum, an open formulary is needed for recent long term care admissions. Without it, there is a dangerous potential to make harmful and clinically unnecessary changes in medications during the transition.

If CMS does require adoption of formularies for long term care patients, more than two drugs per class should be required. There are some drugs for which two medications per class is inadequate for long term care patients (including atypical antipsychotics, anticonvulsants, oral hypoglycemics, and anticonvulsants, among others). We feel that limiting the number of drugs per class will result in inappropriate and inadequate care of the frail elderly and long term care patients. They need access to a wide variety of medications and dosage forms to appropriately manage their multiple chronic conditions and medical problems. We are also concerned that many types of medications that are commonly used in the elderly are grouped together with older medications that are either less effective or have serious side effects in the elderly.

Furthermore, if CMS does require the application of formularies to long term care patients, there should be one nationwide formulary based on geriatric medicine for the

entire continuum of long term care, in order to facilitate transitions to and from community care without barriers or mishaps as patients move to the optimal care setting. Any formulary applied to a long term care patient should be specific to the needs of that population. A formulary designed for other populations, such as for ambulatory patients, hospitals, or managed care patients, is unlikely to meet the unique characteristics of long term care patients.

AMDA is particularly concerned that the current proposal for formulary development will exclude important therapeutic options for older adults, including but not limited to:

- antibiotics, which are frequently needed in intravenous form for prompt treatment of frail older adults;
- anticonvulsants, which are not interchangeable medications and therefore must be available;
- new categories of antidepressants (SSRIs and SNRIs), which are needed for their improved effects in adults compared with tricyclic antidepressants, which are frequently associated with side effects due to their anticholinergic properties;
- nonsteroidal anti-inflammatory drugs (NSAIDs and COX-2 inhibitors), which are particularly relevant for the treatment of symptoms associated with arthritis commonly affecting those age 65 and over;
- antidiabetic agents, particularly new rapid-acting insulins which result in safer, more consistent and stable blood glucose levels throughout the day;
- HMG-coA reductase inhibitors, which are some of the most widely used drugs for lowering levels of cholesterol and other fats in the blood because of their safety and effectiveness; and
- Oral contraceptives, which are widely used by older women in Intermediate Care Facilities for the Mentally Retarded (or Developmentally Disabled).

Recommendation:
CMS should allow an open formulary for Part D enrollees in long term care facilities, as well as those deemed eligible for nursing facility care (HCBS and PACE).

Drug Plan Pharmacy and Therapeutic Committees (§423.120(b)(1))
CMS proposes that each drug plan sponsor would be required to include on its pharmacy and therapeutics (P & T) committee at least one practicing physician and one practicing pharmacist who are experts in the care of the elderly and disabled, and are independent and free of conflict of interest with respect to the Part D drug plan. AMDA believes that knowledge of geriatric medicine is essential in determining the drugs and dosages that should be covered under Part D plans. We also believe that independence is crucial in making decision based on scientific evidence and standards of practice. Therefore AMDA believes that the P & T committee should be comprised of a majority of practicing physicians and pharmacists who experts in long term care and are free of conflict of interest.

AMDA is concerned that formularies will favor inexpensive older drugs and shun or provide disincentives for newer (often more expensive) medications that are generally safer in the elderly. Our worst fear is a small formulary that is driven by costs and

rebates. Absent regulatory requirement, there is little motivation for Part D drug plans to embrace clinical and therapeutic appropriateness when creating formularies. Instead drug plans will be driven by economic incentives to manage costs. For those reasons we support the requirement that the committee must base its clinical decisions on the strength of scientific evidence and standards of practice, including peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other information that it deems appropriate. We also support requiring the committee to consider whether the inclusion of a drug has any therapeutic advantages in terms of safety and efficacy. Committee decisions regarding formulary development and revision should be required to be documented in writing.

Recommendation:
CMS should require that the majority of members of the P&T committee must be practicing physicians and pharmacists who are experts in the care of the elderly and disabled, and who are independent and free of conflict of interest with respect to the Part D drug plan. The committee should base its clinical decisions on scientific evidence and standards of practice, as well as therapeutic advantages regarding safety and efficacy. Decisions must be documented in writing.

Covered Part D Drugs - §423.100
AMDA is very concerned with the selection of excluded agents listed in the proposed drug regulation. Many of the excluded drugs are used wisely and appropriately in long term care patients, and depriving patients of access to them will be detrimental to patients' health. We are particularly concerned with the exclusion of benzodiazepines and drugs to treat weigh loss or gain from the covered Part D drugs.

There are many legitimate clinical reasons for prescribing benzodiazepines, including seizures, neuromuscular disease, refractory anxiety, etc. AMDA does not believe that these medications should be excluded carte blanche. While these drugs are sometimes prescribed unwisely, there are some uses which are appropriate and medically necessary. Substitutes for benzodiazepines may be available, but may be more expensive or more toxic to patients in whom such use is appropriate. Without prompt access to benzodiazepines, some patients with acute seizure disorder may require hospitalization. AMDA supports coverage of benzodiazepines under Part D.

Unintended weight loss is common to 50 to 60 percent of nursing home residents.[7] Such weight loss can contribute to anemia, falls, muscle loss, and pressure ulcers, among other side effects. CMS nursing facility regulations require that a facility must ensure that a resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible (42 CFR 483.25(i)). Medications may be useful in treating the weight loss that may occur in long term care settings, leading to improved appetite, weight gain, and a greater sense of well-being. AMDA supports covering drugs to treat weight loss or gain, at least in long term care patients.

[7] Bouras. E.P., Lange, S. M, Scolapio, J. S., Rational Approach to Patients with Unintended Weight Loss. 76 Mayo Clin. Prec. 923. 2001/

The regulation should clarify that injectible prescription drugs are covered under Part D.

The final regulation should also specify that individuals have the right to pay out-of-pocket for drugs that are not covered under Part D. There has been considerable confusion regarding the right to make private payment for services not covered by Medicare regarding some Medicare services, and the regulation should prevent such confusion over non-covered Part D drugs.

Recommendation:
CMS should pursue administrative or legislative remedies to ensure appropriate coverage of benzodiazepines and medications to treat unintended weight loss, at least for long term care patients. CMS should also clarify that injectible drugs are covered under Part D, and that individuals have a right to pay out-of-pocket for drugs that are not covered under Part D.

Long-Term Care Facility - §423.100
CMS proposes to expand the definition of long term care facilities to include intermediate care facilities for the mentally retarded (ICFs/MR) that contract with a long term care pharmacy to provide medication, in order to extend Part D coverage to dual eligibles residing in ICFs/MR.

Recommendation:
AMDA supports the proposed expansion of the definition of long term care facility.

Medication Therapy Management Programs - §423.153
Each Part D plan must have a medication therapy management program (MTMP) to assure appropriate drug regimens for targeted individuals (those with multiple chronic diseases who are taking multiple covered drugs and are likely to have covered drug costs that exceed an amount to be set by CMS). The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians. AMDA recommends that the MTMP be developed in cooperation with at least one physician who is an expert in the care of the elderly and disabled.

The proposed regulation stipulates that MTMP may be performed by a pharmacist. AMDA requests that physicians, who are experts in the care of the elderly and disabled, as well as non-physician practitioners working under their supervision, also be included as health care professionals who may perform MTPT. Many of the services that CMS anticipates will be included in MTMP, 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 coordinating medication therapy with other care management services, are most appropriately performed by long term care physicians. With the addition of Part D, it is essential that attending physicians in long term care facilities continue to take an active role in drug regimen review. While a pharmacist performs the monthly nursing facility drug regimen review, AMDA's House of Delegates

has long recognized that it is the role of the physician to coordinate overall patient care with pharmacists and other members of the interdisciplinary care team. Only the physician has the whole picture and the training to make complex decisions about care.

> "The attending physicians should periodically review all medications and monitor both for continued need based on validated diagnosis or problems and for possible adverse drug reactions. The medication review should consider observations and concerns offered by nurses, consultant pharmacists, and others regarding beneficial and possible adverse impacts of medications on the patients."
> AMDA House of Delegates Resolution E03, March 2003; March 2001.

Physicians would likely use non-physician providers, such as physician assistants and nursing practitioners, working under their supervision, to assist in performing some of the activities of MTPT.

Payment for to physicians and non-physician providers for MTPT would be made through Part D, not Part B.

Recommendation:
The MTMP should be developed in cooperation with at least one physician who is an expert in the care of the elderly and disabled. Physicians, who are experts in the care of the elderly and disabled, as well as non-physician providers working under their supervision, should also be included as health care professionals who may perform MTPT. Payment to physicians and non-physician providers should be provided under Part D.

Electronic prescription program - §423.159
CMS is soliciting comments on additional steps to spur adoption of e-prescribing. AMDA supports payment of separate or differential payment by either type of Part D plan to a participating physician who prescribes Part D drugs in accordance with electronic prescription standards. It should be noted that for nursing facility patients, prescriptions are generated at the facility level, so that incentive payments to nursing facilities should be considered in an effort to promote more rapid adoption of e-prescribing.

One of the most helpful aspects of an e-prescribing program would be an electronic authorization for medications on a formulary, so that coverage decisions are made upon receipt of a prescription, with no delay to physicians and patients in accessing appropriate medications.

Recommendation:
Incentive payments for e-prescribing should be available to both physicians and nursing facilities under both types of Part D plans. An e-prescription system should include immediate e-authorization for prescriptions, to facilitate coverage decisions and reduce grievances.

Cost Sharing Subsidy - §423.782

The regulation proposes that full subsidy eligible institutionalized individuals will have no cost-sharing for their covered Part D drugs. AMDA supports this provision, as these individuals have only very limited personal needs allowances that would not cover cost-sharing expenses. AMDA recommends that this provision be expanded to cover individuals who have been deemed to require a nursing facility level of care (those covered by HCBS waivers and PACE). Inclusion of those dual eligibles would serve to maintain a level playing field for both institutional and non-institutional long term care patients regarding costs. Without such expansion, HCBS and PACE enrollees will be financially disadvantaged vis a vis nursing facility patients. The incentive then would be for nursing facility placement in order to eliminate cost sharing, which could drain the meager incomes of dual eligibles living in the community.

Recommendation:

CMS should expand the proposed prohibition on cost sharing for institutionalized dual eligibles to include those who are eligible for nursing facility care (HCBS and PACE patients) as well.

Enrollment Process - §423.34

There does not appear to be a system for Medicare to notify long term care facilities of a resident's choice of drug plan or of automatic assignment of a dual-eligible to drug plan. That omission enhances the potential for confusion over drug coverage.

Recommendation:

Part D plans should be required to notify nursing facilities of Part D enrollment of their patients.

Subpart M – Grievances, Coverage Determinations, and Appeals – §423.560 ET. seq.

The proposed regulations include extensive provisions for coverage determinations, expedited coverage determinations, exceptions, redeterminations, reconsiderations, and further hearings. Medication should be promptly available to older adults; delays must be avoided. In some cases, a delay could precipitate a life-threatening condition or result in significant suffering for the individual who must do without the needed medication.

The timeframes specified in these provisions are far too lengthy to adequately serve the needs of fragile, often unstable long term care patients. (Specified timeframes allow up to 14 or 28 days for a determination whether to provide or pay for a covered Part D drug, §413.566; up to up to 72 hours or more for an expedited coverage determination, §423.575; up to 14 to 28 days to consider an exceptions request §423.578; up to 30 to 44 days for a redetermination, §423.590; up to 72 hours or 14 days for expedited redeterminations, §423.590.)

The proposed regulation makes it extremely difficult for prescribing physicians to produce clinical evidence to demonstrate that the formulary drug is like to be ineffective or have adverse effects on the patients. These grievance procedures will all require extensive administrative work on the part of prescribing physicians, with different documentation requirements for different forms of grievances. These documentation requirements will pose a significant burden on physicians, which we believe are grossly underestimated in the proposed regulation (e.g., 30 minutes for a prescribing physician to provide documentation needed to support an exception, with an estimated 100 plans receiving only 10 exception requests annually, for a total physician burden of 500 hours; no physician time estimated for documentation needed to support other grievances). This significant administrative burden may deter some physicians from availing themselves and their patients of the grievance process. The administrative burden on long term care physicians would be decreased if CMS adopts an open formulary for long term care patients, thus making grievance procedures less necessary and onerous.

At a minimum, medications should be provided under the Part D plan until the grievance procedure is exhausted.

Recommendation:
The grievance procedures should be shortened, with coverage determinations managed electronically on submission of the prescription or within 24 hours if processed manually. Similarly, timeframes should be shortened for expedited for exceptions, redeterminations, reconsiderations, and other grievances. The regulation should defer to the judgment of the prescribing physician and presume that a prescription is medically necessary. Prescribed medications should be provided under the Part D plan until grievance procedures have been exhausted. Physician documentation requirements should be standardized and streamlined so as not to deter use of the grievance system.

Transition Issues
Transition to the new Part D program may be confusing and chaotic for all Medicare beneficiaries, given the implementation timetable, but it could be especially harmful to dual eligibles who comprise nearly 70 percent of nursing facility residents,[8] and who will lose their Medicaid coverage on January 1, 2006.

Decisions on chose of a Part D plan will be complex. Patients will have to discover and consider whether their pharmacy is included in the network, whether their medications will be covered by the plan's formulary, and what restrictions and costs will apply. AMDA is concerned that state Medicaid programs will not have the funding levels to properly assist dual eligibles in making these important decisions. The concerns are even greater that if dual eligible patients do not decide on a plan, they will be randomly assigned to a plan with a formulary that is not a good match for their medical needs.

[8] Open enrollment will begin Nov. 15, 2005. Dual eligibles who have not selected a plan by Dec. 1 will be randomly assigned to a plan, which will be effective January 1, 2006

The timetable for plan selection will be incredibly short. Dual eligibles will only have two weeks in which to choose a plan or be randomly enrolled. Once a plan is chosen, they will have only a month (during a holiday period) in which to compare the plan's formulary to their own medication needs, obtain different prescriptions to formulary medications, and make arrangements to transfer their prescriptions to in-network pharmacies.

Medicaid beneficiaries residing in nursing facilities are allowed to retain only a nominal personal needs allowance, usually about $60.00 per month. While non-Medicaid Part D enrollees will presumably have the option of paying out-of-pocket for drugs that are excluded on not included on their plan's formulary, dual eligibiles will not be in a position to pay privately. While Medicaid programs have the option of paying for such drugs through the nursing facility per diem payment that will be a state-by-state decision. Required state contributions to Medicare for Part D will leave little additional state funding for medications not covered by Part D. This disparity underscores the need for an open formulary for long term care patients.

Recommendation:
CMS should require states to assist dual eligibles in determining which Part D plan is best suited to their medical needs. CMS should establish an open formulary for long term care patients.

Grandfather Period for Current Prescriptions
Arriving at the most appropriate balance of medication for long term care patients often takes a lengthy treatment period. Stable patients should not be subjected to precipitous shifts in medications. If CMS does not adopt an open formulary for long term care patients, stable long term care patients should not be required to change medications immediately. Rather, current medications should be "grandfathered" in for a period of time, for example, 6 months, to enable physicians to review the pharmaceutical regimen and make appropriate changes.

As noted above, the very short time frame for implementation presents significant challenges. Assuming that enrollment is completed smoothly, Medicare/Medicaid patients will have only a few weeks (including the holiday season) in which to have physicians change prescriptions to formulary medications and work with in-network pharmacies. A transition period in which drug plans are required to cover current medications at current pharmacies for six months would alleviate many transition issues, and would allow patients and physicians to pursue the grievance process if the patient may be harmed by the change to the formulary drugs.

Recommendation:
If CMS does not adopt an open formulary for long term care patients (including those deemed eligible for nursing facility care), it should allow a six month transition period in which current patient prescriptions are honored during the transition to the new formulary.

Physician visits

If CMS does not adopt open formularies for long term care patients, in many instances physician visits will be required for Part D enrollees in order for the physician to review the current pharmaceutical regimen and make necessary changes to accommodate the plan formularies. The final regulation should specify the appropriateness and medical necessity of physician visits to alter medications to accommodate newly-established formularies, and Part B intermediaries should also be instructed regarding the medical necessity of such visits. Furthermore, the final regulation should clarify that if telephone consultation is needed regarding prescription changes to accommodate Part D formularies, that such additional care interventions may be documented during the next office visit, and will justify adjustment of the subsequent visit evaluation and management (E&M) code to reflect this additional complexity of decision making. Similar provisions should be incorporated to address changes in formularies.

Recommendation:

CMS should clarify that the transition to new Part D formularies may necessitate physician visits and should instruct fiscal intermediaries that such should be covered as medically necessary under Part B. CMS should also clarify that telephone consultation regarding prescription changes to accommodate Part D formularies may be documented during the next office visit, and will justify adjustment of the subsequent visit evaluation and management (E&M) code to reflect this additional complexity of decision making.

Study of Part D on Nursing Facilities

MMA calls for an assessment of long term care pharmacy services provided to patients in nursing facilities. This study was to serve as the basis for development of regulations regarding nursing facility patients. The study was to be completed within 18 months of enactment, yet we note with concern that this regulation is going forth without benefit of the study's conclusions. Without this study and serious consideration of the findings, long term care residents are at risk for increased morbidity and mortality associated with improper medications, adverse drug reactions, de-stabilization of health status, and hospital admissions, among other adverse outcomes.

Recommendation:

AMDA recommends prompt completion of this study, in order to inform needed revisions in the final regulation.

Study of Cost Containment Strategies

AMDA is concerned that the impact of various cost containment strategies, such as prior authorization and tiered co-payments, could result in the choice of less effective drugs over more appropriate, albeit more costly drugs, to the detriment of patients' health.

Recommendation:

CMS should study the impact of cost containment strategies by Part D plans on appropriate drug use, with a report one year after implementation of Part D.

The new Part D drug benefit has the potential to assist many Medicare beneficiaries with the costs of prescription drugs. The application of the benefit to the long term care population requires special consideration, however, and must proceed carefully, given the many "unknowns" among current policy options. AMDA members' concerns focus on their desire to improve the quality of care of their patients by assuring access to the medicine and services they need. Inappropriate choices in implementing the Part D benefit could leave long term care patients worse off clinically and financially than they were before Part D was created.

AMDA appreciates the opportunity to comment on this important proposed regulation. Please do not hesitate to call me if you have questions on these comments, or if I may be of further assistance.

Sincerely,

Lorraine Tarnove
Executive Director

CMS-4068-P-925

Submitter : Mr. Carmelo Cinqueonce **Date & Time:** 10/04/2004 03:10:23

Organization : Massachusetts Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The Massachusetts Pharmacists Association and Massachusetts Independent Pharmacists Association hereby submit comments on Docket: CMS-4068-P as attached.

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

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3. The document was protected file and would not allow for CMS to attach the ile to the original message.

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CMS-4068-P-926

Submitter : Dr. n.chuck mccort **Date & Time:** 10/04/2004 03:10:55

Organization : brookside pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

we have signed up several customer for the card and have found that most do not qualify. Need to broaden to coverage field.

CMS-4068-P-927

Submitter : Shane Reeves **Date & Time:** 10/04/2004 03:10:49

Organization : Reeves-Sain

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

My name is Shane Reeves and I am an independed pharmacist in middle Tennessee. I employ over 100 people and I very concerned about the future of my profession under this new Medicare Prescription Drug Benefit program. I am attaching a word document that contains my concerns and reccommendations:

W. Shane Reeves, Pharm.D.
Reeves-Sain Family
1809 Memorial Blvd
Murfreesboro, TN 37129
615-278-3146
615-895-0395 (fax)
sreeves@reevessain.com

CMS-4068-P-927-Attach-1.doc

Pharmacy Access Standards:

 I want to be able to serve my patients. To do that, CMS should revise the pharmacy access standard to require plans to meet the TRICARE requirements on a local level, not on the plan.s overall service level. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.

 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.

Medication Therapy Management Program:

 I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004.

Submitter : Mr. Robert Gettings **Date & Time:** 10/04/2004 03:10:26

Organization : NASDDDS

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments.

CMS-4068-P-928-Attach-1.doc

National Association of State Directors of Developmental Disabilities Services, Inc.

NASDDDS
113 Oronoco Street
Alexandria, VA 22314
Tel: 703-683-4202
Fax: 703-683-8773 or 703-684-1395
Web: http://www.nasddds.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

To Whom It May Concern:

The National Association of State Directors of Developmental Disabilities Services (NASDDDS) welcomes the opportunity to offer comments on proposed rules to implement the Medicare prescription drug provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA; P.L. 108-173, as published in the August 2, 2004 edition of the ***Federal Register*** (69 FR 46632).

NASDDDS is a private, non-profit organization that represents the interests of state agencies responsible for serving children and adults with developmental disabilities in the fifty states and the District of Columbia. Collectively, these agencies serve over 900,000 children and adults with lifelong disabilities at an aggregate cost of nearly $40 billion annually.

We are concerned that the proposed rule does not provide sufficient protections for Medicare eligible individuals with developmental disabilities, many of whom experience co-occurring chronic health conditions, plus physical disabilities and emotional/behaviorial disorders.

Although the precise number of Medicare beneficiaries who receive long-term care services due to mental retardation or a related developmental disability is not available, Social Security Administration (SSA) figures suggest that a significant proportion of the population served by MR/DD agencies – probably 50 percent or more are Medicare eligible. According to the most recent SSA data available, in December of 2002 there were 744,532 recipients of Disabled Adult Children (DACs) Social Security benefits, These are individuals who, due to severe disability originating during in childhood and continuing into adulthood, are eligible of OASDI benefits based on the earnings record of a retired, deceased or disabled parent. Of this number, 397,810, or 53 percent, were also receiving Supplemental Security Income (SSI) benefits. SSA data establishes that of the

total number of DACs (744,532), 421,660 qualify for this status through a diagnosis of mental retardation or another mental disorder. Not included in these figures are DACs who qualify for Social Security (and, following a 24-month waiting period) Medicare benefits based on cerebral palsy, autism, epilepsy and other developmental disabilities.

This portion of the MR/DD population tends to have the most complex prescription drug needs due to the severity of their disabilities and related medical conditions. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, studies indicate that the prevalence of epilepsy among individuals with profound mental retardation is as high as 40 percent. Psychiatric and behavioral problems occur in individuals with mental retardation at 3 to 6 times the rate of occurrence in the general population. As a result, NASDDDS strongly supports open access to medically necessary medications and the inclusion of strong consumer protections in CMS regulations implementing the applicable provisions of MMA. The following recommendations, in NASDDDS' opinion, are crucial to protecting the well being of dual eligibles with developmental disabilities.

Long-Term Care Pharmacies

The MMA authorizes CMS to include standards regarding access to long-term care pharmacies for Part D enrollees who reside in long-term care facilities in establishing rules for convenient access to network pharmacies. CMS has interpreted "long-term care facility" to mean a "skilled nursing facility or a nursing facility." In the preamble to its proposed regulations, however, agency officials request comments on whether intermediate care facilities for persons with mental retardation or related conditions (ICF/MRs) should explicitly be included in this definition. CMS explains that its proposal to limit the applicability of long-term care (LTC) pharmacies to skilled nursing and nursing facilities is based on the agency's understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. Many publicly and privately operated ICFs/MR, however, also maintain exclusive contracts with long-term care pharmacies for the same compelling reasons that nursing facilities maintain such arrangements. While precise national statistics are currently unavailable, over 70 percent of public ICF/MR residents and between 60-70 percent of private ICF/MR residents are dually eligible for Medicare and Medicaid services and, consequently, will be impacted by the Part D drug coverage program. **NASDDDS recommends that the final rule contain a definition of "long-term care facility" that explicitly includes ICFs/MR and assisted living facilities.** Since these facilities manage pharmacy services in methods similar to skilled nursing facilities (SNFs), we urge CMS to add this class of long-term facilities to its regulatory definition.

Furthermore, the Association recommends that participants in Medicaid home and community-based waiver services (HCBS) authorized under Sections 1915 (b) and (c) as well as Section 1115 of the Social Security Act be given the same rights and protections under Medicare Part D as are individuals living in institutions. By

definition, individuals participating in HCBS waiver programs otherwise would require care in a Medicaid-certified institution (i.e., a hospital, NF or ICF/MR) in the absence of such home and community services. Indeed, states are required by law to make an individual determination that an applicant for HCBS waiver services otherwise would require institutional services before she or he is enrolled in waiver-financed services. Over 400,000 individuals with developmental disabilities currently participate in HCBS waiver programs, or more than three times the number of persons receiving services in ICF/MR-certified facilities. The Section 1915(c) waiver authority is the primary vehicle states have used to offer individuals with substantial, lifelong disabilities the opportunity to live in home and community-based settings rather than in institutions. It is important to note, that these efforts to reduce the institutional bias of Medicaid policy are consistent with the Bush Administration's New Freedom Initiative and the U.S. Supreme Court's 1999 landmark ruling in ***L.C. v. Olmstead***. To treat HCBS participants differently than institutional residents under the Part D Medicare program would be tantamount to introducing a new form of institutional bias, in violation of the Administration's New Freedom Initiative and the spirit of the ***Olmstead*** decision. Therefore, HCBS participants should receive the same exemption from co-pays and premiums under Medicare Part D as will individuals living in LTC facilities.

The practice of entering into exclusive contracts for the provision of prescription medications is not nearly as common in HCBS waiver programs as it is among publicly and privately operated ICFs/MR. Nonetheless, given the parallel need profiles of the populations served through the two programs, the risks associated with the free market principles upon which the Part D program is based, and the additional protections afforded to individuals receiving medications through LTC pharmacies, as detailed below, NASDDDS believes that the final rules should offer states the option of furnishing prescription drugs to HCBS waiver participants through LTC pharmacies.

Institutional pharmacies provide a wide range of prescription-drug related services that otherwise are unlikely to be covered under the Part D benefit, including maintenance of Medication Administration Records (MARS), specialized packaging (bubble packs), 90 day client medication profile reviews, and emergency deliveries to a range of homes and facilities, including nursing homes, ICFs/MR, assisted living facilities, group homes, and others types of living arrangements. Without continued federal participation in the costs of these services, either someone else will purchase them (the facilities, the clients, or the state), resulting in a cost shift to that entity, or these critical services no longer will be available to this vulnerable segment of Part D enrollees. If clients lose access to these services, the medication administration error rate will rise, resulting in a significant impact to the clients' health and safety. Without these safeguards, facilities will not meet their licensing requirements and will have increased administrative costs and require additional staff to closely supervise the administration of medications.

Currently, most states fund these services through an increased reimbursement rate to institutional pharmacies. The funds for these services will be included in the calculation of the clawback for each state and, therefore, transferred to the federal government. Any cost shift back to the states will result in the states paying, in effect, for these services

twice. **Therefore, NASDDDS recommends that the additional services typically provided by LTC pharmacies under state Medicaid programs be covered under the Medicare Part D program.** This objective could be accomplished by explicitly including services typically provided by long-term care pharmacies, such as those listed above, in a clear definition of the Medication Therapy Management Plan (MTMP) benefit covered by Part D.

Dual eligibles with developmental disabilities residing in Medicaid-certified long-term care facilities and supported through Title XIX HCBS waiver programs must have access to LTC pharmacies because of the types of prescription drug-related services they provide, as well as the special relationships they build with facilities. Two approaches have been suggested for achieving an appropriate balance of convenient access with appropriate payment. **First, CMS could require prescription drug plans to contract with all LTC pharmacies; or, alternatively, CMS could require prescription drug plans to make available a standard contract to all LTC pharmacies**. If CMS chooses the latter option, plan enrollees residing in facilities or other residential settings where the LTC pharmacy has elected not to contract with a PDP must be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

Enrollment

The proposed rules state that CMS will establish a process to automatically enroll "full benefit" dual-eligibles by either the end of the individual's initial enrollment period or once the individual becomes dually eligible following his/her initial enrollment period. However, the initial enrollment period proposed by CMS as part of the implementation of the Part D program would run from November 15, 2005, until May 15, 2006, for those individuals who already are eligible to enroll in a Part D plan as of November 15, 2005. Dual eligibles with developmental disabilities are unlikely to be able to sift through the information regarding new Medicare Part D Prescription Drug Plans (PDPs), select a plan, and navigate the enrollment process without significant assistance. It is, therefore, likely that a substantial number of dual eligibles will not enroll before January 1,2006. Since Medicaid drug coverage for dual eligibles ends on December 31, 2005, *there will be a significant period in which many dual eligibles will not be enrolled in any federally-assisted plan whatsoever to cover their prescription drug needs.*

This situation is clearly untenable. As noted above, dual eligibles with developmental disabilities are among our most vulnerable populations served by the Medicaid and Medicare programs, with complex and significant prescription drug needs and lower incomes than the rest of the Medicare population. Furthermore, although completing automatic enrollment before January 1, 2006 might help dual eligibles to avoid a period without prescription drug coverage, it will not prevent this population from experiencing periods in which they are unable to obtain necessary medications because many of the low-income plans into which dual eligibles are likely to be enrolled will not cover their complex prescription drug needs. Therefore, beneficiaries who are automatically enrolled will need time to be informed about their new drug plan and to change plans if necessary. To allow adequate time, automatic enrollment must be completed sufficiently in advance

of January 1, 2006 to allow the beneficiary, with the assistance of his/her support network, to evaluate the strengths and weaknesses of a plan. Under these circumstances, the actual period during which dual eligibles will be able to select a plan will be considerably shorter than the six weeks from November 15 to December 31, 2005. Forcing dual eligibles to choose a drug plan in such a short time is unfair to beneficiaries who are at risk of being worse off as a result of the transition to Medicare Part D.

Therefore, NASDDDS recommends that CMS delay the implementation of the Part D program for dual eligibles. Given logistical and technical problems associated with identifying, educating, and enrolling 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period -- to January 1, 2006), we recommend that the transfer from Medicaid to Medicare of the responsibility for covering the costs of prescription medications of dual eligibles be delayed by at least six months. NASDDDS views such an extended timetable as essential to protecting the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that such a delay may require a legislative change and hope that CMS will actively support the enactment of such legislation during the current session of Congress.

In its proposed regulations, CMS anticipates conducting a significant public information campaign to educate beneficiaries about the new Medicare drug benefit, placing an emphasis on ensuring that low-income individuals and "hard-to-reach populations" are aware of the additional benefits available to them and the actions they must take to receive these benefits. The August 2 regulations propose that CMS provide enrollment assistance with and through "appropriate State and Federal agencies," although, with the exception of State Health Insurance Assistance Programs, these agencies are not specified. It is difficult to imagine most dual eligibles with developmental disabilities successfully navigating this flow of information without some additional assistance. Unfortunately, no agency at the federal or state level is specifically charged with the responsibility of educating dual eligibles about the choices they face and assisting them in making those choices in an informed manner. We are concerned that if the responsibility for coordinating this effort is not clearly delineated, many dual eligibles will not receive the assistance they will need to enroll in the Medicare Part D program.

We strongly support the initiation of the "widespread education and information campaign" described in the proposed regulations to "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." This is a critical step in transitioning dual eligibles into the Medicare Part D program. However, no matter how comprehensive a public information campaign CMS launches, dual eligibles with developmental disabilities, as well as the families and friends who support them, still will turn for guidance and support to the state agency or private provider agency staff with whom they have an established relationship. Furthermore, many of these individuals will be unable to take proactive steps to enroll in the new prescription drug benefit program on their own, thus leaving it up to the local agencies that traditionally have coordinated their medical care and supports to ensure that they are successfully enrolled in the most appropriate Prescription Drug Plan (PDP).

However, the challenge of identifying dual eligibles across the state (especially those living in their own homes rather than in a publicly financed residential setting), helping them to choose a plan, and aiding them through the enrollment process -- all within the specified six week period of November 15-December 31, 2005 -- will create an impossible workload for state MR/DD agency staff and private providers who will be assisting clients with their choices. Again, a CMS decision to complete auto-enrollment of dual eligibles before January 1, 2006 would not alleviate the time pressure, as state MR/DD agencies and private providers still would need to assist dual eligibles to determine whether the PDP randomly selected for them will adequately meet their prescription drug coverage needs, and, if not, help them to re-enroll in another PDP. **Therefore, CMS should provide funding and technical support to state MR/DD agencies to allow them to partner with providers in their state to help dual eligibles enroll in Medicare Part D.**

Formulary

The array of drugs available under many PDPs is likely to be less inclusive that drug formularies under many existing state Medicaid plans. For dual eligibles the situation is exacerbated by the fact that low income Part D participants in all likelihood will be able to afford to enroll only in PDPs with average or below-average premiums since otherwise they will not qualify for the premium subsidies offered under the legislation. While state Medicaid programs generally are required to cover all medically necessary drugs, Part D plans have far more flexibility in limiting the array of drugs they cover. Although beneficiaries can appeal a decision by their Part D plan to deny coverage of a particular prescription medication, the proposed process is extremely complex and impossible to for people with cognitive impairments, facing a psychiatric crisis, or both, to navigate. Moreover, the timelines established are extremely drawn out. For example, an expedited determination could take as long as two weeks, and drug plans are not required to provide an emergency supply of medications until at least two weeks following a request.

For people with serious and complex medical conditions, such as dual eligibles with developmental disabilities and co-occurring conditions, access to the right medications can make the difference between life and death, or, at a minimum, between their ability to live in the community vs. an institution, or to hold a job vs. being unemployed. People with disabilities, because of their increased vulnerability to drug side effects, often need access to the latest medications. Many dual eligibles have multiple disabilities in combination with chronic health conditions and require access to a broad array of drugs in order to allow their physicians to find safe drug combinations. Individuals with cognitive impairments moreover frequently are less able to articulate the symptoms of drug side effects, making it more difficult for the treating physician to select the most appropriate medications for the individual. Often the process of selecting the proper medication and dosage level takes time since many people with significant disabilities must try multiple medications and only after considerable experimentation is the most effective medication identified given their needs and circumstances. Furthermore, patients requiring some specific classes of medications, such as anti-seizure medications

and anti-psychotics, may experience negative health effects if forced to switch to an alternative medication. As a result, states may experience an increase in number of individuals needing a more intensive treatment setting or a cost shift to medications purchased with state general revenues funds only. **Therefore, CMS should require PDPs to cover existing medications for the very vulnerable dual eligible population.** Higher reimbursement rates for this coverage could be based on "allowable and allocable costs" as CMS has proposed to pay fallback plans.

NASDDDS strongly supports the observation in the preamble to the proposed rules that certain populations require special treatment due to their unique medical needs. We wish to underscore the enormous potential for serious harm (including death) if individuals with complex medical conditions are subjected to the formulary restrictions and cost management strategies envisioned under the legislation authorizing the Part D program. The consequences of denying the appropriate medication to 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. In order to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, dual eligibles should be exempted from all formulary restrictions and guaranteed access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. **CMS should require PDPs to establish an alternative, flexible formulary for dual eligibles as suggested in the preamble to the proposed regulations.** If dual eligibles are not to be worse off when Part D prescription drug coverage begins, these individuals must have continued access to an alternative, flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

****

Thank you for considering the Association's comments on the August 2 NPRM. Should you have any questions concerning our comments, please contact Dan Berland, NASDDDS Federal Policy Analyst, at (703) 683-4202 or via e-mail at dberland@nasddds.org. We stand ready to work with you to ensure that the implementation of this important new program provides essential prescription medication benefits to some of our nation's most vulnerable citizens.

Sincerely,

Robert M. Gettings

Robert M. Gettings
Executive Director

CMS-4068-P-929

Submitter : **Date & Time:** **10/04/2004 03:10:44**

Organization : **Medicare Cost Contractors Alliance**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The Medicare Cost Contractors Alliance is pleased to submit the attached comments to the proposed rule implementing the Medicare prescription drug benefit.

CMS-4068-P-929-Attach-1.doc

Submitter : Dr. Kendrick Smith **Date & Time:** 10/04/2004 03:10:55

Organization : McFarland Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Patients should be able to get their medical care and prescriptions from the pharmacy and the doctor of their choice. Otherwise, they may be hindered in getting the best health care, because it is their choice.

Submitter : Dr. Mike Sigmon **Date & Time:** 10/04/2004 03:10:02

Organization : McFarland Apothecary

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Patients should be able to get their medical care and prescriptions from the pharmacy and the doctor of their choice. Otherwise, they may be hindered in getting the best health care, because it is their choice.

Submitter : Linus Zumberge **Date & Time:** 10/04/2004 04:10:10

Organization : Schwieterman' Pharmacies

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Medicare beneficiaries are much more comfortable and likely to benefit from LOCAL ACCESS to the Medicare drug program. Any attempt to deny access to any willing provider will greatly hurt the Medicare seniors. 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. We have a wonderful working relationship with these clients and they wish to be able to continue to use my pharmacy for convenient and "unconfused" LOCAL service. "Preferred Pharmacies" should not be allowed. This would disrupt current local pharmacist-patient relationships.

I want to serve my patients locally and my patients want local service. Please keep it local and "unconfused". Please do not allow plans to coerce patients into other pharmacies.

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

The pharmacists are the ideal professionals to provide MTM programs. Please to not allow the plans to choose other providers who do not have the proper background and knowledge. Medication therapy management should be left exclusively in the hands of pharmacists.

Fees: should be uniform for all providers, and will it be high enough to entice pharmacists to provide the MTMS the law provides for.

CMS-4068-P-933

Submitter : Mr. Robert Ripley **Date & Time:** 10/04/2004 04:10:38

Organization : Individual

Category : Congressional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See Attached

CMS-4068-P-933-Attach-1.rtf

Mark B. McClellan, M.D., Ph.D
> Administrator
>
> Centers for Medicare and Medicaid Services
>
> Department of Health and Human Services
>
> Attention: CMS-4068-P
>
> P.O. Box 8014
>
> Baltimore, MD21244-8014
>
> Dear Dr. McClellan:
>
> I as a [Concerned Consumer] welcomes 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.
>
> As advocates for people with or at risk of mental illness, we
> recognize that access to psychiatric medications is a critical
> component of community-based care, and deem it critical that
> the Medicare drug benefit provide coverage for all medically
> necessary mental health medications. We appreciate the
> enormous challenges associated with implementing this new
> benefit, but urge that CMS substantially revise the proposed
> rule in accordance with these comments to ensure adequate
> access to mental health medications for the many Medicare
> beneficiaries who need them. As Congress itself recognized in
> the conference report on the Medicare Modernization Act,
> Medicare beneficiaries with or at risk of mental illness have
> unique, compelling needs that must be given special
> consideration in implementing this important new benefit.
>
> Many Medicare beneficiaries face mental illness.Research has
> shown that some 37% of seniors show signs of depression when
> they visit their primary care physician.Yet most are not
> receiving the mental health services they need.In fact,
> seniors have the highest rate of suicide of any age group in
> the country.It is estimated that only half of older adults who
> acknowledge mental health problems actually are treated by
> either mental health professionals or primary care physicians
> (US DHHS, 2001).Beneficiaries who qualify for Medicare based
> on a disability also frequently experience mental illness and
> studies have shown that over half of all under-65 disabled
> beneficiaries have problems with mental functioning (Kaiser
> Family Foundation, 1999).
>
> We urge CMS to address the following concerns (discussed more
> fully below) in the final rules for the Medicare Part D drug
> benefit.
>
> Coverage of Dual Eligibles.Ensure continuity of care for
> dual eligibles by:
>

> * extending the deadline for switching their coverage from Medicaid to Medicare; and
> * grandfathering coverage of medications on which mental health consumers have been stabilized.
>
> Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses.For other Medicare beneficiaries with mental health needs and particularly dual eligibles , require plans to use alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution.
>
> InvoluntaryDisenrollment for Disruptive Behavior.Establish greater protections for beneficiaries threatened with and subjected to involuntary disenrollment by their drug plans for disruptive behavior.
>
> Appeals Procedures.Simplify the grievance and appeals procedures to prioritize ease of access and rapid results for beneficiaries and their doctors and provide a truly expedited process for individuals with immediate needs, including individuals facing psychiatric crises.
>
> Outreach and Enrollment.Partner with and provide resources to community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.
>
> Coverage of Dual Eligibles (§ 423.34)
>
> Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles.There is a high rate of mental illness among this segment of Medicare beneficiaries: according to Medpac, 38% of dual eligibles have cognitive or mental impairments (Medpac, 2004).CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.
>
> Based on our work with this population, we are gravely concerned that the proposed regulations would cause harmful disruption in care for dual eligibles as well as inadequate drug coverage for other beneficiaries with mental illness.In particular, the proposed regulations do not address how access to needed medications by dual eligibles will be maintained when their drug coverage is switched from Medicaid to Medicare.
>
> We urge CMS to take account of the unique circumstances and needs of this population, and delay transfer of drug coverage from Medicaid to Medicare for the dual eligibles for at least six months to allow adequate time to educate and enroll these

> vulnerable and often hard-to-reach individuals and to ensure
> they receive the drug coverage to which they are entitled.
>
> CMS must also address the real threat of adverse health
> outcomes facing dual eligibles.Under the proposed rule, duals
> would effectively be forced to enroll in the lowest cost plans
> in their areas because the low-income subsidy they will
> receive will only cover the premium for these plans (and
> automatic enrollment would require placement in a low-cost
> plan).While it is critical that the transfer from Medicaid to
> Medicare drug coverage maintain continuity of care, the
> proposed regulations provide no such protection.To the
> contrary, the formularies for these low-cost drug plans will
> not be as comprehensive as the drug coverage these individuals
> currently have through Medicaid.Without access to the coverage
> they need, dual eligibles would have no real choice but to
> switch medications.Yet changing psychiatric medications is
> very difficult and dangerous.Abrupt changes in psychiatric
> medications bring the risk of serious adverse drug reactions
> and interactions.
>
> These regulations must give meaningful effect to the concern
> Congress itself voiced, stating in the conference report on
> the Act that: "[i]f a plan chooses not to offer or restrict
> access to a particular medication to treat the mentally ill,
> the disabled will have the freedom to choose a plan that has
> appropriate access to the medicine needed.The Conferees
> believe this is critical as the severely mentally ill are a
> unique population with unique prescription drug needs as
> individual responses to mental health medications are
> different." [Report No. 108-391, pp. 769-770]Unfortunately,
> the proposed rule does not adequately provide the protection
> for people with mental illness that Congress called for.We
> urge that the regulations be revised to provide for
> "grandfathering"coverage of mental health medications for
> dual eligibles into the new Part D benefit, as a number of
> states have done in implementing preferred drug lists for
> their Medicaid programs.
>
> Alternative, Flexible Formularies for Beneficiaries with
> Mental Illnesses (§ 423.120(b))
>
> We have critical concerns regarding the unfettered discretion
> drug plans would be given under the proposed rules to use
> restrictive utilization management techniques, including prior
> authorization, fail first, and step therapy.Given the dangers
> posed by such practices to individuals with mental illnesses,
> protections are needed and we appreciate recognition by CMS of
> the need for special exemptions from these techniques for
> certain beneficiaries, including those with mental illness.
>
> Restrictive practices such as prior authorization, fail first,
> and step therapy are altogether inappropriate 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 the diseases themselves
> are highly variable in terms of symptoms and effects on
> consumers, and physicians must carefully tailor drug therapies
> to each individual to take into account 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
>
> 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.
>
> The FDA only requires that 80 to 125 percent of a medication
> be the same to be considered therapeutically equivalent.Thus,
> therapeutic substitution is highly inappropriate for this
> population given the many factors that treating physicians
> must take into account, the wide range and varying side
> effects, the variability of mental illnesses themselves in
> terms of how they present themselves, and the
> non-interchangeability of many of these medications given
> critical differences in mechanisms of action and how they
> affect brain chemistry.
>
> 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.
>
> Most states (30 out of 40 with restrictive preferred drug
> lists and prior authorization requirements) have recognized
> that these types of restrictive utilization management
> strategies are inappropriate for mental health consumers and
> have exempted mental health medications from restrictive
> preferred drug lists and prior authorization requirements.
>
> The final regulations must assure Medicare beneficiaries
> access to the newer medications that are generally more
> effective and have fewer side effects.The Report of President
> Bush's New Freedom Commission on Mental Health states that
> "[a]ny 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 Final Report, 2004).
>
> CMS does recognize that restrictions like prior authorization,
> therapeutic substitution, or step therapy, may not be

> appropriate for certain vulnerable populations and they
> "request comments regarding any special treatment (for
> example, offering certain classes of enrollees an alternative
> or open formulary that accounts for their unique medical
> needs, and/or special rules with respect to access to dosage
> forms that may be needed by these populations" (Proposed
> Regulations for Medicare Prescription Drug Benefit, p. 46661).
>
> In response to CMS's request for recommendations on how
> utilization management should be structured for individuals
> who need special treatment, including those with mental
> illness, we propose a requirement that drug plans offering the
> new Medicare Part D benefit incorporate an alternative,
> flexible formulary for mental health medications into their
> benefit designs.This formulary would provide access to the
> full array of mental health medications for individuals with
> mental illnesses diagnoses, including dual eligibles, without
> fail first, prior authorization, step therapy, therapeutic
> substitution, or any similar restrictive policies.Instead of
> forcing these vulnerable beneficiaries to bear the burden of
> cost control as required under these types of policies,
> utilization management would be carried out using policies
> that focus on improving the prescribing behavior of providers.
>
> Our proposed alternative, flexible formulary would focus
> utilization management on practices to improve or at least
> maintain consumer health while containing costs such as:
>
> * Provider peer education initiatives which improve
> clinical practice;
> * Closer review and retrospective intervention with cases
> of polypharmacy or other potentially inappropriate
> prescribing;
> * Case management of chronic illness to improve
> coordination of all medical and mental health care,
> including medications; and
> * Closer data review to identify fraud, deviation from
> clinical best practice, outlier prescribers, and
> clinicians that are "under"dosing.
>
> In a very recent report 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 use of multiple
> prescriptions, reduced compliance, and poor outcomes.
>
> Involuntary Disenrollment for Disruptive Behavior (§ 423.44)
>
> The proposed regulation raises grave concerns in allowing
> Medicare drug plans toinvoluntarilydisenroll beneficiaries for
> behavior that is "disruptive, unruly, abusive, uncooperative,
> or threatening" (§ 423.44(d)(2)).These provisions create
> enormous opportunities for discrimination against individuals
> with mental illness.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.
>
> We are alarmed that CMS has proposed an expedited disenrollment process that would undermine the minimal standards and protections included in the proposed rule.This expedited process proposal must not be included in the final rule.In addition, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well.The final rule must include the following protections:
>
> * Drug plans must be prohibited from disenrolling a beneficiary because he/she exercises the option to make treatment decisions with which the plan disagrees, including the option of no treatment and/or no diagnostic testing;
> * Drug plans may not disenroll a beneficiary because he/she chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan;
> * Documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include:
>
> - o documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities in accordance with the Americans with Disabilities Act; and
> - o documentation that the plan provided the beneficiary with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment;
>
> * Drug plans must provide beneficiaries subject to involuntary disenrollment with the following notices:
>
> - o Advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;
> - o Notice of intent to request CMS' permission to disenroll the individual; and
> - o A planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.
>
> Appeals Procedures (§§ 423.562-423.604)
>
> The appeals processes outlined in the proposed regulations are overly complex, drawn-out, and inaccessible to

> beneficiaries.Under these proposed rules, there are too many
> levels of internal appeal that a beneficiary must request from
> the drug plan before receiving a truly independent review by
> an administrative law judge (ALJ) and the timeframes for plan
> decisions are unreasonably long.In order to qualify for a
> hearing by an ALJ, beneficiaries must first request a coverage
> determination or exception from a tiered cost-sharing scheme
> or formulary which can take between 14 and 30 days, unless a
> plan honors a beneficiary's request that the determination or
> exception be expedited in which case it could still take up to
> 14 days.To appeal adverse determinations or exception
> decisions, beneficiaries must request plans to review their
> decision again and make a redetermination within 30 days
> unless the beneficiary paid out-of-pocket for the medication
> at issue, in which case the plan has 60 days to decide.Even if
> a plan honors a request to expedite a redetermination, the
> deadline for plans to make a decision could be as long as 14
> days.Following a redetermination, beneficiaries may appeal to
> a so-called independent review entity for a reconsideration of
> their case, but these entities will not be authorized to
> review or question the criteria plans use to evaluate
> exceptions requests.The proposed rules do not even set
> deadlines for reconsideration decisions.After receiving a
> reconsideration decision, beneficiaries are only allowed to
> appeal to an ALJ if the amount in controversy meets a
> threshold level of $100 and it is unclear how CMS will
> calculate whether a beneficiary has met this threshold.
>
> In addition to imposing unreasonable delays and burdens on
> beneficiaries, these appeal processes are far from
> transparent.Drug plans would be authorized to establish their
> own criteria for reviewing determination, exceptions,
> and redetermination requests and these criteria will vary from
> plan to plan.Plans would also be authorized to establish
> varying degrees of paperwork requirements for beneficiaries
> and their prescribing physicians who wish to request
> exceptions from tiered cost-sharing schemes or formularies.Far
> from ensuring that beneficiaries' rights are protected, which
> should be their primary function, these procedures would
> actually impede the right of beneficiaries to a fair hearing.
>
> These appeals procedures would be inaccessible for
> beneficiaries facing mental illness and must be significantly
> revised.As Michael Hogan, former chair of the President's New
> Freedom Commission on Mental Health and Director of the Ohio
> Mental Health Department has stated in a letter dated June 1,
> 2004 to CMS Administrator, Mark 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."To accommodate the special needs of these
> beneficiaries and others facing disabilities or low income,
> CMS must establish a simpler process that puts a priority on
> ensuring ease of access and rapid results for beneficiaries
> and their doctors and includes a truly expedited exceptions
> process for individuals with immediate needs, including

> individuals facing psychiatric crises,which should be modeled
> after the federal Medicaid requirement that states respond to
> prior authorization requests within 24 hours.
>
> Outreach and Enrollment (§ 423.34)
>
> The proposed regulations do not adequately address the need
> for collaboration with state and local agencies and
> community-based organizations on outreach and enrollment of
> beneficiaries with disabilities, including individuals with
> mental illness.In the conference report for the Medicare
> Modernization Act, Congress directed that "the Administrator
> of the Center for Medicare Choices [sic] shall take the
> appropriate steps before the first open enrollment period to
> ensure that Medicare beneficiaries have clinically
> appropriated [sic] access to pharmaceutical treatments for
> mental illness" (Report No. 108-391, pp. 769-770).
>
> To respond to Congress's concern with ensuring enrollment and
> comprehensive coverage for beneficiaries with mental illness,
> CMS must partner with community-based organizations focused on
> addressing the needs of people 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 at these sites
> will help inform beneficiaries with mental illness about the
> new benefit, but providing community-based organizations with
> pamphlets and brochures alone is not adequate.To answer the
> many difficult, detailed, and time-consuming questions that
> beneficiaries will have about the new program, extensive
> face-to-face counseling services will be
> needed.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, including mental illness,
> in each region that incorporates collaborative partnerships
> with and additional funding for state and local public and
> nonprofit agencies and organizations focused on mental
> health.In addition, in their bids, drug plans should include
> specific plans for encouraging enrollment of often
> hard-to-reach populations, including individuals with mental
> illness.
>
> We strongly believe that the concerns discussed above must be
> addressed in order to ensure access to mental health
> medications under the Part D drug benefit for the many
> Medicare beneficiaries who need them.
>
> Thank you for your consideration of our comments.
>
> Sincerely,
>
> References:

>
> The Henry J. Kaiser Family Foundation, The Faces of Medicare:
> Medicare and the Under-65 Disabled, July 1999.
>
> Medpac, Report to Congress: New Approaches in Medicare, June
> 2004, p. 72.

U.S. Department of health and Human Services, Administration On Aging, Older Adults and Mental Health: Issues and Opportunities, January, 2001,pp, 3, 9, and 11.

Submitter : Mr. Patrick O'Hearn **Date & Time:** 10/04/2004 04:10:17

Organization : Mr. Patrick O'Hearn

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Regarding the new Medicare pharmacy benefit I strongly feel that all Pharmacists should be allowed to participate and to bill for services. If this isn't done it's unfair competition by a select few.
Thank You

CMS-4068-P-935

Submitter : Mr. John Dutcher **Date & Time:** 10/04/2004 04:10:42

Organization : Capital District Center for Independence

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file from the Disability Community!

CMS-4068-P-935-Attach-1.doc

CMS-4068-P-935-Attach-2.doc

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

To Whom It May Concern:

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

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have
Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, these 7 million people with disabilities the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into nursing homes and mental institutions to get needed medications that have become unaffordable in the community, contrary to the Olmstead and the Freedom initiative supported by CMS.

As CAP Coordinator for the Capital District Center for Independence I work with many individuals who will be badly impacted by Part D of the program. These individuals do not have an estimated $6,000.00 to put into their prescription drugs. Many of these people are working or want to work. They do not want to stay home in order to be poor enough to get the medications the desperately need. Part D will be a tragedy for so many people who want to live a free life in the community.

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work.

The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.
Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

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

Thank you for your consideration of my views.

Yours sincerely,

John Dutcher
CAP Coordinator
Capital District Center For Independence
518-459-6422

855 Central Ave.
Albany, N.Y. 12206

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

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

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Congress.

Thank you for your consideration of my views.

Yours sincerely,

John Dutcher
CAP Coordinator
Capital District Center For Independence
518-459-6422

855 Central Ave.
Albany, N.Y. 12206

CMS-4068-P-936

Submitter : Mr. Dave Baldridge **Date & Time:** 10/04/2004 04:10:25

Organization : National Indian Project Center

Category : Individual

Issue Areas/Comments

Issues 1-10

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

Elderly and disabled American Indians/AK Natives should be exempted from proposed regs that eliminate their Medicaid coverage beginning in 2006. The Federal Trust Responsibility, as already applied through the Indian Health Care Improvement Act and provisions for tribal self-determination, should supersede the Medicare Modernization Act. Proposed regs will cause loss of Medicaid revenue for already-underfunded Indian health programs. They will require many elderly and disabled tribal members to pay significant amounts toward prescription drugs, which are now available to them without charge!

CMS-4068-P-937

Submitter : Miss. Tiffany Wiley **Date & Time:** 10/04/2004 04:10:42

Organization : University of Tennessee College of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BACKGROUND

October 4, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than 'on average' in a regional service area.
To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.
Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a 'clinical pharmacist.' I recommend changing 'clinical pharmacist' to 'pharmacist.' CMS should not limit monitoring to 'clinical pharmacists,' as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a 'Clinical Pharmacist' in its rules and regulations. Nationally, there is no clear definition of a 'clinical pharmacist.'

GENERAL PROVISIONS

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create 'preferred' pharmacies and 'non-preferred' pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one 'preferred' pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only 'preferred' pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy

willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered 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.

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.

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Tiffany Wiley
PharmD Candidate 2006

CMS-4068-P-938

Submitter : Mr. dennis stanley **Date & Time:** 10/04/2004 04:10:44

Organization : virginia pharmacist association

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

The MTM program has the potential for improving the health of many participants and financial benefit to CMS. Pharmacists are an important portion of the pool of providers and patients should have equal access to MTM services without plan direction to a "preferred" provider. Any willing provider should be compensated at an equal rate with out consideration of a plans "preferred provider" list.

GENERAL PROVISIONS

Pharmacy acceisibility should match Tricare standards for local numbers of available pharmacies and not and average of available pharmacies offered by the plan.

CMS-4068-P-939

Submitter : Mr. Matthew Warburton **Date & Time:** 10/04/2004 04:10:03

Organization : Forest Research Institute

Category : Drug Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for the opportunity to comment on the proposed rules implementing the Medicare Part D prescription drug benefit. We are submitting, for your consideration, a copy of our comments to the US Pharmacopeia regarding the model formulary guidlines. These comments are attached hereto and incorporated by reference herein.

CMS-4068-P-939-Attach-1.doc

Forest Research Institute
A Division of Forest Laboratories, Inc.

Fax: 201-427-8100
Direct Line: 201-427-8353

September 17, 2004

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

RE: Comments to Medicare Prescription Drug Benefit Draft Model Guidelines

To the United States Pharmacopeial Convention, Inc.:

Forest Laboratories, Inc., is pleased to have the opportunity to comment on the Medicare Prescription Drug Benefit Draft Model Guidelines. We fully endorse the Guidelines' stated goal of assuring beneficiary access to needed drugs, and support the premise that the Model Guidelines are not a formulary. We also recognize the significant challenges associated with designing adequately inclusive yet practical guidelines.

The draft guidelines have identified 43 therapeutic categories, and then assigned to 35 of these categories one or more pharmacologic classes based on mechanism of action (or in some cases, chemical structure). A benefits plan choosing to follow the guidelines would be required to include on its formulary at least two drugs for each pharmacologic class (assuming there are at least two available), and at least two drugs (again, assuming availability) for each therapeutic category to which no specific pharmacologic class is assigned.

A concern we note with this approach is that all pharmacologic classes assigned to a given therapeutic category are given equal "weight" (in terms of the regulatory requirement for formulary inclusion of at least two drugs from the class), with no means of discrimination between drugs, or groups of drugs, with regard to their usage in routine clinical practice. At the same time, using a broadly-defined primary mechanism of action to classify drugs disregards important secondary pharmacologic activities that may contribute to profound clinical differences between two drugs that are placed into the same class.

In particular, the draft model guidelines for antidepressants are out of step with state-of-the-art clinical practice. Three pharmacologic classes – monoamine oxidase inhibitors, reuptake inhibitors, and other – are assigned to this therapeutic category, with the "reuptake inhibitor" class comprising SSRIs, SNRIs, and tricyclics (TCAs). This classification system conceivably could lead to formulary decisions in which two monoamine oxidase inhibitors (MAOIs) must be added, but an SSRI need not be included, despite the SSRIs' broad acceptance as first-line treatments. Indeed, treatment guidelines published by the American Psychiatric Association (APA) state that MAOIs "should be restricted to patients who do not respond to other treatments because of their potential for serious side effects and the necessity of dietary restrictions," and all but one of the antidepressants that the APA considers first-line belong to the USP-designated "reuptake inhibitor" class.[1]

Furthermore, in many other respects, the SSRIs, SNRIS, and tricyclics are quite dissimilar, and a number of these differences – particularly with regard to safety and tolerability – are distinctly relevant to an elderly or medically ill patient population. The anticholinergic, antihistaminic, and antiadrenergic effects associated with tricyclics (but not SSRIs or SNRIs) can be highly problematic for older patients.[2] At therapeutic doses, tricyclics can increase heart rate, decrease heart rate variability, slow cardiac conduction, and produce orthostatic hypotension.[3] While these effects generally are of little consequence in otherwise healthy depressed patients, the potential for TCA-induced cardiotoxicity is greatly increased in patients with existing heart disease,[3] a common co-morbidity among older patients.

Reports of intracardiac defects following overdose[4] (and evidence from animal studies[5]), suggest that TCAs act as quinidine-like antiarrhythmics which as a class have been associated with increased morbidity and mortality in the context of ischemic heart disease. Thus, TCAs are contraindicated in patients who have suffered from angina, and problematic in patients with a history of myocardial infarction or significant conduction delays.

As even moderate overdoses of TCAs can induce cardiovascular collapse, this class of agents has become one of the most common causes of overdose deaths reported to poison centers.[6] This is of particular concern for the elderly population, in which suicide rates are higher than other age groups.[7] An additional concern associated with the TCAs' narrow therapeutic index is the potential for toxicity induced by pharmacokinetic drug-drug interactions. As medical co-morbidity is common among the elderly, so, too, is the frequency of polypharmacy.[8]

The cardiac safety of SNRIs is generally considered to be superior to that of TCAs, however, treatment with an SNRI (venlafaxine as an example) has been associated with dose-dependent and clinically significant increases in blood pressure,[9] and potentially significant decreases in heart rate variability.[10] Additionally, the noradrenergic effects of SNRIs in overdose may be associated with substantial toxicity. A recent analysis of deaths per million prescriptions of antidepressants in the United Kingdom, for example, revealed that venlafaxine was associated with a "fatal toxicity index" similar to those of some TCAs.[11]

By contrast, the SSRIs have been shown to have little or no effect on cardiovascular function (other than inducing small, clinically nonsignificant reductions in heart rate),[12] and to be vastly safer in overdose compared with the TCAs.[6, 11] Overall, the improved tolerability of the SSRIs (i.e., the relative absence of anticholinergic, cardiovascular, and antihistaminic side effects) relative to the tricyclics (and to some extent, the SNRIs) is thought to be associated with greater patient adherence to treatment.

Apart from questions of safety and tolerability, there are clinical data to suggest that patients who do not respond to an adequate initial trial with one SSRI will respond to a trial with a second SSRI or SNRI,[13-14] and current treatment guidelines reflect this.[1] In this sense, adherence to recommended guidelines requires the availability of more than one SSRI or SNRI.

Moreover, SSRIs in recent years have emerged as the treatment of choice not just for depression, but also for a broad spectrum of anxiety disorders including generalized anxiety disorder, panic disorder, social anxiety disorder, and obsessive-compulsive disorder.[15] With few exceptions (e.g., clomipramine, which potently inhibits serotonin reuptake) the tricyclic compounds have not demonstrated effectiveness in the treatment of anxiety. Since many anxiety disorders require chronic treatment, SSRIs are also considered superior to the benzodiazepines which during long-term treatment are associated with development of tolerance, psychomotor impairment, cognitive and memory changes, physical dependence, and withdrawal reaction on discontinuation.[16-17] Of note, the anxiolytic category was one of eight to which the Draft Model Guidelines assigned no pharmacologic class.

We have used the antidepressant category to demonstrate concerns related to a classification of drugs based on mechanism of action, where mechanism of action is defined too broadly. However, there are a number of other categories to which this concern is applicable. Within category No. 18 — antidotes, deterrents, and poison control — the identified pharmacologic class of "deterrents" does not satisfy the stated classification scheme that pharmacologic classes are primarily based on their mechanism of action. Even within the recommended subdivision of alcohol deterrents, the three available products (disulfiram, naltrexone, and acamprosate) have three completely different mechanisms of action, with attendant differences in efficacy and safety profiles.[18-20]

Alcoholism is a chronic disease that impacts numerous brain structures and neurotransmitter systems, providing multiple possible points to direct treatment strategies.[21] Disulfiram interferes with the metabolism of alcohol, resulting in serum acetaldehyde concentrations and strongly aversive physical symptoms, limiting it's applicability to highly motivated individuals or those in compulsory treatment settings.[18, 22] Naltrexone blocks opiate receptors, blocking the "high" associated with alcohol ingestion, interfering with positive reward circuitry and preventing craving for continued alcohol intake.[19, 22] Acamprosate impacts yet another facet of the disease, decreasing glutamate neurotransmission in patients who are already withdrawn from alcohol and preventing the advent of pseudo-withdrawal,[20, 22] a major reason for relapse.

Relapse has been shown to occur at high rates during the first year of withdrawal from alcohol and each product in this class has proven efficacy for different lengths of treatment. Naltrexone, for example, was studied over a period of three months after withdrawal, while acamprosate's efficacy was shown to continue over a period of one year after cessation of drinking.

These three compounds also have very different safety profiles. It is well documented that a large proportion of alcohol dependent individuals are dependent upon other substances,[23] and while acamprosate has been shown to be safe in polysubstance abusers, naltrexone, due to its mechanism of action, is contraindicated in anyone taking narcotics, including methadone, cough and cold preparations and many antidiarrheals.[19] Similarly, naltrexone would be contraindicated for anyone in acute opioid withdrawal. In addition, patients requiring opioid analgesia would need extra medical attention, as higher doses of the opioid would be needed to achieve the effect, possibly resulting in compromised respiratory function.

Medications available as alcohol deterrents are also eliminated differently, preventing those with hepatic impairment, acute hepatitis or acute renal failure from using naltrexone[19] and those with severe renal impairment from using acamprosate.[20] Concomitant use of disulfiram and acamprosate has been proven safe, however, the concomitant use of disulfiram with naltrexone is contraindicated, due to the similar routes of elimination.[19]

If only two medications per pharmacologic class are available on formulary, then a proportion of alcohol dependent patients might be denied a medication that is most appropriate or the only safe option for their particular condition. Utilizing the proposed classification scheme would not provide the "safety net" for alcohol deterrents that is the Model Guidelines' primary goal.

In conclusion, we encourage the USP in its development of final Model Guidelines to consider expanding the number of pharmacologic classes to reflect adequately the clinically meaningful differences among groups of compounds used for the treatment of a particular disorder. Additionally, we recommend that the Model Guidelines in some manner differentiate among pharmacologic classes that are considered first-line treatments and those that are not. We believe that these changes are necessary to be consistent with accepted clinical practice.

Thank you for the opportunity to comment on the Medicare Prescription Drug Benefit Draft Model Guidelines.

Yours sincerely,

Joanne M. Bell, PhD
Senior Director
CNS Medical Affairs
Forest Research Institute

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CMS-4068-P-940

Submitter : Mr. Edward Coyle **Date & Time:** 10/04/2004 04:10:05

Organization : Alliance for Retired Americans

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

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

Overall Comments
We are concerned that many constructive statements in the Preamble do not appear to be reflected in the Proposed Rule. We urge that more be done to reflect the Preamble?s good intentions in the actual body of the regulation. For example:

? The Preamble discusses providing affected enrollees, prescribers, pharmacists, and pharmacies with written notice when a drug will be removed from the formulary or moved to a different tier for cost-sharing. The regulatory language only says that notice should be provided, without specifying that the notice should be in writing. Requirement for written notice is critical and should be specified.

? The Preamble gives examples of situations when a plan will be required to allow an enrollee to use a non-network pharmacy. These include situations when an enrollee?s plan does not contract with the long-term care pharmacy, which an enrollee in a nursing home must use. The regulatory language does not include the examples CMS discusses in the preamble.

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

CMS-4068-P-940-Attach-1.doc

CMS-4068-P-941

Submitter : Mr. Kevin Fitzgerald **Date & Time:** 10/04/2004 04:10:20

Organization : General Electric Company

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

I attach the comment letter of General Electric Company.

CMS-4068-P-941-Attach-1.doc

GE
Corporate

Kevin J.F. Fitzgerald
Health Care Counsel
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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
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Comments on Proposed Rule Regarding Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)**

Dear Administrator McClellan:

General Electric Company welcomes the opportunity to comment on the proposed regulations concerning the new Medicare prescription drug benefit. We would like to take this opportunity to highlight several of our specific concerns, primarily from our perspective as a large employer providing health insurance coverage for approximately 250,000 of our retired employees through a number of retiree benefit plans.

This letter will present comments in relation to and in the order in which they are discussed in the preamble to the proposed regulations.

Subpart J - Coordination Under Part D Plans With Other Prescription Drug Coverage
6.d Collection of Data on Third Party Coverage

GE has been a participant in a voluntary data sharing agreement with CMS for several years, and as will be discussed further herein, supports its continued use and modification to help facilitate sharing of information between CMS and employer group health plans. With respect to determining duplicate coverage, however, we would advocate the creation of an electronic instant-access method, most likely Web-based, that would enable employer groups to verify Medicare Part D enrollment of a plan participant. This type of tool would preempt unnecessary secondary payer complications, erroneous subsidy payments, and, of course, unneeded Part D premium expenses and inconvenience for plan participants.

6.e. Tracking TrOOP Costs

GE supports the concept of a TrOOP facilitation coordinator as a vehicle to simplification and standardization of the data collection process as well as the most effective means to coordinate benefits between Part D plans, administrators and employer plans. As noted in the preamble, such a vehicle could further serve to promote real-time coordination of benefits and retiree payments at the point of sale, which would offer convenience to the beneficiary and ease of administration.

The design of the facilitation coordinator role and the selection of a supplier must focus on simplification and standardization. To the extent possible, existing data feed formats, similar to the

HIPAA transaction formats, should be employed. The introduction of new formats or platforms will reduce efficiency and increase per-transaction costs, reducing the incentive to pursue coordination, which is crucial to maintaining employer participation and program stability. This proposal can be a breakthrough in the reducing the inherent inefficiency in pharmacy COB, but not if it is too costly and cumbersome to operate.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans
3.b.2. Establishing Actuarial Equivalency

All of the proposed testing models, whether single- or two-prong, do not take into consideration key yet widely varying factors not directly related to benefit design, such as variation in utilization between plan populations or the beneficial effects of efficient purchasing of prescription drug products and services by employers. The cost-based models proposed are essentially blunt instruments based entirely on the amount expended.

Our suggestion is that CMS utilize, either in addition to or in the alternative of a cost-based test, an actuarial tool based on a benefit index measure, which would calculate the relative value of various plan designs while normalizing for the effects of utilization, demographics, geography and efficient purchasing. Such benefit indices are regularly employed in measuring qualitative differences across benefit plans and are widely accepted in the health care and benefits industries.

The basic premise would be that the Medicare standard plan would be scored at 100, and in order for a employer plan to qualify for the subsidy, its benefit value must match or exceed that score. This approach would negate random fluctuations in spending that may occur from year to year, since the inherent value of the employer plan would be established through this method. At any time that the employer changed its plan design, it would need to have its plan rescored in order to continue to qualify for the subsidy.

Definition of a Health Plan for Determining Actuarial Equivalency

The definition of a health plan must recognize the position of multistate employer with numerous affiliates and acquired employee and retiree groups. The broad COBRA definition fails to differentiate the history, purpose and intent of varying benefit designs, which go beyond health coverage, for different populations within an entity as large as GE. A “one-size-fits-all” approach simply cannot account for the variations between different populations.

Many different plan populations may have operational commonality (such as the same PBM supplier), but no other relationship. Thus, the operational requirement proposed would fail to recognize separate plans, bargaining arrangements or geographical factors, to name a few examples. On the other hand, grandfathered closed groups, whether with more or less valuable coverage than non-grandfathered groups, may have been added to a benefit plan, but are not intended by the employer to be otherwise affected by changes applicable to the bulk of participants in the plan.

For this reason, we would ask that CMS consider a flexible approach that would require the employer to have a basis for differentiation of its various populations, including but not limited to corporate structure, date of retirement, collective bargaining purposes, geographic factors, salary basis and any other reasonable classification, as well as simple segregation by plans or clear delineation within a plan (via appropriate corporate action and documentation.) For large employers, a rigid standard will be at best a disincentive and at worst an inequitable bar for participation even though such employers may have sizeable groups of retirees who could be helped by the new benefit.

3.c. Sponsor Application for Subsidy Payment and Required Information

In our discussions with our employee benefits coalitions and other health industry participants, we have come to a general consensus that the proposed September 30 application date is very aggressive (especially with respect to the first year of the program) and does not comport with most employers' enrollment periods and is likely to force use of less than satisfactory data. We request that CMS consider alternative approaches and timing within the application process.

First, a cost-based actuarial attestation in advance of the applicable year will require use of the current data trended forward, and the availability and accuracy of this data will vary between employers given the differences in plan design and the methods or suppliers used to aggregate the data. In addition, a trending assumption would need to be made by employers or provided by CMS , but this would add an additional burden to the agency and would require the figures to be issued well in advance of the application date. From a reliability and ease standpoint, a benefit index, such as proposed in respect to our comment under section 3.b.2 above, would be more reliable and consistent in practice. GE would advocate that this means of attestation be made available accordingly.

Second, provision should be made to permit the submission of data, either partially or wholly, supporting the actuarial attestation after September 30. This would permit the use of more accurate data, reducing the error level in subsidy payments.

Data submission

As noted previously, GE has entered into a voluntary data sharing agreement ("VDSA") with CMS. As with tracking potential double enrollees, it is necessary to build into the VDSA process an ability to rapidly and accurately share and exchange data as part of the application process. The introduction of electronic tools and potentially even migration to HIPAA-compliant formats would help to standardize the process and increase the number of VDSAs in place. However, we do not wish to have the burden of maintaining the match files fall completely on the employer. The database should be owned and managed by CMS, which should produce continued migration by plans to this digitized, one-stop data submission and collection tool.

Surety Bonding

CMS solicits comments on the potential of requiring a surety bond as a condition of receipt of an employer subsidy. Such a requirement would generate enormous transaction fees, and if part of the final regulations, should not be applied against entities with a solid credit rating, since it would simply be money unnecessarily spent.

3.d. Creditable Coverage and Notification

Employers that sponsor group health plans have expertise in communicating benefit options and materials to their employees and retirees, and a key lesson is providing only the information that helps the recipient take best advantage of the benefits that are available. CMS proposes that plans be required to provide an annual notice to each affected retiree of the actuarial attestation of the sponsor as well as information pertaining to the value of the drug benefit and the contributions required for such coverage. These requirements, and their proposed form, are unduly burdensome and will not provide a meaningful benefit to the recipient.

A plan participant does need to know the details of the coverage he or she has and the cost of that coverage. The attestation information and the value figure simply do not assist the beneficiary to get needed drugs and medicines, and may cause confusion and questions as to the reason for inclusion.

GE does not object to an initial notice announcing the availability of the Part D program and its implications for our retirees. It's a communication that would have been made in any case, and in some form would also be made to all newly-eligibles in the future. But the form of the notice should focus on the essential information described above. Once the initial notice is given, it should be communicated thereafter in the applicable summary plan description, or a summary of material modifications for any changes in cost and coverage, as would be required for any ERISA plan.

5.b. Payment Methodology

GE prefers the second alternative payment methodology, although we would endorse CMS permitting plans to select from one or more of the options that were presented, such as between the CMS choice and the second alternative. Given our large size, the CMS choice of a monthly data feed would be expensive to operate and, inevitably, prior months' submissions would be subject to continuous revision due to processing errors, delayed claims or adjustments. A once per year reconciliation would avoid those hazards. Large employers also have the ability to forecast sufficiently accurate estimates so as to not require outsized true-up figures in either direction at reconciliation.

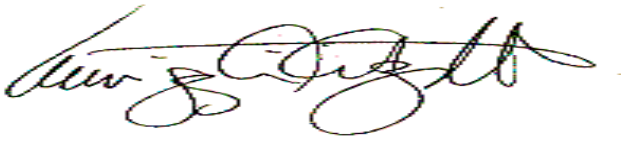
However, given our experience and understanding of complexity of the contractual arrangements within the pharmaceutical industry, we believe that reconciliation should occur by June 30 of the following year, not the beginning of the fourth month. The ability to ascertain the final claims costs and rebate or other contractual arrangements rests in great part on the ability of PBMs and pharmaceutical manufacturers close out their books.

Conclusion

A stated purpose of the Part D benefit in the Medicare Modernization Act was to preserve and enhance employer provision of retiree health benefits. A number of advocacy groups have and will continue to advocate that CMS go outside the statutory authority granted by Congress and mandate such measures as maintenance of effort, freezing of benefits, restrictions on the use of subsidy payments, and overly broad disclosure and challenge rights. The inclusion of such unsupported provisions would contradict the stated statutory purpose and could lead to an erosion of employer participation even prior to the implementation date.

GE thanks CMS for the opportunity to submit these comments. As requested by CMS, these comments have been submitted (without any duplicates by mail or by hand) electronically to www.cms.hhs.gov/regulations/ with the text attached in the preferred Microsoft Word format.

Very truly yours,



Kevin J.F. Fitzgerald

CMS-4068-P-942

Submitter : Miss. Rachel Engstrom **Date & Time:** 10/04/2004 04:10:29

Organization : The University of Tennessee College of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment for comments

CMS-4068-P-942-Attach-1.rtf

October 4, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than "on average" in a regional service area.
To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.
Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a "clinical pharmacist." I recommend changing "clinical pharmacist" to "pharmacist." CMS should not limit monitoring to "clinical pharmacists," as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a "Clinical Pharmacist" in its rules and regulations. Nationally, there is no clear definition of a "clinical pharmacist."

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create "preferred" pharmacies and "non-preferred" pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one "preferred" pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only "preferred" pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require

plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered 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.

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.

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Rachel Engstrom

CMS-4068-P-943

Submitter : Lani ` Sanjek **Date & Time:** 10/04/2004 04:10:50

Organization : NY StateWide Senior Action Council

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BACKGROUND

5. We urge CMS to provide an opportunity for additional comments prior to final issue, to allow for greater clarification of many complex issues, including coordination with state pharmaceutical assistance programs (SPAPs) and other insurance programs providing drug coverage.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

1. In reference to Subpart J: Coordination under Part D with Other Prescription Drug Coverage, we are urging a flexible approach that allows SPAPs, such as our EPIC program, to encourage enrollment in particular Part D PDPs that best coordinate benefits with the state program under contractual agreements. This would build on our experience with the

Medicare-approved discount card for low-income beneficiaries. We believe it would also ensure better access and coordination around cost-sharing, pharmacy networks, and formularies, as well as contribute to more cost-effective administration. Without such flexibility, in light of the more comprehensive coverage currently provided by our EPIC program to about 300,000 New York seniors, beneficiaries will not enroll in Part D plans that may complicate or interfere with their EPIC coverage and this will further penalize the very states that have already contributed significantly to providing drug coverage.

ELIGIBILITY, ELECTION, AND ENROLLMENT

3. In reference to Subpart B: Eligibility and Enrollment, we urge CMS to provide specific requirements re the information and capacity for individual counseling that must be available to beneficiaries (Sec.423.48, Information about Part D). CMS must seek adequate funding for State Health Insurance Assistance Programs (SHIPs) and broaden its partnership with Area Agencies on Aging and other community-based organizations if its goals are to ensure informed decisions and to protect beneficiaries from barriers to appropriate coverage.

4. We urge CMS to delay implementation of the late enrollment penalty (Subpart B: Sec.423.46) for all enrollees for two years. The complexities of the new drug benefit will be difficult to navigate for most beneficiaries, particularly for many of the most vulnerable beneficiaries. Moreover, based on our experiences with the Medicare Savings Program and the Medicare-approved discount cards, and since we do not yet know what Part D PDPs and Medicare or Medicaid (for dual eligibles) Advantage plans will actually be available in many areas of our state, the implementation timetable is insufficient to protect beneficiaries from unfair and inappropriate penalties. This consequently could further undermine the enrollment in Part D plans.

GENERAL PROVISIONS

New York StateWide Senior Action Council (StateWide) submits the following comments on the proposed regulations to implement the MMA with grave concerns about the negative impact on beneficiaries of this extraordinarily complicated legislation. We believe that the MMA creates an unprecedented burden for beneficiaries to understand and make informed decisions about access to their Medicare benefits, calling upon them to navigate what continues to be a very confusing `marketplace? with many critical uncertainties. We strongly endorse the Comments submitted by the coordinated efforts of the Medicare Consumers Working Group, of Famlies USA and also of the New Yorkers for Accessible Health Coverage, with which we are a cooperating organization.

StateWide is a nonprofit membership organization of seniors and senior organizations throughout New York State, established to advocate for the well-being and security of older New Yorkers. StateWide played a leading role in the establishment of New York?s Elderly Pharmaceutical Insurance Coverage (EPIC) program, has had a hospital patients rights advocacy project since 1988 in response to problems resulting from the

implementation of the Medicare prospective payment system, and assisted hundreds of New Yorkers of all ages seeking affordable medicines, including Medicare beneficiaries stranded by the withdrawal of Medicare+Choice plans from certain areas of NY and retirees facing erosion of their benefit programs. We are, therefore, very concerned about the implementation of the new law, its impact on the nearly three million Medicare beneficiaries in our state and on our state and retiree programs that provide drug coverage for elderly, retired, disabled and chronically ill New Yorkers.

PAYMENTS TO PDP AND MA-PD PLANS

6. CMS should seek 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.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

2. In reference to Subpart M: Grievances, Coverage Determination, Reconsiderations and Appeals, we oppose the broader authority granted to Part D PDPs to apply more restrictive and burdensome procedures and standards to beneficiaries and their physicians for non-formulary drugs. Exceptions should not be limited to a narrowly defined ?serious? jeopardy (?423.584) variously interpreted by PDPs. Physicians and beneficiaries should be permitted to rely on standards that reflect other negative effects that impact level of functioning or prevention of further deterioration or injury to access formulary exceptions.

CMS-4068-P-943-Attach-1.doc

CMS-4068-P-943-Attach-2.doc

CMS-4068-P-943-Attach-1.doc

CMS-4068-P-943-Attach-2.doc

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CMS-4068-P-943-Attach-2.doc

CMS-4068-P-944

Submitter : Dr. Amy Gamlin **Date & Time:** 10/04/2004 04:10:56

Organization : Veterans Affairs 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. I offer the following comments for consideration as CMS develops the final regulation.

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 Defenses 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.

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create preferred pharmacies and non-preferred pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one preferred pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.

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.

In conclusion, I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.
Sincerely,
Amy Gamlin
Pharmacy Resident
VA Hospital
Memphis, TN 38103

CMS-4068-P-945

Submitter : Mr. Richard Zuchowski **Date & Time:** 10/04/2004 04:10:40

Organization : Capital District Center For Independence

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for a comment from the disability community

CMS-4068-P-945-Attach-1.doc

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

To Whom It May Concern:

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

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have
Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, these 7 million people with disabilities the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into nursing homes and mental institutions to get needed medications that have become unaffordable in the community, contrary to the Olmstead and the Freedom initiative supported by CMS.

As a Peer Advocate for the Capital District Center for Independence I work with many individuals who will be badly impacted by Part D of the program. These individuals do not have $6,000.00 to put into their prescription drugs. Many of these people are working or want to work. They do not want to stay home in order to be poor enough to get the medications they desperately need. Part D will be a tragedy for so many people who want to live a free life in the community.

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

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

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

Thank you for your consideration of my views.

Yours sincerely,

Richard Edward Zuchowski
Capital District Center For Independence
518-459-6422

855 Central Ave.
Albany, N.Y. 12206

CMS-4068-P-946

Submitter : **Date & Time:** **10/04/2004 04:10:21**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the new Medicare prescription Drug Benefit.

Under Subpart C please ensure that the plans meet the TRICARE pharmacy access requirements on a local zip code level, rather than on the plan's regional overall or average level. This will ensure choice in pharmacy access. CMS should be sure that the intent to provide fair and equitable competition for community pharmacies is followed, and that plans cannot favor mail order pharmacies by the inappropriate use of preferred networks.

Under Subpart D please be sure that plans are required to include comminity pharmacists and community pharmacies in the delivery of MTM services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conviently, and personably to beneficiaries.

CMS-4068-P-947

Submitter : Mr. Kenneth Hansen **Date & Time:** 10/04/2004 04:10:44

Organization : Samish Indian Nation

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-947-Attach-1.doc

September 30, 2004

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

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

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

Dear Administrator:

On behalf of the Samish Indian Nation, I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

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

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

Sincerely yours,

Kenneth C. Hansen
Chairman

Attachment -- Part D Comments

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

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part D's implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part D does not result in inadvertent and unintended harm to that system.

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

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

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

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

- Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when

these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold harmless" mechanism Congress established for FQHCs in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian tribes.[1] Pursuant to statutory directive,[2] this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); **pharmacy operations**; an extensive (but underfunded) contract health services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights[3] reveals a number of alarming statistics such as:

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[1] *See, e.g.*, 25 U.S.C. § 1601.
[2] 42 U.S.C. § 2001.
[3] U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

- AI/ANs have the highest prevalence of Type II diabetes *in the world*, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
- The cardiovascular disease rate among AI/ANs is two times greater than the general population.
- AI/ANs are 770% more likely to die from alcoholism.
- Tuberculosis deaths are 650% higher among AI/ANs than the general population.
- AI/AN life expectancy is 71 years, five years less than the general U.S. population.
- The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
- The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

- The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
- Indian tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
- In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report[4], the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.[5]

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug

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

coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Pharmacy Services for Dual Eligibles

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963[6] and 30,544[7] individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918. [8] We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between **$23.8 million**[9] **and $53.6 million**.[10] It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

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[6] This number represents 85 percent of the three-year total of active users.
[7] This is the number of active users, defined as at least one visit in the past three years.
[8] From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.
[9] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
[10] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

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

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

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

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

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

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

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

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

have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit *all* Medicare beneficiaries, does not produce the opposite result for *Indian* Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS

Comments regarding: Section 423.120: Pharmacy Access Standards

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

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

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

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

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

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

perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.[13]

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

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

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

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) *Assuring pharmacy access.*

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

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

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

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

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

Insert the following new subparagraph (iv):

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

(A) Acknowledge the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.

(B) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.

(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq.* and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.

(D) Recognize that I/T/Us are non-taxable entities.

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

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

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

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

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

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

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

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

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

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

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

Option 1: *In-Network Status + Wrap-Around Payment.* One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network providers and for CMS to provide "a wrap-around payment" modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.

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

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

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

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for **AI/AN dual eligibles drug costs ranges between $23.8 million[15] and $53.6 million.[16]** It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

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

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

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

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

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

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a "wrap-around payment" to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy

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[15] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.

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

[17] Washington State Administrative Code provides a precedent and contains sample language for this provision. **WAC 284-43-200 Network adequacy.** "(7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility."

would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

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

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

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"§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy."

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

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

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

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

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

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

Section 423.124(a) ***

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

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

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

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

Option 3: Special Endorsements with Wrap-Around Payment

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

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

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

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

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

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

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

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

may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

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

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)

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

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

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

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

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

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

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

"(4) **Pharmacy network contracting requirements**. In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage –
(i) Must contract with any pharmacy that meets the prescription drug plan's or MA-PD plan's terms and conditions;
(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA-PD plan's network; *and*
(iii) May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b. "

FORMULARY

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

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

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

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

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

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

AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U

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

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

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

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

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

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

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

Comment: The effect of CMS's decision to treat I/T/U programs as "insurance or otherwise" is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, "most IHS beneficiaries would almost never incur costs above the out-of-pocket limit." (69 FR at 46657). And, as CMS further recognizes, this policy "would likely provide plans with additional cost-savings." (69 FR at 46657). We do not believe that Congress intended Part D to

be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as "incurred costs." By using the phrase "not reimbursed by insurance or otherwise," Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not "reimbursed" by their IHS or tribal health care providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. "fulfills the Secretary's unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes." In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

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

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

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

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

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible

for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

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

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

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

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

Comments regarding Section 423.286 Rules regarding premiums.

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

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

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

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

WAIVER OF COST SHARING

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

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

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

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

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

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

CREDITABLE COVERAGE

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

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

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

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

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate

off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

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

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

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

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

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

ELIGIBILITY AND ENROLLMENT

Comments regarding Section 423.48: Information about Part D.

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

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

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

outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate." In implementing this provision CMS must reach out to AI/AN beneficiaries.

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

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

2. Definitions.

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

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

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

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

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

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

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

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

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

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

3. Description of Provider.

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

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

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

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

4. Co-pays, deductibles.

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

5. Persons eligible for services of Provider.

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

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

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

6. Applicability of other Federal laws.

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

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

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

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

(1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*

(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

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

8. Insurance and indemnification.

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

9. Employee license.

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

10. Provider eligibility for payments.

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

11. Re-Enrollment Period.

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

12. Dispute Resolution.

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

resolve any such disputes.

13. Governing Law.

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

14. Pharmacy/Dispensary Participation.

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

15. Acquisition of Pharmaceuticals.

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

16. Formulary.

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

17. Transitional Assistance Claims.

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

18. Payment Rate.

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

19. Information, Outreach, and Enrollment Materials.

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

20. Hours of Service.

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


SAMISH
NATION

CMS-4068-P-948

Submitter : **Date & Time:** **10/04/2004 04:10:32**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Issues 1-10

BACKGROUND

October 4, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than 'on average' in a regional service area.
To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.
Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a 'clinical pharmacist.' I recommend changing 'clinical pharmacist' to 'pharmacist.' CMS should not limit monitoring to 'clinical pharmacists,' as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a 'Clinical Pharmacist' in its rules and regulations. Nationally, there is no clear definition of a 'clinical pharmacist.'

GENERAL PROVISIONS

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create 'preferred' pharmacies and 'non-preferred' pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one 'preferred' pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only 'preferred' pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy

willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered 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.

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.

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Michael Gebhardt

Submitter : Ms. Suzanne Mintz **Date & Time:** 10/04/2004 04:10:27

Organization : National Family Caregivers Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Attached

CMS-4068-P-949-Attach-1.doc

National Family Caregivers Association

Comments on

Medicare Modernization Act
Medicare Benefit- Part D
Proposed Regulations
69 Fed. Reg. 46632 (August 3, 2004)

File Code: CMS-4068 - P

Presented to:

Mark McClellan, MD, PhD
Administrator Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

October 4, 2004

National Family Caregivers Association 10400 Connecticut Avenue Kensington MD 20895
www.thefamilycaregiver.org; 301/942 6430

The National Family Caregivers Association (NFCA) is pleased to submit comments on the proposed rule for the new Medicare prescription drug benefit (the Proposed Rule)[1] established under the Medicare Modernization Act (MMA) of 2003.

NFCA is the nation's leading grassroots organization for the more than 50 million Americans caring for chronically ill, aged, or disabled loved ones. **NFCA** reaches across the boundaries of different diagnoses, relationships and life stages to address common caregiving needs and concerns with education, support, empowerment programs, and advocacy.

Family caregivers have a great stake in the final rules of the MMA because family caregivers provide over 80% of all homecare services,[2] and are the one constant coordinator of services for persons with chronic conditions. In 2000, these services were valued at $257 billion dollars, twice what was spent on homecare and nursing home services combined.[3]

Thus family caregivers find themselves in the unwanted role of healthcare provider, responsible for personal care and medical care regimens. Family caregivers are on the frontlines of care and know better than most the benefits and hazards of drug therapies. It is family caregivers who monitor medication compliance and observe drug reactions and interaction symptoms. It is family caregivers who must advocate for their loved ones within the healthcare establishment and take their loved one to the ER when something goes wrong.

The **National Family Caregivers Association (NFCA)** understands the difficulties inherent in balancing the need to provide Medicare beneficiaries with a comprehensive prescription drug benefit with the need for cost-efficiency. With such a balanced approach in mind, **NFCA** proposes the following recommendations, covering four broad areas:

- Access to Medications
- P & T Committees
- Appeals
- Financial Considerations

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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] US General Accounting Office. (1994). *Long-Term Care: Diverse, Growing Population Includes Millions of Americans of All Ages* (GAO/HEHS 95-26). Washington, DC: GAO, and Agency for Healthcare Research and Quality (2000). *The Characteristics of Long-Term Care Users*. Silver Spring, MD: AHRQ.
[3] Arno, P. S. (February 24, 2002). *Economic Value of Informal Caregiving*. Orlando, FL: Annual Meeting of the American Association of Geriatric Psychiatry

ACCESS TO MEDICATIONS

Access to Medications for Vulnerable Populations

CMS should recognize patients with three or more chronic diseases/disabilities as a vulnerable population for purposes of the Part D benefit. **Safe guards and restrictions on plan sponsors, beyond those already proposed, should be incorporated to protect this vulnerable population.**

> *My name is Ted. I am 59…. I cared for my father Charles) from September 1997 when he first fell and injured his back with a spinal compression fracture until his death in January 2001…. I now care for my mother Genevieve (83), diagnosed with Alzheimer's/ Dementia shortly after my father's death.*
>
> *My father had a reaction to the pain medication and muscle relaxant prescribed for his back shortly after starting to take it. He was diagnosed as psychotic/demented and further psychoactive medications with further bad side effects were prescribed. He recovered in large part when I took him off of these medications …. He went to a nursing home (for rehabilitation) after a second stay in the hospital. …He suffered from Akathesia (terrible restlessness) for months as a side effect of the medications.given there He began to fall frequently …. The neurologist diagnosed Parkinson's Disease. Unfortunately, these symptoms were mostly caused by drug reactions…. He received many inappropriate medications prescribed by doctors without geriatric experience or knowledge of drug side effects or interactions.*
>
> TV, Jacksonville, FL

To better protect vulnerable populations, the **National Family Caregivers Association (NFCA)** recommends that:

- CMS ensure the design of ALL plans and their respective benefits do not discourage enrollment of people with chronic diseases/disabilities.
- CMS require plans 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.
- CMS clarify that it intends to vigorously review all plans for antidiscrimination behavior that may impact beneficiary access to prescription drugs and enforce the antidiscrimination provision by implementing other beneficiary protections in the

formulary development process, including protections discussed elsewhere in these recommendations.

- CMS establish timeframes to ensure 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 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 prepare all consumer-focused information in formats consistent with clear health communication principles so that Medicare consumers and their families are able to obtain, process, and understand all Medicare communications that impact on their lives.

Access to Medications for Beneficiaries Who Travel

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.

Many beneficiaries reside in more than one region of the country during the year or relocate on a temporary basis for health or personal reasons. These individuals may face difficulties obtaining new/revised prescriptions or refills on favorable cost-sharing terms if they have enrolled in a plan offering a geographically-limited pharmacy network. To avoid these problems many enrollees may opt to forgo vital medications. To ensure continuous access to medication therapies, the **National Family Caregivers Association (NFCA)** recommends:

- CMS ensure that all beneficiaries have the option of selecting a plan with a national pharmacy network, and are made well aware of the potential ramifications of enrolling in a geographically limited plan.

Access to the Full Range of Prescription Drugs Commonly Used in Clinical Practice

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 it is the designated role of U.S. Pharmacopeia (USP) to develop a list of categoriesand classes of drugs that may be used by plans, CMS retains significant discretion under the statute regarding formulary development. The scope of prescription drugs covered under plan

formularies will dramatically affect beneficiary access to care. **National Family Caregivers Association (NFCA)** urges CMS to work aggressively to ensure the full spectrum of necessary medications is available.

NFCA believes that the Guidelines as currently presented will create problems for family caregivers and their loved onesbecause many of the drugs they need are either not currently included in the Guidelines or may be excluded when plans create their formularies, using the USP Guidelines.

NFCA believes the Guidelines do not sufficiently take into account evidence-based research and standard clinical practice for many of the categories and classes in the Guidelines. This is particularly disconcerting in the area of depression because family caregivers are prone to depression at much higher rates that the rest of the population.[4] The Guidelines are biased towards the use of older medicines in a way contrary to established clinical practice. This will allow plans to avoid providing safer, more effective therapies. When family caregivers become depressed it is two people who are suffering. If the final Guidelines usurp safety, clinical effectiveness, or quality of life issues, healthcare costs to the Medicare program overall will inevitably increase.

The Final Model Medicare Guidelines should reflect a broad range of categories and classes to ensure Medicare beneficiaries, especially the chronically diseased or disabled, have sufficient access to critical prescription drug therapies. In many instances, the Guidelines are too narrow to encompass drugs needed by Medicare beneficiaries. **NFCA** recommends:

- The list of categories and classes be expanded to prevent barriers to beneficiary access caused by an overly restrictive formulary

- The pharmacologic classes be restructured based on products' specific mechanism of action. Consistent with the Administration's goal of using the private sector as a model for the Medicare program, the Final Medicare Model Guidelines – including its level of granularity – should be at least as favorable to enrollees as formularies used by commercial health plans. At a minimum, the Final Model Guidelines should have as many categories and classes as the Medicare Prescription Drug Discount Card and the Veterans Affairs health plans.

- The final Model Guidelines require – rather than recommend – subclasses of drugs to ensure sufficient access for Medicare beneficiaries.

[4] Cannuscio, C.C., C Jones, C., Kawachi, I., Colditz, G.A., Berkman, L., & Rimm, E. (2002). Reverberation of family illness: A longitudinal assessment of informal caregiver and mental health status in the nurses' health study. *American Journal of Public Health, 92*, 305-1311.

- 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.
- CMS consider clinical evidence and accepted standards of practice in determining the number of drugs per category or class in a plan formulary. While two drugs may be sufficient to treat certain diseases, in many instances, especially among the chronically diseased and/or disabled Medicare populations, two drugs per category or class will not provide sufficient access to prescription drug therapies. Forcing a switch in medications could cause adverse health outcomes among this vulnerable population.

Family caregivers, who, noted earlier suffer unduly from depression, provide an example. The Guidelines currently divide the category of antidepressants into three classes, one of which is reuptake inhibitors. Selective serotonin reuptake inhibitors (SSRIs) are not segregated as a distinct class, but are collapsed into a single class with older tricyclic medications that are now widely recognized as outdated and no longer part of standard clinical practice. Tricyclics tend to have greater risk profiles and are less well tolerated, particularly in elderly patients and those with multiple chronic diseases who usually take many different medications. However, because of the way the Guidelines are set up, it is possible that plans will only choose to offer two older tricyclic medications as the only treatment option for depression, creating untenable choices for doctors and patients.

Protecting Access

Although plans 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.

The **National Family Caregivers Association (NFCA)** believes it is critical that CMS be vigilant in its oversight to ensure that the drug benefit is implemented well and cost effectively, but always in the best interest of protecting access. That is why **NFCA** recommends:

- 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 and use this data during its annual consideration of plan bids.

- CMS 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.

- CMS create a program to educate pharmacists, physicians, and other relevant healthcare 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.

Protecting Access for Dual Eligibles

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 **National Family Caregivers Association (NFCA)** 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, whom are more 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.

NFCA 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 must ensure that this vulnerable population will have access to a meaningful drug benefit.

Protecting Access for Those Who Appear Disruptive or Threatening

The Proposed Rule would permit plans to disenroll individuals due to disruptive, unruly, abusive, uncooperative or threatening behavior.[5]

The **National Family Caregivers Association (NFCA)** strongly believes that this provision is inappropriate. Some Medicare beneficiaries suffer from mental disorders such as dementia or

[5] 69 Fed Reg. at 46642; 42 C.F.R. § 423.44(d)(2)(i).

other neurological diseases that may cause behaviors perceived to be "disruptive." These provisions also create potential opportunities for discrimination against individuals with mental illnesses, and cognitive impairment. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period, and as a result they could also be subject to a later enrollment penalty increasing their premiums. **NFCA** recommends:

- CMS require plans to develop mechanisms for accommodating the special needs of these individuals.

- CMS make a special effort to ensure that "disruptive" individuals do not lose access to drug coverage.

Access to "Off-Label" and Combination Therapies

The final Guidelines must contain sufficient categories and classes of drugs so as to include the drugs most often used for life-saving and life-enhancing off-label uses.

The **National Family Caregivers Association (NFCA)** strongly recommends that CMS preserve the flexibility for drugs to be prescribed for "off-label"[6] uses. Access to these drugs is critical to ensure that chronically diseased and/or disabled beneficiaries have access to medically necessary therapies. In addition, the Guidelines should provide coverage, including cost-sharing requirements equivalent to the formulary's most favorable terms, for off-label uses of formulary drugs, regardless of whether the drug is classified under the formulary for treating the enrollee's specific condition.

PHARMACEUTICAL AND THERAPEUTIC COMMITTEES

Pharmaceutical and therapeutic committees (P&T committees) will play an important role in the administration of drug plans, serving as gatekeepers to medications through the creation of formularies and other utilization controls. P&T committees also will be responsible for reviewing new drugs and biologics and considering their inclusion in the plan formulary. Plan sponsors will have incentives to aggressively administer a cost-effective prescription drug benefit and likely will use a P&T committee to further this goal. As a result, CMS should provide appropriate oversight to protect enrollees.

Composition of P&T Committees

The **National Family Caregivers Association (NFCA)** urges CMS to adopt the following

[6] 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 include in the USP Drug Information Compendium or is supported by peer reviewed medical literature published in a reputable medical journal.

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 to CMS financial interest, including specific dollar amounts, and other potential ethical conflicts that a member has with the plan sponsor, the plan or any pharmaceutical manufacturer. 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 beneficiary interests are adequately represented during development of plan formularies, including classification decisions and medication selection.

Procedural Safeguards on P & T Committees

To ensure beneficiary rights and access to needed medications, CMS should institute procedural requirements for P&T committees.

The **National Family Caregivers Association (NFCA)** recommends:

- CMS ensure that evidence-based clinical guidelines weigh heavily in any P&T committee decision relating to formulary coverage or classification.

- CMS require that P&T committees engage in a timely review of every newly approved drug, biologic and 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 them through a plan sponsor's exception request process.

- Patient and physician organizations, as well as other stakeholders, should be provided an opportunity to provide timely and meaningful comments as part of the review of new drugs, biologics and therapeutic uses.

- Plans be required to 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.

- P&T committee meetings be open to the public to ensure transparency in P&T committee determinations related to formulary coverage and classification decisions.

- P&T committees 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 the P&T committees for consideration.

- P&T committees review the data on their plans' exceptions requests and appeals to assess the impact on plan enrollees of their determinations related to formulary coverage, classification decisions and medication selection.

Without implementation of these procedural safeguards, beneficiaries may encounter barriers, such as potentially long and unnecessary delays that hinder their access to medication therapies.

APPEALS AND EXCEPTIONS

Exception and appeals processes are not adequate solutions to an inadequate formulary or overly restrictive P&T committee requirements, and therefore should be both timely and simple to provide adequate protections for beneficiaries.

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Notice Period

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.[7] **The National Family Caregivers Association (NFCA)** believes this is insufficient time to respond to a formulary change, and therefore strongly proposes the following:

- CMS should 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.

[7] 69 Fed. Reg. at 46661.

- CMS should require plan sponsors to provide immediate notification to patients who attempt to refill an existing prescription or fill a new 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 assist the enrollee in obtaining an alternative medication.

- CMS should require plans to provide patients with a 72-hour supply of the prescription drug if it has been removed from the formulary.

Consistency of the Exceptions Process

CMS should ensure a high level of consistency in the exceptions processes among all plans 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.[8] Although the Proposed Rule provides some guidelines for plan sponsors to follow, they 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. **The National Family Caregivers Association (NFCA)** strongly recommends that:

- CMS develop a standardized process to minimize the burden on providers and patients to ensure that beneficiaries and their providers can access necessary prescription drugs through the exceptions process.

Refills During Appeals Process

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.[9]

The **National Family Caregivers Association (NFCA)** strongly supports this requirement and urges CMS to adopt it in the Final Rule. Such a requirement would ensure that beneficiaries for whom certain drugs have been determined to be necessary will have uninterrupted access to these important medication therapies.

[8] 69 Fed. Reg. at 46720-21.
[9] 69 Fed. Reg. at 46721.

FINANCIAL CONCERNS

Benefit Thresholds

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 **National Family Caregivers Association (NFCA)** strongly supports CMS' proposal to count out-of-network prescription drug expenses toward the drug benefit thresholds that define beneficiaries' financial obligations. .

Incentives to Promote Quality

CMS should help protect and promote the quality of care provided to Medicare beneficiaries by establishing sufficient incentives for participating pharmacists to counsel patients regarding medication adherence programs and participate in activities designed to minimize adverse drug reactions and medical errors, over and above the compensation they get for fulfilling prescriptions.

Pharmacists are among the most trusted professionals in the country, and play a critical but often unrecognized role in the healthcare process, but currently are not reimbursed for spending time with patients or family caregivers. The **National Family Caregivers Association (NFCA)** believes this is wrong and proposes that:

- CMS 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.

- CMS should encourage pharmacists 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.

Using Cost-savings to Enhance Quality and Access

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.[10] Instead, the **National Family Caregivers Association (NFCA)** urges CMS to use savings to improve beneficiary access to prescription drugs and to improve the quality of beneficiary care. Cost savings could be used to improve the medication therapy management program, implement an electronic medical record or chronic care improvement programs.

The **National Family Caregivers Association (NFCA) s**trongly 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 for them and their family caregivers. Please contact me by e-mail at suzanne.mintz@thefamilycaregiver.org or by telephone at 301/ 942 6430 if we can be of further assistance.

NFCA is grateful to the National Health Council for its help in preparing this document.

[10] 69 Fed. Reg. at 46691.

CMS-4068-P-950

Submitter : Dr. Evelyn Roberts **Date & Time:** 10/04/2004 04:10:46

Organization : National Alliance for the Mentally Ill of NYC

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached letter.

CMS-4068-P-950-Attach-1.rtf

October 4, 2004

TO: Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

FR: Evelyn Roberts, Ph.D.
NAMI-NYC Metro
505 Eighth Avenue, Suite 1103
New York, NY 10018
212-684-3365
execdir@naminyc.org

RE: CMS-4068-P

On behalf of the members of NAMI-New York City Metro, I implore you to consider the unique needs of Medicare beneficiaries living with mental illnesses. During Congressional consideration of the MMA last year, our national NAMI raised concerns to Congress regarding how the new drug benefit would impact beneficiaries with severe mental illnesses, particularly those disabled and currently receiving their drug coverage through state Medicaid programs. Specifically, NAMI supported the inclusion of appropriate safeguards to protect these beneficiaries and ensure open access to critically important medications.

In our view, it is extremely important that Medicare enrollees with severe mental illness, such as schizophrenia, bipolar disorder and major depression have sufficient protections to ensure access to the full range of treatments currently available to them. Without such protections, beneficiaries could suffer substantial irreversible clinical harm resulting in significantly higher overall Medicare costs, if their access to psychotropic drugs is compromised.

As you know psychiatric medications are unique and different from other classes of medication and from each other. Individual responses to psychotropic medicines vary as a result of many factors, including race, ethnicity, gender, severity of illness, and other illnesses or medicines. It can take weeks or even months to determine whether mental health medicines are having their intended effect. Delaying access to appropriate medicines may leave some patients without effective treatment for months. Psychiatric medications in the same class can work on different areas or chemicals in the brain, so they may be effective for one consumer, but not another. Psychotropic medications differ in their side effects, dosing and interactions with other medicines or health conditions. Minimizing side effects and interactions is critical to encourage patients to take their medicines and control their illness. Newer psychotropic medications generally offer improvements in effectiveness and have fewer and more tolerable side effects. Older anti-

psychotics in particular have debilitating side effects that make compliance extremely difficult.

Restrictions on access to medications can harm patients and further tax the health care system and national economy. A recent study of 47 Medicaid programs found that restrictive formularies decreased drug spending by 13.4%. However, these savings were more than offset by a 28.7% increase in physician spending and a 39.1% increase in mental health hospital spending. Adding short-sighted bureaucratic hurdles makes it even more difficult and more costly to treat complex brain disorders. Treatment failures usually mean a further spiraling down for the individual, leading to more intensive, and more costly medical treatment than would previously have been required. The personal and social costs of getting it wrong can be too high to calculate when dealing with individuals with mental illness. It does not mean a lost work day or simple inconvenience or discomfort. Psychotic breaks put vulnerable beneficiaries and their families at risk. These treatment failures have enormous costs for states and communities including incarceration, homelessness and even suicide.

We join national NAMI in making the following recommendations with respect to the final regulations implementing the MMA.

1. **Continuity of Care for Dual Eligible Beneficiaries**: NAMI urges CMS to include in the Final Rules a requirement to ensure "continuity of care" for dual eligibles with mental illnesses by requiring prescription drug plans and Medicare Advantage plans to continue coverage for medications that are already effective in maintaining stability for individual beneficiaries.
2. **Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses**: NAMI urges the inclusion of a requirement for prescription drug plans and Medicare Advantage plans to put in place alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution.
3. **Pharmacy and Therapeutic Committees**: NAMI urges greater clarity to ensure that P&T Committee operations are more transparent and reflect an independent assessment of all coverage restrictions.
4. **Therapeutic Substitution**: NAMI recommends that the Final Rules incorporate protections for therapeutic substitution and, in particular, a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician.
5. **Changes in a Plan Formulary**: NAMI urges CMS to expand beneficiary protections in cases where a prescription drug plan enacts a change in the plan formulary in the midst of a plan year.
6. **Appeals and Grievance Procedures**: NAMI urges CMS to simplify the grievance and appeals procedures detailed in the Notice of Proposed Rulemaking (NPRM) by easing access, ensuring rapid results for beneficiaries and their

doctors, and providing greater clarity for the expedited process for individuals with immediate needs.

7. **Outreach and Enrollment**: NAMI urges CMS to partner with, and provide support to, community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.
8. **Involuntary Disenrollment for Disruptive Behavior**: NAMI urges CMS to establish greater protections for beneficiaries with mental illnesses threatened with and subjected to involuntary disenrollment by prescription drug plans and Medicare Advantage plans for "disruptive behavior."

Thank you for your consideration of these important issues.

Sincerely**,**

Evelyn Roberts, Ph.D.
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CMS-4068-P-951

Submitter : Ms. Sue Abderholden **Date & Time:** 10/04/2004 04:10:10

Organization : NAMI Minnesota

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see below

CMS-4068-P-951-Attach-1.wpd

October 4, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

Attention: CMS-4086-P

On behalf of the 5,000 members of NAMI Minnesota, I am pleased to submit the following comments on Notice of Proposed Rulemaking (NPRM) implementing the Medicare Prescription Drug Improvement and Modernization Act (MMA, P.L. 108-173).

Unique Needs of Medicare Beneficiaries Living with Mental Illness

During Congressional consideration of the MMA last year, NAMI raised concerns to Congress regarding how the new drug benefit would impact beneficiaries with severe mental illnesses, particularly those disabled and currently receiving their drug coverage through state Medicaid programs. Specifically, NAMI supported the inclusion of appropriate safeguards to protect these beneficiaries and ensure open access to critically important medications. Congress recognized the unique needs of this population and attempted to begin to address this situation by adding the following language to the final House-Senate Conference Report on P.L. 108-173.

"It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Centers for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes.

The conferees anticipate that disabled individuals will enroll in one of the many private sector prescription drug plans or MA-PD plans. Competition will necessitate plans offering the full complements of medicines including atypical antipsychotics, to treat the severely mentally ill. If a plan chooses not to offer or to 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."[1]

[1] H.Rpt. 108-391, p. 769.

In NAMI's view, it is extremely important that Medicare enrollees with severe mental illness, such as schizophrenia, bipolar disorder and major depression have sufficient protections to ensure access to the full range of treatments currently available to them. Without such protections, beneficiaries could suffer substantial irreversible clinical harm resulting in significantly higher overall Medicare costs, if their access to psychotropic pharmaceuticals is compromised. In moving forward in developing the final regulations, NAMI would like to remind CMS that:

Psychiatric medications are unique, different from other classes and each other

- Individual responses to psychotropic medicines vary as a result of many factors, including race, ethnicity, gender, severity of illness, and other illnesses or medicines.
- It can take weeks or even months to determine whether mental health medicines are having their intended effect. Delaying access to appropriate medicines may leave some patients without effective treatment for months.
- Psychiatric medications in the same class can work on different areas or chemicals in the brain, so they may be effective for one individual, but not another.
- Psychotropic medications differ in their side effects, dosing and interactions with other medicines or health conditions. Minimizing side effects and interactions is critical to encourage patients to take their medicines and control their illness.
- Newer psychotropic medications generally offer improvements in effectiveness and have fewer and more tolerable side effects. Older anti-psychotics in particular have debilitating side effects that make compliance extremely difficult.

Restrictions on access harm vulnerable individuals living with mental illness

- A recent study of 47 Medicaid programs found that restrictive formularies decreased drug spending by 13.4%. However, these savings were more than offset by a 28.7% increase in physician spending and a 39.1% increase in mental health hospital spending.
- Adding short-sighted bureaucratic hurdles makes it even more difficult and more costly to treat complex brain disorders.
- Treatment failures usually mean a further spiraling down for the individual, leading to more intensive, and more costly medical treatment than would previously have been required.
- The personal and social costs of getting it wrong can be too high to calculate when dealing with individuals with mental illness. It does not mean a lost work day or simple inconvenience or discomfort. Psychotic breaks put vulnerable beneficiaries and their families at risk. These treatment failures have enormous costs for states and communities including incarceration, homelessness and even suicide.

NAMI would therefore make the following recommendations with respect to the final regulations implementing the MMA.

1) **Continuity of Care for Dual Eligible Beneficiaries**: NAMI urges CMS to include in the Final Rules a requirement to ensure "continuity of care" for dual eligibles with mental illnesses by requiring prescription drug plans and Medicare Advantage plans to continue coverage for medications that are already effective in maintaining

stability for individual beneficiaries. In Minnesota a high number of people with mental illness are dually eligible and currently have access to the medication that will best treat their mental illness.

2) **Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses**: NAMI urges the inclusion of a requirement for prescription drug plans and Medicare Advantage plans to put in place alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution.

3) **Pharmacy and Therapeutic Committees**: NAMI urges greater clarity to ensure that P&T Committee operations are more transparent and reflect an independent assessment of all coverage restrictions.

4) **Therapeutic Substitution**: NAMI recommends that the Final Rules incorporate protections for therapeutic substitution and, in particular, a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician.

5) **Changes in a Plan Formulary**: NAMI urges CMS to expand beneficiary protections in cases where a prescription drug plan enacts a change in the plan formulary in the midst of a plan year.

6) **Appeals and Grievance Procedures**: NAMI urges CMS to simplify the grievance and appeals procedures detailed in the Notice of Proposed Rulemaking (NPRM) by easing access, ensuring rapid results for beneficiaries and their doctors, and providing greater clarity for the expedited process for individuals with immediate needs.

7) **Outreach and Enrollment**: NAMI urges CMS to partner with, and provide support to, community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.

8) **Involuntary Disenrollment for Disruptive Behavior**: NAMI urges CMS to establish greater protections for beneficiaries with mental illnesses threatened with and subjected to involuntary disenrollment by prescription drug plans and Medicare Advantage plans for "disruptive behavior."

Attached is a more detailed analysis of the summary recommendations included above. NAMI Minnesota appreciates the opportunity to submit comments on these important regulations.

Sincerely**,**

Sue Abderholden
Executive Director

DETAILED COMMENTS ON THE NOTICE OF PROPOSED RULEMAKING (NPRM) ON THE MEDICARE PRESCRIPTION DRUG IMPROVEMENT AND MODERNIZATION ACT (MMA)

Continuity of Care for Dual Eligible Beneficiaries (§ 423.34)
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.

Currently, these beneficiaries are receiving coverage for medications under Medicaid. To protect these vulnerable beneficiaries, CMS should enforce a "continuity of care" requirement to ensure access to the same array of mental health and other medications that are available under Medicaid. 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.

Why is a "continuity of care" requirement for dual eligibles justified?
As noted above, 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.

It is essential that under the MMA, dual eligible beneficiaries with mental illness be able to access existing medications that are best suited to their treatment needs and that are most likely to produce optimal treatment outcomes. In NAMI's view, a "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.

In addition, under existing Medicaid law, dual eligibles cannot be denied access to their medications if they are unable to remunerate for their co-payments. While the co-payment for any single drug may be nominal, beneficiaries taking multiple drugs may face multiple co-payments that in the aggregate, can pose a substantial financial burden. Consequently, it is imperative that this Medicaid protection be included in the Final Rules so that beneficiaries who are unable to meet their co-payment responsibilities are not denied access to necessary medications.

Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses
As noted above, 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.

As the NPRM notes:
We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring plans with respect to special populations, as well as suggestions regarding the particular special populations for whom we may want to make allowances.[2]

In response to this request, NAMI respectfully 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). Instead of imposing the burden of cost control on these vulnerable beneficiaries, utilization management would be carried out using policies that focus on improving the prescribing behavior of providers.

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.

Why is such an alternative, flexible formulary justified?
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

[2] 69 Fed. Reg. at 46,661

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.

It is essential that under the MMA that beneficiaries with mental illness be able to access the medications that are best suited to their treatment needs. Utilization management techniques, such as "fail first" requirements and step therapy that require individuals to try and fail with preferred medications before being able to access coverage for the medication prescribed by their physician, can have severe and permanent effects on individuals with mental health disorders.

Likewise, use of therapeutic substitution for psychiatric medications is inappropriate for this population given the many factors that treating physicians must take into account including the wide range and varying side effects, the variability of mental illnesses themselves in terms of how these conditions present themselves, and the non-interchangeability of many of these medications given critical differences in mechanisms of action and
how they affect brain chemistry.

Limits on access to appropriate medications and delays that inevitably result from policies such as prior authorization can cause relapses and can impair the ability of individuals to achieve recovery. Moreover, these policies may also impose a significant risk of death since persons with depression or schizophrenia are at a significantly higher risk of suicide compared to the general population.

Of the states that have imposed restrictive preferred drug lists and prior authorization requirements in their state Medicaid programs, most have recognized that these types of restrictive policies are inappropriate for beneficiaries with mental illnesses and elected to exempt such beneficiaries from restrictive preferred drug lists and prior authorization requirements.

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 that "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.

Pharmacy and Therapeutic Committees (§ 423.120)

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."[3] 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.

To ensure that all coverage policies are based on objective, clinical rationales and are developed by clinical experts, we also recommend that adoption of rules making it explicit that P&T committee responsibilities extend beyond the development of simple formularies to include the development of all restrictive coverage policies. 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 formulary be binding on the plan."[4] In addition, the NPRM states that it expects "P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs)."[5]

However, these provisions are not included in the actual regulations, but are only discussed in the preamble. NAMI therefore urges CMS to include these requirements in the regulations themselves to ensure that prescription drug plans understand their obligations. As noted above, the rationales and clinical justifications for these coverage policies should be subject to discussion and validation in an open forum with an appropriate opportunity for public input, including input from patient advocacy organizations.

NAMI also recommends limiting the number of voting P&T committee members with conflicts so as to avoid diluting the voices of independent members. The recent settlement of the government's investigation of Merck-Medco Managed Care provides guidance in this regard.[6] Pursuant to that agreement, a majority of P&T committee members must be actively practicing physicians, pharmacists, or health care professionals and not be employed by Medco,[7] thus limiting the risk that conflicted members will

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[3] See 42 U.S.C. § 1394w-104(b)(3)(B).

[4] 69 Fed. Reg. at 46,659.

[5] Id.

[6] See United States v. Merck-Medco Managed Care, Civil Action No. 00-737, Consent Order of Court for Permanent Injunction (E.D. Pa.).

[7] See id.

marginalize the input of independent members. This protection should be incorporated into the Final Regulations.

Therapeutic Substitution (§ 423.153)
As noted above, 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.[8] Alternatively, CMS should also consider a requirement for plans to defer to state laws on therapeutic substitution. Many states have laws requiring prescriber consent before plans may make a substitution.

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.

Protections in Cases of Mid-Year Changes in a Plan's Formulary (§ 423.120)
The MMA allows prescription drug plans to change their formularies in the middle of the plan year. Such a change is allowed so long as the plans provide "appropriate notice" to affected beneficiaries and other stakeholders prior to removing a covered drug from a formulary or changing its cost-sharing status. "Appropriate" is defined as 30 days in the Proposed Rule. NAMI believes that this is insufficient notice and does not recognize the real world, crucial nexus between drug plan choice and access to vital medicines for beneficiaries. Medicare beneficiaries are locked into one plan for an entire year and may have specifically chosen the plan based on its formulary. Beneficiaries who cannot obtain the same treatment due to a formulary change may fail to complete their treatment regimens, thus increasing other Medicare costs if more expensive medical interventions are subsequently required.

If CMS believes that it cannot limit prescription drug plans in this manner, the agency should at a minimum require that plans "grandfather" coverage of chronic medications until the next open enrollment period. While this approach would still permit plans to use "bait and switch" marketing strategies involving popular medicines, it would provide the most vulnerable beneficiaries on established medicines the ability to continue their existing treatment regimen without having to pursue coverage through the plan's appeals process.

Appeals and Grievance Procedures (§§ 423.562-423.604)

[8] 69 Fed. Reg. at 46,667 ("Therapeutic substitution would always require explicit prescriber notification and approval.").

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. In general, we believe that CMS should endeavor to clarify these highly important procedures, so that beneficiaries and their families are fully aware of their rights under the new benefit.

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.

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. CMS states that an IRE, when reviewing an appeal of a denial of a formulary exceptions request, is limited to determining whether the prescription drug plan properly applied its own formulary exceptions criteria and that "the IRE would not have any discretion with respect to the validity of the plan's exception criteria or formulary."[9] This limited review is not supported by the MMA. CMS should clarify in the final rule that it does not intend to limit the scope of IRE review.

Third, 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. 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."[10] 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."[11]

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-

[9] Id. at 46,721.

[10] 42 § 1395w-104(g)(2); see also 69 Fed. Reg. at 46,720.

[11] 42 § 1395w-104(h)(2) (emphasis added); see also 69 Fed. Reg. at 46,721.

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.

Further, assuming a beneficiary is successful in an appeal to obtain coverage or preferred status for a drug, the plan appears to have complete discretion to determine the beneficiary's cost-sharing obligations.[12] A beneficiary who obtains coverage of a necessary drug but cannot afford the plan-established cost-sharing has wholly illusory appeal rights. We strongly urge CMS to establish reasonable parameters for the cost-sharing obligations of beneficiaries who file successful appeals.

Finally, CMS should clarify the scope of the plan decisions that are appealable. To ensure that appeal rights are meaningful, the appeal provisions should apply to the full scope of coverage denials – including denials of requests for prior authorization.

Outreach and Enrollment (§ 423.34)

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. As noted above, the Conference Report accompanying the MMA directs CMS and the Center for Medicare Choices to "take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness". (Report No. 108-391, pp. 769-770).

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 beneficiaries 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

[12] See 69 Fed. Reg. at 46,721, 46,844.

in their bids, specific plans for encouraging enrollment of often hard-to-reach, vulnerable beneficiaries such as individuals with mental disabilities.

Involuntary Disenrollment for Disruptive Behavior (§ 423.44)
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"[13]. 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. 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.

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. 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.

Moreover, 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.

[13] (§ 423.44(d)(2))

CMS-4068-P-952

Submitter : Mr. Barry LeBlanc **Date & Time:** 10/04/2004 04:10:03

Organization : Pamlab, L.L.C.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please refer to the comments in the attached Word document

CMS-4068-P-952-Attach-1.doc

Pamlab, L.L.C.

Quality Pharmaceuticals Since 1957

Barry D. LeBlanc

President and C.O.O.

October 4, 2004

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

Re: Comments on Proposed Rule for the Medicare Prescription Drug Benefit (CMS-4068-P): Section II.C

Dear Dr. McClellan:

Pamlab, LLC ("Pamlab") appreciates the opportunity to comment on section II.C of the proposed rule for the Medicare Part D drug benefit.[1] Pamlab is a manufacturer of drugs and medical foods based in Covington, Louisiana. We at Pamlab encourage CMS to clarify in the final rule that Medicare Part D plans may and, in fact, must cover medical foods prescribed for the clinical management of diseases and conditions with distinctive nutritional requirements.

Medical foods are more than food. Medical foods are essential, physician-directed tools in the clinical management of diseases that are common in Medicare patients. As the Food and Drug Administration ("FDA") has acknowledged, "Congress intended these foods to be an

[1] 69 Federal Register 46632, 46660 (August 3, 2004).

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integral component of the clinical management of patients."[2] Medical foods often are too expensive for patients to purchase on their own, however. It is appropriate that Medicare cover these highly cost-effective products.

The Institute of Medicine ("IOM") has assessed the value and benefit of providing Medicare coverage for certain nutritional services. Earlier this year, the IOM concluded that "[r]eimbursement systems must be strengthened to ensure provision of adequate nutrition care in acute care, home care, dialysis centers, and skilled nursing and long-term care facilities."[3] In particular, the IOM stated:

> To avoid the complications of extended semistarvation and possible rehospitalization, reimbursement for enteral or parenteral nutrition in selected Medicare beneficiaries who would otherwise be unable to eat or to assimilate adequate nutrition due to gastrointestinal dysfunction or neurological impairment for longer than 7 days, must be evaluated as a prudent, potentially cost-saving, alternative. Patients who are already malnourished or highly stressed due to infection or response to trauma may not even tolerate this duration of starvation or semistarvation.[4]

In accordance with the IOM recommendation, CMS should clarify that Part D plan sponsors must cover medically necessary, physician-ordered medical foods. As described in detail below, these products provide significant benefits. Medical foods can help prevent malnutrition and its associated costs. Three specific products, Foltx®, Diatx®, and Cerefolin™, provide excellent examples of medical foods that should be covered for the management of sulphur-bearing amino-acid metabolism disturbances and the management of conditions resulting from deficiencies in particular micronutrients.

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[2] 61 Federal Register 60661, 60668 (November 29, 1996).

[3] Committee on Nutrition Services for Medicare Beneficiaries, Institute of Medicine, The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population 3 (2004)["IOM Report"].

[4] *Id.* at 320.

Enteral medical foods are preferred over parenteral nutrition in many circumstances, yet have a lower cost and result in fewer complications. Coverage of medical foods also will provide a consistent benefit to patients who are dually eligible for both Medicare and Medicaid ("dual-eligibles") and to retirees for whom drug coverage will now be provided by Medicare.

CMS can cover medical foods under the Medicare Prescription Drug Improvement, and Modernization Act of 2003 ("MMA"),[5] although CMS might limit coverage to only those medical foods that are dispensed upon a prescription or order. Medical foods can be considered "covered part D drugs" because the term includes more than just drugs. Medical foods are of proven scientific value, and CMS should exempt medical foods from the requirement for FDA approval because FDA has determined that medical foods need not be approved. Finally, medical foods cannot be excluded as "prescription vitamins."

I. Background

A. Definition of Medical Foods

A thorough discussion of the definition of medical foods is included in our comments to the U.S. Pharmacopeia regarding the draft Model Guidelines for the Part D benefit. We attach those comments as Appendix 1, and do not reiterate them here.

Briefly, a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."[6] Congress enacted this definition as part of the Orphan Drug Act. In FDA's view, this definition narrowly constrains the types of products that can be considered medical foods.[7] FDA has

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[5] Pub. L. No. 108-173 (Dec. 8, 2003).

[6] 21 U.S.C. § 360ee(b)(3). FDA originally created an administrative category for medical foods in 1972. *See* 37 Federal Register 18229, 18230 (September 8, 1972).

[7] 56 Federal Register 60366, 60377 (November 27, 1991).

identified four primary categories of medical foods: medical foods for metabolic disorders, nutritionally complete formulas, nutritionally incomplete formulas, and oral rehydration products.[8]

Goals in the use of medical foods include ameliorating clinical manifestations of disease, favorably influencing the disease process, and positively influencing morbidity and mortality, *i.e.*, patient outcomes.[9] Medical foods have been described as a form of life-support system, because they "often provide the sole source of nourishment for their intended populations."[10] Indeed, FDA recognizes that the products "are used extensively as a life support modality in the management of the critically ill and elderly."[11]

B. Current Coverage of Medical Foods

Medicare Part B currently provides limited coverage for the outpatient use of medical foods, through the prosthetic device benefit.[12] The coverage applies only to nutrients taken through a feeding tube. In order to quality for the benefit, the patient must not be able to maintain weight or strength through oral feeding as a result of pathology or nonfunction of the structures that normally permit food to reach the digestive tract. The impairment must last for more than 90 days. A limited number of disorders can meet these criteria.[13]

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[8] Center for Food Safety and Applied Nutrition, Food and Drug Administration, Food Compliance Program: Medical Foods - Import and Domestic (issued December 21, 1998; last amended September 30, 2001) ["FDA Food Compliance Program"].

[9] Life Sciences Research Office, Federation of American Societies for Experimental Biology, Guidelines for the Scientific Review of Enteral Food Products for Special Medical Purposes 10 (1990) ["FASEB Guidelines"].

[10] David G. Hattan, Ph.D. & Denis R. Mackey, M.Ph., A Review of Medical Foods: Enterally Administered Formulations Used in the Treatment of Diseases and Disorders, 44 Food, Drug & Cosmetic L.J. 479, 494 (1989).

[11] FDA Food Compliance Program.

[12] Medicare Coverage Issues Manual §§ 65-10, -10.2.

[13] *See id.* § 65-10.2 (providing a list of typical diseases).

The IOM concluded that this limited coverage "needs to be reevaluated."[14] Patients cannot receive the benefit if they are able to take enough food by mouth to maintain strength, even if they are unable to take the correct balance of nutrients. Any patient with a disorder that will last for 90 or fewer days is ineligible for coverage, although a patient may suffer from severe malnutrition after fewer than 90 days. If the regulations implementing Part D do not specify that plans must cover medical foods, these patients will continue to be at risk.

Some Medicare-Medicaid dual-eligibles receive coverage for medical foods through their state Medicaid programs. Almost all state Medicaid programs cover medical foods that are taken by tube, and more than two-thirds of the states cover medically necessary medical foods taken orally.[15] For instance, Oregon's Medicaid program considers home use of medical foods by mouth or by tube to be "medically appropriate to maintain body mass and prevent nutritional depletion which occurs with some illnesses or pathological conditions."[16] The medical food must be dispensed upon a physician's written order or prescription.[17] Some states may cover medical foods only for particular diagnoses. Some state Agencies on Aging also may cover medical foods under Medicaid waiver programs.

In addition, a number of states mandate that private insurance plans cover medical foods. Maine, for instance, requires that "[a]ll group insurance policies and contracts . . . must provide coverage for metabolic formula and special modified low-protein food products that have been prescribed by a physician for a person with an inborn error of metabolism."[18] Similarly, Vermont requires health insurance companies, nonprofit hospital and medical service corporations, managed

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[14] IOM Report, *supra* note 3 at 17.

[15] *See* Reimbursement: Medicaid Policy/Coverage, *at* http://www.ross.com/reimbursement/Medicaid.asp.

[16] Oregon Department of Human Services, Office of Medical Assistance Programs, Home Enteral/Parenteral Nutrition and IV Services: Billing and Procedures Guide § 410-148-0040(2) (Aug. 1, 2004).

[17] *Id.* § 410-148-0020.

[18] Me. Rev. Stat. Ann. tit. 24-A, § 2837-D(2) (2003). The provision does not apply to limited benefit health insurance policies and contracts.

care organizations, and health maintenance organizations to cover "medical foods prescribed for medically necessary treatment for an inherited metabolic disease."[19]

II. CMS Should Cover Medical Foods in the Part D Drug Benefit

Medical foods are a cost-effective disease management tool. The IOM concluded that expanded coverage for nutrition therapy, with the accompanying reduction in healthcare expenditures, is likely to generate economically significant benefits for the Medicare program.[20] By covering these products, Medicare may avoid the expense of treating malnutrition as well as the incidental effects of metabolic disorders.

The IOM concluded that Medicare should expand coverage of these products——even in the absence of cost savings——because medical foods play an important role in improving patient outcomes.[21] Enteral products provided on an outpatient basis offer many advantages over parenteral feeding, which is a covered Medicare benefit. Omission of these products from the Part D benefit could endanger the health of more than 4.6 million dual-eligibles and retirees, who may have to discontinue their use of these products when the Part D benefit takes effect.

A. Cost Effectiveness

Medical foods are cost-effective tools of disease management. Omission of medical foods from Part D plans will increase Medicare's overall patient care expenses for two reasons. First, patients requiring specialized, nutritionally complete medical foods or a combination of nutritionally incomplete formulas are at risk of malnutrition if Medicare does not cover the necessary products. Malnutrition increases morbidity and mortality, increases the length of hospital stays, and increases overall treatment costs. Second, patients with inborn metabolic disorders are unable to metabolize certain dietary ingredients. Consumption of particular nutrients or

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[19] Vt. Stat. Ann. tit. 8 § 4089e (2003).

[20] IOM Report, *supra* note 3 at 19.

[21] *Id.* at 20.

micronutrients could jeopardize their health. Medical foods are often the best solution for these patients.

1. Some Patients Are Likely to Suffer Malnutrition in the Absence of Medical Food Coverage

Malnutrition may result if medical foods are not covered by Part D. The IOM has concluded that enteral nutrition is effective "in preventing complications and overt malnutrition . . . for many conditions."[22] Medical foods are too expensive for many patients to purchase on their own, however.[23]

Many elderly patients are malnourished when admitted to the hospital, due to a long period of starvation caused by their underlying disease.[24] The effects of malnutrition often are heightened in elderly patients whose defenses already may be weakened.[25] One study described malnourished seniors:

> The patients had entered the hospital from independent living situations, but at the time of the study they were bedridden, confused, and slated for entry into chronic care institutions. Following nutritional rehabilitation, not only did their symptoms diminish, but many of the patients were discharged to their homes.[26]

By covering medical foods, CMS can prevent some of these hospital admissions altogether.

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[22] *Id.* at 12.

[23] "Like essential amino acid supplements, [liquid meal replacements with low levels of electrolytes] are too expensive for many ESRD patients to purchase." IOM Report, *supra* note 3 at 145, 240.

[24] Mardi K. Mountford, M.Ph. & Richard E. Cristol, The Enteral Formula Market in the United States, 44 Food Drug Cosm. L.J. 503, 507 (1989).

[25] Donald M. Watkin & David A. Lipschitz, Enteral Nutrition for Older Persons, in Enteral and Tube Feeding 480, 488 (John L. Rombeau & Michael D. Caldwell eds., 1984).

[26] Hattan & Mackey, *supra* note 10 at 488, *citing* Lipschitz & Mitchell, The Correctability of the Nutritional, Immune and Hematopoietic Manifestations of Protein-Calorie Malnutrition in the Elderly, 1 J. Am. Clinical Nutrition 17 (1982).

Covering outpatient medical foods can reduce the length and cost of hospital stays. Older patients who are malnourished when they enter the hospital have double the actual hospital charges of properly nourished patients. They stay in the hospital an average of 5.6 days longer than properly nourished patients.[27] Studies also have demonstrated that poorly nourished patients have three times the number of major complications as well-nourished patients, take longer to recover, and are three times more likely to die during hospitalization.[28]

Nutritionally complete medical foods, which constitute one category of medical food identified by FDA, can help prevent malnutrition among patients with particular disorders. These products provide protein, fat, carbohydrates, vitamins, and minerals in sufficient quantities to maintain a normal individual's nutritional status. The products may vary in compositional profile, *e.g.*, amount of fiber, caloric density, or lactose content.

Nutritionally complete medical foods are recommended in the clinical management of a wide variety of disorders and conditions. For instance, the scientific community broadly supports the use of commercial medical foods by patients with certain types of liver disease, including decompensated cirrhosis and encephalopathy, ascetic cirrhosis, and active and chronic hepatitis.[29] Research supports the use of medical foods

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[27] American Dietetic Ass'n, Position of the American Dietetic Association: Cost-Effectiveness of Medical Nutrition Therapy, 95 J. Am. Dietetic Assn 88, 88 (1995), *citing* G. Robinson *et al.*, Impact of Nutritional Status DRG Length of Stay, 11 JPEN 49 (1987). *See also* Hattan & Mackey, *supra* note 10 at 487 n.28.

[28] Position of the American Dietetic Association, *supra* at 90; Hattan & Mackey, *supra* note 10 at 489, *citing* Presentation by Anita Owen, Pres., American Dietetic Assn of Study Conducted by Arthur Anderson & Co. at Congressional Briefing on Cost Effectiveness of Nutrition Support, Washington, DC (Jan. 23, 1986). *See, e.g.*, Watkin & Lipschitz, *supra* note 25 at 489.

[29] FASEB Guidelines at 31. *See, e.g.,* Danny O. Jacobs *et al.*, *Enteral Nutrition and Liver Disease*, *in* Enteral and Tube Feeding 376, 393-397; Howard Levinsky & Alan H. Spiro, Nutritional Support and the Liver, *in* Hyperalimentation: A Guide for Clinicians 299, 307-309 (Mitchell V. Kaminski, Jr. ed., 1985).

by patients suffering from malabsorption disorders such as Crohn's disease, short bowel syndrome, and inflammatory bowel disease;[30] other gastrointestinal diseases;[31] hypermetabolic stress, including that arising from general surgery and trauma; and acute and chronic renal disorders.[32]

Specific medical foods also may meet the special energy, vitamin, mineral, and amino acid requirements of cancer patients.[33] As one clinician states, "enteral nutrition support is of immense, often life-saving, value . . . during the acute and stressful phase encountered during therapy."[34] Other clinicians have asserted that "[i]mproving the nutritional state of patients should improve their sense of well-being, their ability to withstand aggressive cancer treatment, and, it is hoped, their survival."[35]

2. Some Patients Would Be at Risk if They Ate Standard Diets

Some inborn metabolic disorders present such risks that patients cannot consume standard or even certain specialized diets. Medical foods have been specially formulated for patients with specific metabolic disorders such as phenylketonuria ("PKU"), homocysteinuria, glutaric acidemia type I, tyrosinemia types I and II, proprionic anemia, urea cycle

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[30] *See, e.g.,* James Betzhold & Lyn Howard, *Enteral Nutrition and Gastrointestinal Disease*, *in* Enteral and Tube Feeding 338, 345-348.

[31] Catherine H. Bastian & Richard H. Driscoll, Enteral Tube Feeding at Home, *in* Enteral and Tube Feeding 494, 498.

[32] *See, e.g.,* William P. Steffee & Carl F. Anderson, *Enteral Nutrition and Renal Disease*, *in* Enteral and Tube Feeding 362, 362-363; IOM Report, *supra* note 3 at 134, 147.

[33] "While nutritional support does not cure cancer, it can help patients successfully overcome the rigors of the disease and its treatments, and it can improve the quality of their lives." Hattan & Mackey, *supra* note 10 at 488. *See also* Mountford & Cristol, *supra* note 24 at 507; Michael M. Meguid *et al.*, The Use of Enteral Nutrition in the Patient with Cancer, *in* Enteral and Tube Feeding 303, 316.

[34] Meguid *et al.*, *supra* at 330.

[35] John E. Kehoe & John M. Daly, Nutrition in Cancer Patients, *in* Hyperalimentation: A Guide for Clinicians 399, 399.

disorders, and maple syrup urine disease. These medical foods provide complete nutrition for the target patient group, although the products may lack particular nutrients that would be essential for normal patients, *e.g.*, products for phenylketonurics do not contain phenylalanine ("Phe").

The American Academy of Pediatrics Committee on Nutrition has taken the position that commercial medical foods should be reimbursable when used "for the active, ongoing treatment of diagnosed amino acid and urea cycle disorders."[36] Without nutritional management, "these diseases culminate in severe mental retardation or death."[37] The Committee classifies these uses as "indispensable."[38]

The National Institutes of Health similarly concluded that for PKU patients, "specialized medical foods and low-protein products are a medical necessity and should be treated as such. Reimbursement for these medical foods and products should be covered by third-party providers."[39] The clinical management of PKU involves "strict metabolic control using a low-Phe diet that includes specialized medical foods."[40] Data suggest that a failure to adhere to the specialized diet can adversely affect aspects of cognitive function in children, adolescents, and adults.[41] Most clinical practices advocate lifelong dietary treatment.[42] While scientists actively are exploring non-dietary treatments for PKU, none of these treatments have yet been proven effective. Phenylketonurics depend upon access to specialized diets.

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[36] Committee on Nutrition, American Academy of Pediatrics, Reimbursement for Medical Foods for Inborn Errors of Metabolism, 93 Pediatrics 860 (1994).

[37] *Id.*

[38] *Id.*

[39] National Institutes of Health, Phenylketonuria (PKU): Screening and Management, 17 NIH Consensus Statement No. 3, 17 (2000). Among the earliest recognized medical foods, Lofenelac was developed for infants and children with PKU.

[40] *Id.* at 3.

[41] *Id.* at 14, 19.

[42] *Id.* at 12.

3. Specific Medical Food Examples

Foltx®, Diatx®, and Cerefolin™ are examples of medical foods that should be covered under Medicare Part D. Scientific evidence supports their use when prescribed by a physician for the clinical management of specific diseases and conditions. These products manufactured by Pamlab each contain the micronutrients folate, vitamin $B_{12,}$ and vitamin B_6.

These three medical foods have been specially formulated to meet the distinctive nutritional requirements of diseases relating to disturbances of sulphur-bearing amino-acid metabolism. Foremost among these diseases are hyperhomo-cysteinemia and hyperhomocysteinuria. Homocysteinuria is the second most prevalent inborn error of metabolism after PKU. Clinical studies have demonstrated a relationship between elevated total homocysteine levels and such effects as coronary artery disease, peripheral artery disease, stroke, venous thrombosis, cognitive impairment, dementia, and Alzheimer's disease.[43] Many patients with these conditions consider medical foods essential to their continued good health.

These three medical foods also are important tools in caring for patients suffering from deficiencies in the micronutrients folate, vitamin $B_{12,}$ and vitamin B_6. Deficiencies in these micronutrients may lead to a number of diseases, yet 15% of elderly Americans evidence vitamin B_{12} deficiency.[44] All three of the micronutrients are important in the metabolism of homocysteine, so deficiencies may lead to hyperhomocysteinemia and hyperhomocysteinuria, as described above. Vitamin B_{12} deficiency can lead to macrocytic or pernicious anemia as well as a spectrum of neuropsychiatric disorders including dementia and depression. Patients with B_{12} deficiency also are at increased risk of stroke and myocardial infarction.[45] Medicare

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[43] Otter Nygard *et al.*, Plasma Homocysteine Levels and Mortality in Patients with Coronary Artery Disease, 337 New Eng. J. Med. 230 (1997); Sudhar Seshadri *et al.*, Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease, 346 New Eng. J. Med. 476 (2002).

[44] T.S. Dharmarajan *et al.*, *The Need to Screen: A Case in Point*, *in* Vitamin B_{12} Deficiency 9 (Victor Herbert ed., 1999).

[45] Robert C. Oh *et al.*, Vitamin B_{12} Deficiency, 67 Am. Family Physician 979 (2003).

coverage of these products will help these patients maintain good health and avoid costly hospitalizations.

B. Benefits of Enteral Nutrition over Parenteral Nutrition

Enteral nutrition is preferable to parenteral nutrition in many cases, yet Medicare fully covers only parenteral nutrition. Enteral feeding provides "a more physiologic, safer, less time-consuming, and less expensive method of nutritional support" than parenteral nutrition.[46] Indeed, one commentator suggests that "enteral nutrition is the biggest bargain in nutrition today; the gastrointestinal tract is the safest, simplest, least expensive, and most physiological 'catheter' available for alimentation."[47] In fact, parenteral therapy may cost ten to twelve times as much as enteral feeding.[48]

The physiologic benefits of the enteral route are well documented and are evidenced by the well-known dictate, "If the gut works, use it."[49] Among other benefits, enteral nutrition can maintain intestinal epithelium and gut organ mass, and may increase mucosal weight, DNA and protein content, and enzyme activities.[50] Oral feeding avoids the complications that are common with parenteral feeding, including catheter-related infections, mechanical problems, metabolic difficulties related to the nutritional formula, and micronutrient deficiencies.[51]

C. Dual-Eligibles

If Part D plans do not include medical foods, dual-eligibles and some retirees may be forced to discontinue their use of medical foods on January 1, 2006. Once the Part D

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[46] Bastian & Driscoll, *supra* note 31 at 495.

[47] Hattan & Mackey, *supra* note 10 at 498.

[48] Mountford & Cristol, *supra* note 24 at 509.

[49] Bastian & Driscoll, *supra* note 31 at 495.

[50] Meguid *et al.*, *supra* note 33 at 316; Gayle D. Pinchcofsky-Devin *et al.*, Enteral Hyperalimentation, *in* Hyperalimentation: A Guide for Clinicians 99, 103.

[51] Office of Technology Assessment, U.S. Congress, Life-Sustaining Technologies and the Elderly, OTA-BA-306 284 (1987).

benefit takes effect, Medicare will become the primary payor for dual-eligibles, and some private retiree plans may shift enrollees to Part D plans for drug coverage. Beneficiaries thus may lose their coverage if they reside in states that cover medical foods under their Medicaid program or that require private health plans to cover medical foods.

This result would be particularly unfair to dual-eligibles. The 6.4 million patients who currently have access to medical foods through their state's Medicaid program are among the poorest and most vulnerable in our population. Malnutrition or improper nutritional management could have devastating effects on their health. Their nutritional health is likely to deteriorate if the Part D benefit does not cover medical foods.

III. CMS Can Cover Medical Foods in the Part D Drug Benefit

Under the MMA, Part D plans must cover certain "covered part D drugs." "Covered part D drug" includes more than just drugs. The statute specifies that "covered part D drug" includes biologic products, which FDA regulates differently than drugs.[52] Furthermore, the statute references the Medicaid definition of "prescribed drugs." The Medicaid regulations define "prescribed drugs" to include "simple or compound *substances or mixtures of substances* prescribed for the cure, mitigation, or prevention of disease, *or for health maintenance*" that are prescribed by a licensed practitioner and dispensed by a licensed pharmacist.[53] Thus, "covered part D drug" includes products other than drugs, and can include medical foods.

Under the statute, a product will be considered to be a covered part D drug only if it "may be dispensed only upon a prescription."[54] Additionally, covered part D drugs include only those products that have been approved under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or that were approved by FDA before enactment of the 1962 Drug Amendments and have not been determined by FDA to be less than effective for some or all of their labeled uses. The statute also excludes prescription vitamins and minerals from coverage. None of these

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[52] Social Security Act ("SSA") § 1860D-2(e)(1)(B).

[53] 42 C.F.R. § 440.120 (emphasis added).

[54] SSA § 1860D-2(e)(1)(A).

statutory provisions should prevent CMS from requiring Part D plans to cover medical foods.

A. Dispensed Upon a Prescription

Although FDA's regulatory structure technically allows limited over the counter sales of medical foods, CMS can limit Part D coverage of medical foods to those products that are dispensed upon a physician's prescription or order. In this way, CMS can cover medical foods and comply with the statutory requirements. In recommending a similar approach, the IOM noted that "basing nutrition therapy on referral from a physician . . . will prevent self-referral for conditions for which evidence of efficacy is not available."[55]

This restriction on Part D coverage would complement FDA's restrictions on medical foods. FDA's definition of medical foods specifies that the products must be used under a physician's supervision.[56] A physician must determine that a specific medical food is necessary for the patient, and the patient must be subject to active and ongoing medical supervision "for, among other things, instructions on the use of the medical food."[57] Indeed, the FDA website describes medical foods as being "*prescribed* by a physician when a patient has special nutrient needs in order to manage a disease or health condition, and the patient is under the physician's ongoing care."[58]

B. Approved Drug

The statute specifies that a product must be approved by FDA in order to qualify as a "covered part D drug." FDA recognized, however, that the public health would be better served by not requiring medical foods to meet the New Drug

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[55] IOM Report, *supra* note 3 at 313.

[56] FDA Food Compliance Program.

[57] 21 C.F.R. § 101.9(j)(8)(v).

[58] Center for Food Safety and Applied Nutrition, Food and Drug Administration, Medical Foods, *at* http://www.cfsan.fda.gov/~dms/ds-medfd.html (posted May 1997)(emphasis added). In accordance with these requirements, the medical foods Foltx®, Diatx®, and Cerefolin™ described above are labeled for use under the direction of a physician.

Application ("NDA") requirements. For similar public health reasons, CMS should exempt medical foods from the requirement that covered part D drugs must be FDA-approved.

Each marketed medical food is of proven scientific value. FDA has made clear that "[i]t is not enough that a manufacturer merely declare or subjectively intend that the [medical food] product be used for the dietary management of patients with certain diseases or conditions."[59] In FDA's words, "[t]here should be sound, scientifically defensible evidence that the product does what it claims to do."[60] The nutritional requirements associated with a disease or disorder first must be established through recognized scientific principles and established by medical evaluation. The medical food's characteristics, including its formulation and claims, then must be based on those scientifically validated nutritional requirements.

Active enforcement by government agencies keeps unproven medical foods off the market. The Federal Trade Commission ("FTC") in particular has been active in bringing actions against manufacturers of purported medical foods that lack scientific support for their claims. In 2003, for instance, FTC alleged that Unither Pharma and United Therapeutics lacked scientific evidence for their claims regarding HeartBar, a purported medical food.[61] In a consent agreement, the companies

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[59] "[B]ecause the statutory definition of a medical food provides that these foods are part of the clinical management of a disease or condition, the definition necessarily incorporates a requirement that the product actually meet the distinctive nutritional requirements for the disease or condition." 61 Federal Register at 60669. FDA reiterated this opinion in a 1995 letter to the manufacturer of Ensure: "Congress established a strict standard for determining when a food is a medical food. It is inconceivable that the statute should not also be interpreted as establishing a similarly strict standard for determining whether the medical food meets the distinctive nutritional requirements of the patient for whom it was formulated." Letter from Elizabeth A. Yetley, Director, Office of Special Nutritionals, FDA to Michael H. Haney, Director, Regulatory Affairs, Ross Products Division, Abbott Laboratories 2 (November 2, 1995).

[60] 61 Federal Register at 60666.

[61] *See* Complaint, *In the Matter of* Unither Pharma, Inc. and United Therapeutics Corp. (File No. 022 3036), *available at* http://www.ftc.gov/os/2003/06/unithercmp.htm.

agreed to refrain from making any claim unless the companies first possess "competent and reliable scientific evidence" to substantiate the claim.[62] The companies also agreed to request that HeartBar sellers and distributors refrain from using violative promotional materials.[63]

Although FDA and FTC require scientific support for medical foods' claims, FDA affirmatively chose to release medical foods from the NDA requirement. The early medical food Lofenelac originally was marketed as a prescription drug under an NDA. FDA reclassified the product as a medical food in 1972. As the then-FDA Chief Counsel stated, "The agency realized that these products simply could not be developed under an NDA and consciously determined to develop a regulatory approach designed to facilitate their marketing in order to promote the public health."[64] The lengthy and expensive premarket trials and premarket approval would have stymied the development of much-needed products.[65]

FDA recognized that it is a practical impossibility to obtain for medical foods the specific data required for an NDA submission. Dose-ranging studies and studies to satisfy the combination drug policy are impossible in the context of complex combinations of natural and synthetic nutrients and other food components. Furthermore, FASEB acknowledges that it can be impractical and sometimes impossible to obtain data about a medical food's effect on patient mortality and morbidity. The group concludes that improvement in clinical manifestations of disease is an "important question" in medical foods research.[66] Because medical foods in fact and by regulation cannot be approved, it would be manifestly unfair to patients to refuse to cover medical foods on the basis of their lack of approval.

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[62] Agreement Containing Consent Order § I, *In the Matter of* Unither Pharma, Inc. and United Therapeutics Corp. (File No. 022 3036), *available at* http://www.ftc.gov/os/2003/06/unitheragree.htm.

[63] *Id.* § VI.

[64] Peter Barton Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food Drug Cosm. L.J. 3, 70 (1986).

[65] I. Scott Bass, A Legal Overview of the Status of Medical Foods in the United States, 44 Food Drug Cosm. L.J. 467, 470 (1989).

[66] FASEB Guidelines at 10 - 11.

C. Exclusion of Prescription Vitamins

Prescription vitamins and minerals, other than prenatal vitamins and fluoride preparations, are excluded from coverage under Part D.[67] This exclusion does not affect medical foods, however. As discussed above and in Appendix 1, medical foods are significantly different from vitamins, minerals, and other dietary supplements. FDA has stated explicitly that "medical foods are not dietary supplements for the general population."[68]

IV. Conclusion

Physicians and researchers view medical foods as essential tools in protecting and preserving the health of a particular segment of Medicare beneficiaries. For patients with inherited metabolic disorders and certain other diseases and conditions, medical foods are the best source of complete nutritional support. If patients cannot afford these products, malnutrition and the accompanying complications are likely to result. The poorest Medicare beneficiaries are at particular risk. CMS can and should require Part D plans to cover medically necessary medical foods prescribed or ordered by a physician. In so doing, CMS will ensure that all Medicare beneficiaries, including the dual-eligibles whose medical foods currently are covered by state Medicaid programs, have access to the complete range of physician-recommended disease management tools.

Sincerely,

/Barry D. LeBlanc/

Barry D. LeBlanc
President
Pamlab, LLC

Enclosure

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[67] SSA §§ 1860D-2(e)(2)(A), 1927(d)(3)(F).

[68] FDA Food Compliance Program. Similarly, FDA has distinguished medical foods from foods that "are formulated and marketed for use by the general population as supplements to a normal diet or as meal replacements." 61 Federal Register at 60664.

APPENDIX 1

Pamlab, L.L.C.

Quality Pharmaceuticals Since 1957

Barry D. LeBlanc
President and C.O.O.

September 17, 2004

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

Re: Comments to the Draft Model Guidelines

Dear Ms. Lang:

Pamlab, LLC ("Pamlab") appreciates the opportunity to comment on the draft Model Guidelines for the Medicare Part D drug benefit. Pamlab is a manufacturer of drugs and medical foods based in Covington, Louisiana. We at Pamlab encourage the United States Pharmacopeia ("USP") to clarify the draft Model Guidelines to allow for the inclusion of medical foods on Medicare Part D plan formularies.

Specifically, we propose two types of amendments to the draft Model Guidelines, both of which are consistent with the ICD-9 system for disease-linked therapeutic categories and pharmacologic classes. First, Medicare Part D plan formularies should include medical foods prescribed for the management of sulphur-bearing amino-acid metabolism disturbances, consistent with ICD-9 Code 270.4. To this end, we suggest that USP add a subdivision labeled "Medical Foods" to the pharmacologic class "Antianemic Agents," in the therapeutic category "Blood Products/Modifiers/Volume Expanders." Similarly, we recommend that USP include a subdivision labeled "Medical Foods" in the pharmacologic class "Antilipemic Agents," in the therapeutic category "Cardiovascular Medications."

Second, Part D plan formularies should include medical foods prescribed for a patient's particular medical needs. We recommend that the Model Guidelines include a pharmacologic class "Medical Foods" in the therapeutic category "Therapeutic Nutrients/Minerals/Electrolytes." We recommend adding "Micronutrients" as a recommended subdivision in this class.[69]

These changes to the draft Model Guidelines are necessary to allow drug plans to meet the expectation voiced by the Centers for Medicare and Medicaid Services ("CMS") that all plan formularies cover "an amount and variety of drugs sufficient to treat all disease states."[70] CMS's

[69] Alternatively, USP might eliminate the pharmacologic class "Therapeutic Nutrients" altogether. Plans then would be able to cover any two products falling within the category "Therapeutic Nutrients/Minerals/Electrolytes."

[70] 69 Federal Register 46632, 46660 (August 3, 2004).

proposed regulations do not exclude medical foods from coverage under the new Medicare Part D. We believe that such products may be covered under Part D, and our comments to CMS will ask the agency to make this point more clear.

As discussed in greater depth below, medical foods are essential tools in the clinical management of diseases that are common in Medicare patients. These comments first provide background information relating to medical foods generally, which will help to illustrate the distinction between medical foods and other foods and dietary supplements. These comments then provide information about the use of three particular medical foods in the management of sulphur-bearing amino-acid metabolism disturbances and in the management of conditions resulting from deficiencies in particular micronutrients. Select scientific references supporting these assertions are listed in Appendix A.

I. Medical Foods

Medical foods are more than food. Medical foods are physician-directed patient interventions that are essential tools of disease management. As the Food and Drug Administration ("FDA") has acknowledged, "Congress intended these foods to be an integral component of the clinical management of patients."[71] Goals in the use of medical foods include ameliorating clinical manifestations of disease, favorably influencing the disease process, and positively influencing morbidity and mortality, *i.e.*, patient outcomes.[72]

Medical foods have been described as a form of life-support system, because they "often provide the sole source of nourishment for their intended populations."[73] Indeed, FDA recognizes that the products "are used extensively as a life support modality in the management of the critically ill and elderly."[74]

A. Definition of "Medical Food"

Under the statutory definition of the term enacted as part of the Orphan Drug Act, a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific

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[71] 61 Federal Register 60661, 60668 (November 29, 1996).

[72] Life Sciences Research Office, Federation of American Societies for Experimental Biology, Guidelines for the Scientific Review of Enteral Food Products for Special Medical Purposes 10 (1990) ["FASEB Guidelines"].

[73] David G. Hattan, Ph.D. & Denis R. Mackey, M.Ph., A Review of Medical Foods: Enterally Administered Formulations Used in the Treatment of Diseases and Disorders, 44 Food, Drug & Cosmetic L.J. 479, 494 (1989).

[74] Center for Food Safety and Applied Nutrition, Food and Drug Administration, Food Compliance Program: Medical Foods - Import and Domestic (issued December 21, 1998; last amended September 30, 2001) ["FDA Food Compliance Program"].

principles, are established by medical evaluation."[75] In FDA's view, this definition narrowly constrains the types of products that can be considered medical foods.[76] FDA clarifies this definition in its nutrition labeling regulations.[77] In so doing, FDA further limits the range of products that can be considered to be medical foods, as described below.

FDA has interpreted the definition further in two documents. First, FDA promulgated an advance notice of proposed rulemaking regarding medical foods. This document provides insight into FDA's understanding of medical foods. Although FDA did not take further action on the proposed rulemaking and withdrew the proposal for administrative reasons, FDA has not repudiated its statements. Second, FDA issued in 1998 a Food Compliance Program document titled Medical Foods - Import and Domestic. This document, amended in 2001, remains in effect.

FDA's documents clarify the definitional phrases "specific dietary management," "distinctive nutritional requirements," "scientific principles and medical evaluation," and "supervision by a physician." These clarifications help to illustrate that medical foods are a discrete group of products, different from other foods and different from dietary supplements. These highly specialized products are a vital component of care for patients with certain diseases.

1. Specific Dietary Management of a Disease or Condition

Medical foods must be formulated or promoted for the dietary management of a particular disease or condition. Foods "designed to address a problem that is common to several diseases, but not the full range of requirements of any specific disease" are not considered to be medical foods.[78]

Medical foods do not include generalized formulas that are not designed to address any specific disease entity. Thus, products marketed to the general population as supplements to a normal diet or as meal replacements are not medical foods.[79] Similarly, medical foods do not include products "recommended by a physician as part of an overall diet designed to reduce the

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[75] 21 U.S.C. § 360ee(b)(3). FDA originally created an administrative category for medical foods in 1972. *See* 37 Federal Register 18229, 18230 (September 8, 1972).

[76] 56 Federal Register 60366, 60377 (November 27, 1991). Some products are labeled as medical foods but do not meet the FDA definition of medical foods. Pamlab's comments to CMS will reflect the need for regulatory specificity regarding Part D coverage of medical foods. In addition, plan pharmacy and therapeutics committees are well qualified to judge the merit of different products claiming to be medical foods.

[77] 21 C.F.R. § 101.9(j)(8). These regulations exempt medical foods from nutrition labeling health claim, and nutrient content claim requirements, as ordered by the Nutrition Labeling and Education Act of 1990. 21 U.S.C. §§ 343(q)(5)(A)(iv), (r)(5)(A).

[78] 61 Federal Register at 60668. These products instead are foods for special dietary use.

[79] "Medical foods are not dietary supplements for the general population that can be openly purchased from retail shelves or by mail order." FDA Food Compliance Program.

risk of a disease or medical condition, to lose or maintain weight, or to ensure the consumption of a healthy diet."[80]

2. Distinctive Nutritional Requirements

Medical foods must "[b]e labeled for the dietary management of a medical disorder, disease, or condition" that results in distinctive nutritional requirements.[81] In FDA's view, relatively few diseases can meet this high standard.[82] FDA has clarified that distinctive, disease-related nutritional requirements "reflect the total requirement needed by a healthy person, adjusted for the distinctive changes in the nutritional needs of the patient due to the effect of the disease process on metabolism, absorption, or excretion. These distinctive nutritional requirements … may be greater than, less than, or in a narrower range of tolerance than for an otherwise healthy individual…."[83]

Distinctive nutritional requirements may include physical or psychological limitations in a person's ability to ingest or digest conventional foods. FDA's regulations clarify that medical foods may be labeled for use by patients with limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foods or particular nutrients.[84] Medical foods also may be labeled for use by patients with conditions that result in medically determined nutrient requirements that cannot be managed solely through modification of the normal diet, according to FDA.[85]

3. Scientific Principles and Medical Evaluation

FDA has made clear that "[i]t is not enough that a manufacturer merely declare or subjectively intend that the [medical food] product be used for the dietary management of patients with certain diseases or conditions."[86] In FDA's words, "There should be sound, scientifically

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[80] 61 Federal Register at 60668.

[81] 21 C.F.R. § 101.9(j)(8)(iii). Although the regulations specify that the nutritional needs be "unique," FDA has clarified that the needs merely must be "distinctive." 61 Federal Register at 60663 n.2.

[82] Letter from Elizabeth A. Yetley, Director, Office of Special Nutritionals, FDA to Michael H. Haney, Director, Regulatory Affairs, Ross Products Division, Abbott Laboratories 3 (November 2, 1995).

[83] *Id.* at 2-3.

[84] 21 C.F.R. § 101.7(j)(8)(ii).

[85] *Id*.

[86] "[B]ecause the statutory definition of a medical food provides that these foods are part of the clinical management of a disease or condition, the definition necessarily incorporates a requirement that the product actually meet the distinctive nutritional requirements for the disease or condition." 61 Federal Register at 60669. FDA reiterated this opinion in a 1995 letter to the manufacturer of Ensure: "Congress established a strict standard for determining when a food is a medical food. It is inconceivable that the statute should not also be interpreted as establishing a similarly strict standard for determining whether the medical food meets the distinctive nutritional requirements of the patient for whom it was formulated." Letter from Yetley, FDA to Haney, Abbott Laboratories, *supra* note 14, at 2.

defensible evidence that the product does what it claims to do."[87] The nutritional requirements associated with the disease or disorder first must be established through recognized scientific principles and established by medical evaluation. The medical food's characteristics, including both formulation and claims, must be based on those scientifically-validated nutritional requirements.

4. Supervision of a Physician

Medical foods must be used under a physician's supervision.[88] Specifically, the physician must determine that a specific medical food is necessary for the patient, and the patient must be subject to active and ongoing medical supervision "for, among other things, instructions on the use of the medical food."[89] Indeed, the FDA website describes medical foods as being "*prescribed* by a physician when a patient has special nutrient needs in order to manage a disease or health condition, and the patient is under the physician's ongoing care."[90]

As one aspect of physician supervision, medical foods must be "primarily obtained through hospitals, clinics, and other medical and long term care facilities."[91] Under the present regulatory structure, medical foods technically may be sold over the counter. Nonetheless, most manufacturers of true medical foods take steps to ensure that their products are used only upon a physician's order.

B. Existing Types of Medical Foods

FDA has identified four primary categories of medical foods: medical foods for metabolic disorders, nutritionally complete formulas, nutritionally incomplete formulas, and oral rehydration products.[92] This section briefly discusses the scientific support for the inclusion of several of these categories for Medicare beneficiaries.

1. Medical Foods for Metabolic Disorders

Medical foods are manufactured for individuals with metabolic disorders such as phenylketonuria ("PKU"), homocysteinuria, glutaric acidemia type I, tyrosinemia types I and II, proprionic anemia, urea cycle disorders, and maple syrup urine disease. These medical food formulations provide complete nutrition for the target patient group, although the products may

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[87] 61 Federal Register at 60666.

[88] FDA suggests that this element of the definition is instrumental in differentiating medical foods from other types of foods. FDA Food Compliance Program.

[89] 21 C.F.R. § 101.9(j)(8)(v).

[90] Center for Food Safety and Applied Nutrition, Food and Drug Administration, Medical Foods, *at* http://www.cfsan.fda.gov/~dms/ds-medfd.html (posted May 1997)(emphasis added).

[91] FDA Food Compliance Program.

[92] *Id.*

lack particular nutrients that would be essential for normal patients. For instance, products for phenylketonurics do not contain phenylalanine.

The American Academy of Pediatrics Committee on Nutrition ("Committee") views commercially available medical foods as "indispensable for the active, ongoing treatment of diagnosed amino acid and urea cycle disorders."[93] Without such management, "these diseases culminate in severe mental retardation or death."[94] The Committee has taken the position that medical foods used for these types of disorders should be reimbursed.

The use of medical foods in the management of phenylketonuria provides a useful example of medical foods' value. While scientists actively are exploring non-dietary treatments for PKU, none of these treatments have yet been proven effective.[95] Instead, the clinical management of PKU involves "strict metabolic control using a low-Phe diet that includes specialized medical foods."[96] Most clinical practices advocate lifelong dietary treatment.[97] Data suggest that a failure to adhere to the specialized diet can adversely affect aspects of cognitive function in adolescents and adults.[98] As a result, the National Institutes of Health has opined that "specialized medical foods and low-protein products are a medical necessity and should be treated as such. Reimbursement for these medical foods and products should be covered by third-party providers."[99]

2. Nutritionally Complete Medical Foods

Nutritionally complete medical foods provide protein, fat, carbohydrates, vitamins, and minerals in sufficient quantities to maintain a normal individual's nutritional status. These products may vary in compositional profile, *e.g.*, amount of fiber, caloric density, or lactose content. For example, many patients require a single, calorically dense source of nutrition following surgery.

Nutritionally complete medical foods are recommended in the clinical management of a wide variety of disorders and conditions. In particular, research supports their use by patients suffering from malabsorption disorders such as Crohn's disease, short bowel syndrome, and

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[93] Committee on Nutrition, American Academy of Pediatrics, Reimbursement for Medical Foods for Inborn Errors of Metabolism, 93 Pediatrics 860 (1994).

[94] *Id.*

[95] National Institutes of Health, Phenylketonuria (PKU): Screening and Management, 17 NIH Consensus Statement No. 3, 3 (2000). Among the earliest recognized medical foods, Lofenelac was developed for infants and children with PKU.

[96] *Id.*

[97] *Id.* at 12.

[98] *Id*. at 19.

[99] *Id*. at 17.

inflammatory bowel disease;[100] hypermetabolic stress, including that arising from general surgery and trauma; and acute and chronic renal disorders.[101] The use of medical foods in patients with liver disease also has broad support.[102] The Federation of American Societies for Experimental Biology ("FASEB") concluded that research supports the use of commercially available enteral products in a large proportion of patients suffering from decompensated cirrhosis and encephalopathy.[103] Research also supports the use of particular medical foods by patients with ascetic cirrhosis and active and chronic hepatitis, according to FASEB.[104]

C. Benefits of Medical Foods

In FDA's view, "[t]he therapeutic importance of proper nutritional support (in terms of decreased hospital stay and lower incidence of complications and mortality) has been well documented in the literature."[105] FASEB acknowledges that it can be impractical and sometimes impossible to obtain data about a medical food's effect on patient mortality and morbidity. The group concludes, however, that improvement in clinical outcome is the "important question" in medical foods research.[106]

Medicare covers parenteral nutrition; the scientific evidence provides support for similar coverage of enteral nutrition, which is preferable to parenteral nutrition in many cases. Home care is preferable to inpatient care both in terms of patient outcomes and cost. Non-invasive enteral routes offer fewer risks than parenteral feeding. The physiologic benefits of the enteral feeding route also are well documented and evidenced by the well known dictate, "If the gut works, use it."

A majority of states have recognized that medical foods are crucial tools for medical management of certain patients. These states cover medical foods in their Medicaid programs, and some states require private health plans to cover medical foods. Once the Part D benefit takes effect, however, Medicare will become the primary payor for patients who are eligible for both Medicaid and Medicare ("dual-eligibles"), and some private retiree plans may shift enrollees to Part D plans for their drug coverage. If the Model Guidelines do not include medical foods, these beneficiaries may be forced to discontinue this aspect of their medical management on January 1, 2006. At present, 6.4 million dual-eligibles have access to medical foods through

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[100] *See, e.g.*, James Betzhold & Lyn Howard, *Enteral Nutrition and Gastrointestinal Disease, in* Enteral and Tube Feeding 338, 348 (John L. Rombeau & Michael D. Caldwell eds., 1984).

[101] *See, e.g.*, William P. Steffee & Carl F. Anderson, *Enteral Nutrition and Renal Disease, in* Enteral and Tube Feeding 362, 362-363.

[102] *See, e.g.*, Danny O. Jacobs *et al*., *Enteral Nutrition and Liver Disease, in* Enteral and Tube Feeding 376, 393-394.

[103] FASEB Guidelines at 31.

[104] *Id.*

[105] FDA Food Compliance Program. *See also* Hattan & Mackey, *supra* note 5, at 488-489.

[106] FASEB Guidelines at 10 - 11.

their state's Medicaid program. These patients are among the poorest and most vulnerable in our population, and malnutrition or improper nutritional management could have devastating effects on their health.

II. Specific Medical Food Examples

Foltx®, Diatx®, and Cerefolin™ are examples of medical foods that should be covered under Medicare Part D. Scientific evidence supports their use when prescribed by a physician for the clinical management of particular diseases and conditions. These products manufactured by Pamlab each contain the micronutrients folate, vitamin $B_{12,}$ and vitamin B_6.

These three medical foods play an important role in the management of diseases relating to disturbances of sulphur-bearing amino-acid metabolism. Foremost among these diseases are hyperhomocysteinemia and hyperhomocysteinuria. Homocysteinuria is the second most prevalent inborn error of metabolism after PKU.

These diseases result in a variety of clinical symptoms. More than 75 clinical and epidemiological studies have demonstrated a relationship between elevated total homocysteine levels and coronary artery disease, peripheral artery disease, stroke, venous thrombosis, cognitive impairment, dementia, and Alzheimer's disease.[107] Appendices B and C contain a representative sample of studies addressing the risks presented by higher homocysteine levels. Foltx®, Diatx®, and Cerefolin™ have been specially formulated to meet the distinctive nutritional requirements of hyperhomocysteinemia.

These three medical food products also are important tools in caring for patients suffering from deficiencies in the micronutrients folate, vitamin $B_{12,}$ and vitamin B_6. Genetic or acquired factors may impair a patient's ability to absorb or metabolize these three micronutrients. Deficiencies are common: 15% of elderly Americans evidence vitamin B_{12} deficiency.[108]

Deficiencies in these micronutrients may result in a number of diseases. All three of the micronutrients are important in the metabolism of homocysteine, and the conditions that may result from hyperhomocysteinemia and hyperhomocysteinuria have been detailed above. Vitamin B_{12} deficiency can lead to macrocytic or pernicious anemia, as well as a spectrum of neuropsychiatric disorders including dementia and depression. Patients with B_{12} deficiency also are at increased risk of stroke and myocardial infarction.[109]

Medical foods such as Foltx®, Diatx®, and Cerefolin™ are an essential element of the medical management of patients who have or are at risk of hyperhomocysteinemia. Combinations of folate and other B vitamins have been shown to improve endothelial function and the ability of

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[107] Otter Nygard *et al*., Plasma Homocysteine Levels and Mortality in Patients with Coronary Artery Disease, 337 New Eng. J. Med. 230 (1997); Sudhar Seshadri *et al*., Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease, 346 New Eng. J. Med. 476 (2002).

[108] T.S. Dharmarajan *et al*., *The Need to Screen: A Case in Point, in* Vitamin B_{12} Deficiency 9 (Victor Herbert ed., 1999).

[109] Robert C. Oh *et al*., Vitamin B_{12} Deficiency, 67 Am. Family Physician 979 (2003).

blood vessels to dilate;[110] improve endothelial function in diabetics;[111] reduce carotid artery plaque in patients with both elevated homocysteine and normal homocysteine;[112] and improve cognitive function and lower homocysteine in patients with mild to moderate cognitive impairment, dementia, and Alzheimer's disease.[113] The combinations also have been shown to have salutary effects when used as a part of the dietary management of renal disease. The scientific studies listed in Appendices D, E, and F provide support for these uses.

III. Conclusion

Physicians and researchers view medical foods as essential tools in protecting and preserving the health of a particular segment of Medicare beneficiaries. For patients with inherited metabolic disorders and certain other diseases and conditions, medical foods are the best source of complete nutritional support. If patients cannot afford these products, malnutrition and the accompanying complications are likely to result. The poorest Medicare beneficiaries are at particular risk. By adding medical foods to the final Model Guidelines, USP can ensure that all Medicare beneficiaries, including the dual-eligibles whose medical foods currently are covered by state Medicaid programs, have access to the complete range of physician-recommended disease management tools.

Sincerely,

/Barry D. LeBlanc/

Barry D. LeBlanc
President
Pamlab, LLC

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[110] K.S. Woo *et al*., Long-Term Improvement in Homocysteine Levels and Arterial Endothelial Function After 1-Year Folic Acid Supplementation, 112 Am. J. Med. 535 (2002).

[111] R.W. Van Etten *et al*., Impaired NO-Dependent Vasodilation in Patients with Type II (Non-Insulin-Dependent) Diabetes Mellitus is Restored by Acute Administration of Folate, 45 Diabetologia 1004 (2002).

[112] David G. Hackam *et al*., What Level of Plasma Homocyst(e)ine should be Treated?, 13 Am. J. Hypertension 105 (2000).

[113] M. Lehmann *et al*., Vitamin B12-B6-Folate Treatment Improves Blood-Brain Barrier Function in Patients with Hyperhomocysteinemia and Mild Cognitive Impairment, 16 Dementia & Geriatric Cognitive Disorders 145 (2003); K. Nilsson *et al.*, Improvement of Cognitive Functions after Cobalamine/Folate Supplementation in Elderly Patients with Dementia and Elevated Plasma Homocysteine, 16 Intl. J. Geriatric Psychiatry 609 (2001).

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19. Lehmann M et al. Vitamin B12-B6-Folate Treatment Improves Blood-Brain Barrier Function in Patients with Hyperhomocysteinemia and Mild Cognitive Impariment. Dement Geriatr Cogn Disord 2003; 16:145-150.

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21. Bostom AG et al. High Dose B-Vitamin Treatment of Hyperhomocysteinemia in Dialysis Patients. Kidney Int, 1996; 49:147-152.

22. Marcucci R. Vitamin Supplementation Reduces the Progression of Atherosclerosis in Hyperhomocysteinemic Renal-Transplant Recipients. Transplantation, 2003; 75:1551-1555.

23. Clement Louise. Homocysteine: The Newest Uremic Toxin? Renal Nutrition Forum, 2003; 22:1 - 6.

Appendix B: Homocysteine as a Risk Factor

Ref.	Lead Investigator	Study Focus	Outcome
[i]	Nygard, O.	Plasma homocysteine (Hcy) as a predictor of cardiovascular and overall mortality	Hcy Ratio Mortality <9 µmol/L - 9 – 14.9µmol/L 1.9 15 – 19.9 µmol/L 2.8 20 – up µmol/L 4.5
[ii]	Retterstol, L.	Plasma total homocysteine (tHcy) as a predictor of long-term prognosis after premature MI.	Relative risk for death of all causes increased 1.43 per tHcy quartile and was only modestly reduced for age, ejection fraction, total cholesterol, CRP, fibrinogen, smoking, and hypertension to 1.37. Similar results when cardiac death used as endpoint.
[iii]	Boysen, G.	Total homocysteine as a predictor of recurrent stroke	Relative risk for recurrent stroke within 15 months was 1.3 for each increase in tHcy of 10 µmol/L. Patients followed for 15 months.
[iv]	Tanne, D.	Serum homocysteine as a predictor of ischemic stroke among patients with preexisting coronary heart disease	Relative odds associated with a 5 µmol/L increase of total homocysteine were 2.00 for cardioembolic stroke, 1.16 for atherothrombotic stroke and 1.09 for ischemic stroke. When patients' homocysteine were arranged in quartiles, the upper quartile had a 3.07 RR for ischemic stroke compared to the first lowest quartile.
[v]	Lim, U.	Homocysteine as a predictor of hypertension	In comparison of highest and lowest quartiles of homocysteine, women had a 3-fold increase in risk for hypertension and men had a 2-fold increase at the highest quartile. From 3rd NHANES Survey.
[vi]	Seshadri, S.	Establish in patients without dementia whether elevated homocysteine levels precede the onset of dementia or result from dementia-related nutritional or vitamin deficiencies over an 8-year follow-up.	Data from 1092 subjects without dementia (Framingham Study cohort) revealed increased plasma homocysteine level is a strong, independent risk factor for the development of dementia and Alzheimer's disease.
[vii]	McCaddon, A.	Study 32 healthy elderly to determine whether prior homocysteine levels predicted cognitive changes over a 5-year period.	Homocysteine predicted follow-up cognitive scores and rate of decline in cognitive performance independently of age, sex, education, renal function, vitamin B status, smoking, and hypertension.

Appendix C: Homocysteine and the Diabetic Patient

Ref.	Lead Investigator	Study Focus	Outcome
[viii]	Hoogeveen, E.K.	Type 2 Diabetes/ Hyperhomocysteinemia; Cross sectional study to assess the relative risk of 5 year mortality comparing Type 2 diabetics to non-diabetics.	Homocysteine levels >14µmol/L (independent of other risk factors) confirmed a 1.9-fold risk of 5 year mortality in diabetics compared to non-diabetics.
[ix]	Emoto, M.	Type 2 Diabetes/ Hyperhomocysteinemia; Assess relationship of insulin resistance and renal function to tHcy levels in 75 Type 2 diabetes patients.	Diabetic patients showed significant correlation of log tHcy levels and insulin sensitivity index (r= -0.319, P= 0.005) Renal Function and homocysteine: Stage 1 2.6% Hcy >13.8µmol/L Stage 2 11.8% Hcy >13.8µmol/L Stage 3 44.4% Hcy >13.8µmol/L Stage 4 90.0% Hcy >13.8µmol/L
[x]	Hoogeveen, E.K.	Type 2 Diabetes/ Hyperhomocysteinemia – Study the association between homocysteine level and retinopathy among subjects with and without Diabetes Mellitus (DM).	For each 5µmol/L increase of homocysteine among DM patients, the risk of retinopathy rose 50%.
[xi]	Ambrosch, A.	Type 2 Diabetes/ Hyperhomocysteinemia – Determine the association between homocysteine and neuropathy independent of other risk factors.	For each 5µmol/L increase of homocysteine among DM patients, the risk of neuropathy increase 2.60 times.

Appendix D: Clinical Studies on Endothelial Function and Homocysteine

Ref.	Lead Investigator	Objective	Design	Outcome
[xii]	Verhaar, M.C.	Improvement in forearm blood flow after 4 weeks of 5mg FA daily vs. placebo in 20 familial hypercholesterolinemia patients	Prospective, randomized, double-blind, placebo-controlled, cross-over	FA improved endothelial dependent vasodilation in familial hypercholesterolinemia patients.
[xiii]	Chambers, J.C.	Brachial artery flow-mediated dilatation and nitroglycerin-induced dilatation were measured before and 8 weeks after a) 5mg of folic acid and 1 mg of vitamin B_{12} daily or b) placebo. 89 men with CHD.	Treatment allocation was prospective, randomized double-blind, placebo-controlled.	At 8 weeks FMD was improved in the vitamin group vs. controls 1.5±3.5% compared with baseline, (P=0.002). Homocysteine levels were significantly reduced in the vitamin group after 8 weeks but not with the placebo group.
[xiv]	Doshi, S.N.	Study the effect of 5mg/d of folic acid over 6 weeks on homocysteine and endothelial function as defined by FMD. 33 patients.	Randomized, placebo-controlled	FMD improved at both 2 hours (83 µm vs. 47 µm; P<0.001) and 4 hours (101 µm vs. 51 µm; P<0.001) after the first dose of folic acid. FMD improvement was largely independent of homocysteine lowering. At six weeks the treatment group had statistically significant reductions in homocysteine (8.3 µmol/L vs 10.8 µmol/L, P<0.001).

[xv]	Van Etten, R.W.	Improvement in endothelial function in Type II diabetics	Evaluate the effect of local, intra-arterial administration of 5-MTHF (active form of folic acid). 23 Type II diabetics and 21 control subjects were given 1µg/100 mL (forearm volume/min) of 5-MTHF. Effect evaluated using forearm plethysmography. Open label, no placebo control. Subjects served as their own control.	5-MTHF improved nitric oxide-mediated vasodilation from 53±30 to 88±59 M/C%, $p<0.05$) in patients with Type II diabetes compared to no effect on control subjects. Authors conclude that their results supply strong rationale for the initiation of studies that investigate whether supplementation with folic acid prevents future cardiovascular events in this patient group.
[xvi]	Woo, K.S.	Study designed to measure endothelium-dependent dilatation at baseline and after 1-year, 29 asymptomatic subjects with elevated homocysteine. Patients were given 10 mg of folic acid daily for 1 year.	Prospective, open-label.	Both LDL and total cholesterol levels were within normal ranges at baseline and at 1 year. Flow-mediated dilatation improved significantly from 7.4% to 8.9% ($p<0.0001$). Mean vessel diameter did not change from baseline to one year.
[xvii]	Hackham, D.G.	Assessment of the effect of 2.5 mg of folic acid, 25 mg B_6 and 250 µg B_{12} therapy on plaque regression in patients after lowering of plasma homocysteine levels from baselines both above and below 14 µmol/L.	Retrospective chart review of 51 patients with homocysteine >14 µmol/L and 40 patients with homocysteine below 14 µmol/L.	Rate of plaque progression after vitamin therapy was -0.265 ± 0.46 cm^2/yr for patients in the above 14 group, -0.15 ± 0.44 cm^2/yr for the below 14 group. The data suggested a causal relationship between homocysteine and atherosclerosis.

Appendix E: Clinical Studies on Cognitive Function

Ref.	Lead Investigator	Title	Design	Outcome
[xviii]	Nilsson, K.	Improvement of Cognitive Functions after Cobalamin/Folate Supplementation in Elderly Patients With Dementia and Elevated Plasma Homocysteine.	Prospective treatment study. 33 consecutive patients diagnosed with dementia and/or Alzheimer's Disease. All patients received treatment	Patients with mild-moderate dementia and elevated plasma homocysteine levels improved clinically, had better test scores (SKT, MMSE) after 2 month regimen of 5mg/day folic acid and 1mg/day B_{12}.
[xix]	Lehmann, M.	Vitamin B_{12}-B_6-Folate Treatment Improves Blood-Brain Barrier Function (BBB) in Patients with Hyperhomocysteinemia and Mild Cognitive Impairment	30 prospective, consecutive patients diagnosed with mild cognitive impairment (MMSE 24-30) and moderate hyperhomocysteinemia (>13.5µmol/L. All patients received treatment of high dose B_{12}, $B_{6,}$ and folate.	After 270 days of treatment none of the patients progressed into dementia. MMSE scores remained unchanged. CSF-tau decreased numerically but not significantly. Patients also had improved BBB function as measured by reduction in serum/CSF albumin ratio (7.5 baseline vs. 6.7 post-therapy, $P<0.0002$)

Appendix F: Clinical Studies on Chronic Renal Failure and Transplantation

Ref.	Lead Investigator	Title	Design	Outcome
[xx]	Stanford, J.L.	Oral Folate Reduces Plasma Homocysteine Levels in Hemodialysis Patients with Cardiovascular Disease	After a 2 week washout period 28 chronic hemodialysis patients who had been on 400µg of folic acid with mean Hcy 35.2µmol/L were dosed for 6 weeks on 5.4 mg of folic acid, 2mg pyridoxine, cobalamin 6mg.	Hcy fell by 15.0µmol/L (38.9%) (mean). Authors concluded that 5mg of folic acid or additional therapy may be required to further reduce Hcy in the majority of ESRD patients
[xxi]	Bostom, A.G.	High Dose B-Vitamin Treatment of Hyperhomocysteinemia in Dialysis Patients	Placebo-controlled eight week trial of the effect on plasma homocysteine of adding superphysiologic doses of folic acid (15 mg/day), vitamin B_6 (10mg) and vitamin B_{12} 12µg in 27 hyperhomocysteinemic dialysis patients.	Plasma homocysteine was significantly reduced in both 4 weeks (-29.8%) and 8 weeks (-25.8%) compared to the placebo group. 5 of 15 treated patients vs. 0 of 12 placebo group patients had their plasma Hcy reduced to within normative range (<15 µmol/L).
[xxii]	Marcucci, R.	Vitamin Supplementation Reduces the Progression of Atherosclerosis in Hyperhomocysteinemic Renal Transplant Recipients	Fifty-six hyperhomocysteinemic renal transplant patients were randomly assigned to receive folic acid (5mg/day), B_6 (50mg/day), B_{12} (400 µg) or placebo for 6 months in a study designed to document the effect on carotid artery intima media thickness (cIMT) of vitamin supplementation.	Fasting homocysteine decreased from 21.8 µmol/L to 9.3 µmol/L in the treatment group compared to no significant change in the placebo group (20.5 µmol/L vs. 20.7 µmol/L). All except one patient in the vitamin group experienced a reduction in cIMT (mean -32.2%). The placebo patients experienced an increase in cIMT.

[xxiii]	Clement, L.	Homocysteine: The Newest Uremic Toxin?	65 hemodialysis patients were treated with a renal multi-vitamin with 5mg of folic acid, 1 mg B_{12}, 50 mg B_6, plus standard amts of water-soluble B vitamins. 24 patients were given a renal-multi vitamin with 1mg of folic acid plus the water soluble B vitamins. Baseline Hcy were similar for both groups. Goal was to assess efficacy of the two regimens.	The high-dose group had homocysteine levels 16% below the control group at 3 months and 25% below controls at 6 months. Elevated homocysteine levels correlated to more anemia as well as higher requirements for epoetin alfa (EPO). EPO doses declined in the high-dose group and were 19% lower than controls.

Submitter : Miss. Cindy Biance **Date & Time:** 10/04/2004 04:10:25

Organization : Capital District Center for Independence

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file for comment from disability community

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

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CMS-4068-P-954

Submitter : Brett Stark **Date & Time:** 10/04/2004 04:10:17

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist practicing in the community setting. Now a member of district management, I suppose my comments could be construed as biased. However, I do believe that direct contact with pharmacists can make a difference in the overall well-being of beneficiaries, and can improve outcomes relating to drug therapy; I have seen it.

In any final version of the deployment of benefits, pharmacists in community settings must be given the opportunity to interact with patients. Patients must have a choice as to where and how they receive their care, and the playing field must be level. Please do not allow a mail order or community monopoly on services, and take whatever prudent precautions are necesary in order to safeguard patients and jobs.

Thank-you for the opportunity to speak...

Brett

CMS-4068-P-955

Submitter : Cheryl Colwell **Date & Time:** 10/04/2004 04:10:06

Organization : Cheryl Colwell

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

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

Coverage for specialized vitamins for renal/dialysis patients is essential for therapy management because of their greater need of B vitamins at perscription levels to combat high homocysteine, the risk factor of heart disease, the leading cause of death in this population.

CMS-4068-P-956

Submitter : Mr. Carlos Milan **Date & Time:** 10/04/2004 04:10:12

Organization : Mr. Carlos Milan

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Due to the new Medicare law enacted by Congress and President Bush last year, more than 80,000 Americans living with HIV/AIDS will become eligible for a new prescription drug benefit under Medicare.

The vast majority of these individuals--some 60,000 nationwide--are currently receiving prescription drug coverage through Medicaid and will lose these benefits on December 31, 2005. They will then be forced to enroll in the new and potentially less comprehensive Medicare drug program.

The federal Centers for Medicare and Medicaid Services (CMS) recently released a 2,000-page draft document detailing how the government will implement the complex, new benefit. AIDS advocates are concerned that the proposal short-changes people with HIV/AIDS and could severely compromise their health by interrupting HIV treatments and offering them sub-standard healthcare.

AIDS advocates urge CMS to ensure the following concerns are addressed in the final implementation rules:

*People with HIV/AIDS risk life-threatening illness if drug plans are allowed to limit the number of HIV drugs covered. Drug plans must carry all the drugs people with HIV/AIDS need.
*Because restricted access to needed HIV/AIDS medications could lead to drug resistance or severe medical complications, Medicare should treat people with HIV/AIDS as a "special needs population" and require drug plans to offer them an "open formulary." (The ability of companies to change the formulary on a weekly basis is bad policy for those living with HIV/AIDS)

*Individuals eligible for both Medicaid and Medicare (know as "dual-eligibles") may get fewer benefits under Medicare than they now receive in Medicaid. CMS should ensure that new benefits are of equal or greater quality than those provided by Medicaid.
*With the law cutting off Medicaid drug benefits for dual-eligibles on December 31, 2005, but not automatically enrolling them in the new Medicare drug program, dual-eligibles will be at risk for interruptions in drug coverage. Dual-eligibles with HIV/AIDS cannot risk a gap in coverage during the transition from Medicaid to Medicare, which would severely compromise their health.
*The draft grievance and appeals process is inadequate and must be enhanced to provide greater protections for Medicare recipients. Grievance and appeal processes must be effective and easy-to-access, and must include the right to get an emergency supply of medications while an appeal is under way.
*Proposed rules allow drug plans access to the names and medical histories of Medicare recipients in order to aid their marketing and enrollment strategies. Drug plans should not violate the privacy of people with HIV/AIDS and other Medicare beneficiaries.

I urge you to consider this proposals and not to take action on this changes until HIV+ people have been secured with a smooth, uninterrupted, full access to the drugs we need to stay alive.

CMS-4068-P-957

Submitter : Dr. Howard Grossman **Date & Time:** 10/04/2004 04:10:10

Organization : American Academy of HIV Medicine

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comments and call Greg Smiley at (202) 251-2148 or greg@aahivm.org with questions.

Thank you.

CMS-4068-P-957-Attach-1.doc

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October 1, 2004

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

File Code: CMS-4068-P

Re: Proposed Rule; Medicare Program; Medicare Prescription Drug Benefit

On behalf of the American Academy of HIV Medicine (AAHIVM), we appreciate the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Federal Register Notice of August 3rd, 2004 regarding the implementation of the Medicare Modernization Act (MMA)--42 CFR Parts 403, 411, 417, and 423. The American Academy of HIV Medicine is an independent organization of AAHIVM HIV Specialists™ and others dedicated to promoting excellence in HIV/AIDS care. Through advocacy and education, the Academy is committed to supporting health care providers in HIV medicine and to ensuring better care for those living with AIDS and HIV disease. Our 1,800 members provide direct care to more than 315,000 HIV patients in the United States, many of whom are eligible to receive care under Medicare.

As previously stated in a June 7th, 2004 letter to HHS officials and in a September 29th letter to the United States Pharmacopeia, the Academy remains extremely concerned that our patients may not get the medically indicated care that they need under this proposed regulation. The current language in this regulation, some of which still remains highly ambiguous, suggests that many eligible individuals will not receive adequate care under the new benefit. It is our hope that we may rectify these concerns on behalf of our patients before the new benefit is enacted January 1, 2006.

Special populations

We were encouraged to see in the regulation that CMS might consider that people with HIV/AIDS may have extenuating circumstances that could necessitate exempting them as a "special population" under the regulation. By doing so, CMS could then protect this population from life-threatening formulary restrictions and grant them special protections against cost-sharing requirements and other cost-containment measures that might impede access to vital therapeutic regimens.

On page 46661 of the regulation, CMS states that ". . . it is possible that certain vulnerable populations (enrollees in long-term care facilities or those suffering from mental illness or chronic diseases such as AIDS, for example) may be negatively impacted financially if they do not have access to a wide range of drugs in certain therapeutic classes and categories. We seek comments on ways to balance plans' flexibility to use some of the mechanisms described above to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain *special populations* of Part D enrollees."

The Academy strongly recommends that people living with HIV/AIDS should be designated a "special population" under Part D because of the complicated, interconnected factors in successfully managing this population, including adherence, toxicities, drug interactions, and co-morbid conditions. The implications of not adequately managing this disease extend past just the

medical management of the individual patient to larger public health implications including increased HIV transmission from inadequately treated individuals as well as increased health care costs for those who become further infirmed. The Academy offers their assistance to CMS in outlining the specific protections that might be appropriate for people with HIV/AIDS and requests that CMS engage the Academy and other expert organizations before issuing a second notice of proposed rule making (NPRM) on these critical revisions to the regulation.

Formularies

It is critical and therefore, essential, that Medicare beneficiaries with HIV infection have continued and unhindered access to all of the drugs that are medically necessary for treating their disease. We guarantee that requiring prescription drug plans (PDPs) to require only two drugs per "class" will severely impede our clinicians' ability to adequately care for our patients. Antiretroviral medications are simply not interchangeable within any one class due to differences in toxicity, drug interactions, and complex drug resistance mutational interactions.

Further, 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 diabetes, elevated lipids, heart disease, mental health disorders, hepatitis C and the sequelae of chronic 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 co-morbid conditions and side effects. Failure to effectively treat co-morbid 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. Patients and their medical providers need the flexibility to switch treatment regimens when necessary, as indicated not only by the course of their HIV disease, but by the consequences of their therapy as well.

Cost-sharing and access concerns for those "dually eligible" for Medicare and Medicaid

Dual eligibles must not be limited to the "average cost plan" as indicated in Section **§423.30(D)(1)** which says that 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, especially if there are only two plans available in that area, which would by definition of an "average cost plan" limit them to only one option for care and coverage. 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.

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

[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. AIDS Behav. 2004:8(2)141-150.

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 such as those used to treat the conditions outlines above, the drug should available at the lowest cost-sharing tier. We encourage CMS to grant serious consideration to the numerous studies that demonstrate that even modest levels of cost sharing result in low-income individuals, people with chronic illnesses and seniors being deprived of medically necessary prescription drugs.[4] We strongly urge that no cost-sharing be required of dual eligibles.

Under the statute, dual eligible beneficiaries will be required pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. 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. [423.782(a)(iiii)]

In a letter to Senator Dianne Feinstein from November 2003, Health and Human Services Secretary Tommy Thompson stated that, "[t]he new Medicare benefit will not result in a loss of coverage for dual eligibles." We strongly urge CMS and the Department to ensure that the final regulation indeed protects dually eligible individuals, including those with HIV/AIDS from any regulatory impediments to high-quality, life-saving medical care and therapies.

Off-label use

We strongly recommend strengthening the language regarding coverage of drugs for off-label uses. We feel it is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label uses that are standard practice in the medical community. For HIV disease, as with many complex conditions, actual clinical use frequently runs ahead of label

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

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

[4] See: Goldman DP Joyce GF, Escarce JJ et al. Pharmacy benefits and the use of drugs by the chronically ill. Journal of the American Medical Association. 2004;291:2285. Cunningham, PJ. Affording prescription drugs: not just a problem for the elderly. April 2002. Center for Studying Health System Change. Online 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.

indications as practicing 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. Finally, many antiretrovirals are not approved for use in pediatric populations, where their use is critical to the medical care of this population.

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. We strongly recommend that a revised regulation follow the Public Health Service guidelines for treatment of HIV/AIDS and for the treatment and prevention of Opportunistic Infections and explicitly state that prescription drug plans (PDPs) cover off-label indications.

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 (FDA). 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.

Appeals and Exceptions

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.[5] Failure to prevent treatment interruptions by supplying a temporary drug supply will contribute to this horrible phenomenon. Beyond concerns about resistance, treatment interruptions can also lead to serious consequences including irreversible declines in immune functioning, unnecessary hospitalizations, and the development of HIV-related opportunistic infections.

Our concerns over treatment interruptions are heightened due to the absence of adequate protections that ensure that individuals can receive a timely resolution of an appeal, and the 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 (ALJ) level. We recognize that the expedited timeframes and the general 72-hour standard are a significant improvement over the standard timeframe of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of the clinical management of HIV infection, 72 hours is an unacceptable delay. We strongly recommend that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people living with HIV/AIDS automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a

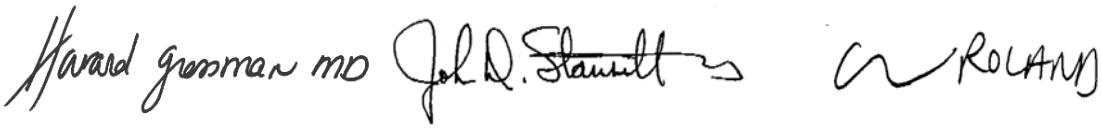
[5] Wensing AM, Boucher CA. Worldwide transmission of drug-resistant HIV. AIDS Rev. 2003;5(3):140-155.

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.

We recommend "requiring" instead of "encouraging" Pharmaceutical and Therapeutic (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 who is a recognized specialist in HIV care, and a member of either the American Academy of HIV Medicine (AAHIVM) or the HIV Medicine Association (HIVMA), to advise the P&T Committee on HIV-related treatment decisions and other specialists whose expertise is not represented on the committee.

Again, we thank you for the opportunity to offer these comments on the proposed implementation of the Medicare Modernization Act. It is critical that our patients with HIV/AIDS receive the highest quality medical care possible under all federally available health systems and we look forward to working with you as the final regulation is ultimately implemented. Please contact Greg Smiley at (202) 251-2148 or through greg@aahivm.org with any questions or concerns you have regarding these comments.

Sincerely,



Howard Grossman, M.D.
Executive Director
AAHIVM

John Stansell, M.D.
Chair, Board of Directors
AAHIVM

Michelle Roland, M.D.
Public Policy Chair
AAHIVM

CMS-4068-P-958

Submitter : **Date & Time:** 10/04/2004 04:10:12

Organization : Massachusetts AIDS Policy Task Force

Category : Other

Issue Areas/Comments

Issues 1-10

BACKGROUND

October 1, 2004

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

To Whom It May Concern:

As AIDS service providers, advocates and consumers in Massachusetts, the undersigned members of the Massachusetts AIDS Policy Task Force are responding to the proposed rule ?Medicare Program; Medicare Prescription Drug Benefit,? 69 FR 46632. We are gravely concerned that the proposed rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit, particularly the 60,000 dually eligible individuals who have been receiving their drug coverage through Medicaid. Many of the provisions in the proposed rule will negatively impact the drug coverage they are currently receiving.

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

Limits on available medications and limits on use

Of primary concern is the provision that the Medicare drug plans would not be required to have open formularies. HIV is an extremely complicated disease to treat. Physicians must be able to consider the full range of all FDA approved and new drugs when determining the appropriate treatment plan for each individual patient. With HIV?s unique ability to mutate into drug resistant forms, new combinations of medications must frequently be prescribed to continue to effectively combat the virus. Although the proposed rule requires plans to cover at least two drugs within each therapeutic class and category, HIV medications are not equivalent compounds, even if in the same class, and may have differing levels of efficacy and side effects.

Allowing drug plans to limit the medications they cover could create an incentive for plans to refuse to cover medications for high cost conditions including HIV/AIDS. This would effectively allow them to exclude higher cost members from their plans.

The proposed rule would also allow drug plans to deny coverage for off-label use of medications. HIV is a complex and ever evolving disease. To effectively combat it creative strategies must be utilized to find the correct mix of medications for each individual. As you know, prescribing off-label is an accepted medical practice and provides effective treatment for people and conditions that would otherwise be ignored due to the financial disincentives of the FDA approval process. Denying coverage for off-label prescriptions unfairly burdens vulnerable populations with the limitations of the FDA process.

If the final rule does not include an open formulary requirement and does not cover off-label use, people with HIV/AIDS must be designated a ?special population? to be granted access to all FDA approved and newly available drugs and physicians must be allowed to prescribe medications for off-label use in treating HIV.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Appeals

The proposed rule requires a $100 threshold for appeal rights. This threshold could leave low income HIV positive individuals unable to access needed medications that cost less than $100 but are still unaffordable and with no rights to appeal. While CMS has stated an intention to allow the bundling of appeals to reach the threshold, this could leave an HIV positive person without life saving medication for a number of months waiting for the threshold to be reached.

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We urge you to revise the proposed rule to protect the health of low-income people living with HIV. Thank you for the opportunity to comment.

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

Cost Sharing

Another concern is the cost sharing requirements in the proposed rule. Dually eligible individuals are significantly poorer than those on Medicare alone. While the proposed low-income subsidy will protect Medicaid beneficiaries from premiums and deductibles, they will still be responsible for cost sharing for each prescription filled. The proposed cost sharing of $1 to $5 per medication for dual eligibles is particularly burdensome on people with HIV/AIDS who often must take multiple daily medications. Studies have shown that increased cost sharing forces some low-income people to choose to forgo health coverage in order to afford food, housing or other necessities.

An important current protection in Medicaid is the requirement that a prescription must be filled even if an individual is unable to pay the cost sharing. Not being able to fill prescriptions due to cost sharing is extremely dangerous for people with HIV and increases the risk to the public health. Even brief treatment interruptions can result in the HIV virus replicating at rapid rate or mutating into drug resistant strains. The risk of infecting others is greater with a higher viral load making this a public health risk as well. It is crucial that HIV treatment is not interrupted due to non-payment of cost sharing and we request that this protection be included in the final rule.

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CMS-4068-P-958-Attach-2.doc

CMS-4068-P-958-Attach-1.txt

CMS-4068-P-958-Attach-1.txt

CMS-4068-P-958-Attach-2.doc

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October 1, 2004

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P.O. Box 8014
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If the final rule does not include an open formulary requirement and does not cover off-label use, people with HIV/AIDS must be designated a "special population" to be granted access to all FDA approved and newly available drugs and physicians must be allowed to prescribe medications for off-label use in treating HIV.

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BI Deaconess, MC, Infectious Disease
Boston AIDS Consortium
Boston Health Care for the Homeless Program
Community Action Committee of Cape Cod & Islands
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Amy Goldman, LICSW
Donna Gallagher, RNCS, MS, ANP, RAAN, PI
Gay & Lesbian Advocates and Defenders
Carole Hohl, MHS, PA-C
Jordan Hospital's ACCESS Program
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Chuck Lacombe, CAB
New England AIDS Education & Training Center
North Shore AIDS Health Project
Project Aware at SSTAR
Barry Rund
Sylvia Saavedra-Keber
South Shore AIDS Project
Span, Inc.
Tapestry Health
Volunteers of America of Massachusetts
Michael Wong, M.D.

October 1, 2004

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Department of Health and Human Services
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P.O. Box 8014
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Tapestry Health
Volunteers of America of Massachusetts
Michael Wong, M.D.

CMS-4068-P-959

Submitter : Mr. Kevin Costello **Date & Time:** 10/04/2004 04:10:45

Organization : Community Legal Services

Category : Attorney/Law Firm

Issue Areas/Comments

Issues 1-10

BACKGROUND

General Comments on Proposed Regulations

As an organization that directly serves low-income Medicare beneficiaries, Community Legal Services is most concerned about the role of the regulations in bridging the disconnect between the enormously complex Medicare Modernization Act and the deep confusion that many of our clients have surrounding their health care benefits. While the proposed regulations answer many of the questions that were raised by the statute, they also squander many opportunities to simplify the delivery of the Part D benefit through enrollment and appeals processes. We recognize the difficulty of striking a balance between the maintenance of respect for beneficiaries? due process rights, their need for information in order to make informed decisions and the absolute essentiality of keeping the program as simple and understandable as possible. The comments outlined below seek to further the proposed regulations? achievement of that balance.

As advocates for low-income beneficiaries, Community Legal Services notes that the role of ?authorized representative? is not consistently defined throughout the proposed regulations. For instance, whereas the authorized representative has clear authority to appeal an initial coverage determination, such authority is not as well defined in the latter stages of the appeals process, nor is it particularly clear in the enrollment provisions. Further, the relationship between the ?authorized representative? in some subparts and the ?personal representative? in others is ill-defined. The final regulations should strive to make this role uniform throughout. The role of the authorized representative is a necessary component of the transparency that is CMS?s stated goal and it should be clearly defined in every aspect of the final regulations regarding beneficiaries.

BENEFITS AND BENEFICIARY PROTECTIONS

We recommend that the final rule define ?person? so that family members can pay for covered Part D cost-sharing.

We strongly oppose the provision at section 423.104(e)(2)(ii) that permits Part D plans to ?apply tiered co-payments without limit?. The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs.

The MMA permits tiered cost-sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the P&T committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary. In another section, we also comment on what we view as a wholly inadequate exceptions process.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual?s request for an exception to a Part D plan?s non-preferred cost-sharing. Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D eligible individuals under the plan.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Overarching Concerns Regarding the Enrollment Process

Community Legal Services is concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries, beneficiaries with mental illness, and other populations with special needs.

Officials at the Centers for Medicare and Medicaid Services (CMS) have indicated that they will rely heavily on State Health Insurance Assistance Programs (SHIPs) to assist with enrollment. SHIPs have played a critical role in helping Medicare beneficiaries navigate the Medicare drug discount cards and will continue to play an important role helping Medicare beneficiaries as enrollment begins for the new prescription drug benefit Here in Philadelphia, however, the local SHIP is staffed by volunteers lacing substantive expertise who serve largely to provide quick screening and referral services. It is rare that consumers contacting the Philadelphia SHIP receive the level of sophisticated and substantive counseling and guidance envisioned by the proposed regulations. Additional funding is critical if SHIPs are to successfully serve the Medicare population and help diverse Medicare beneficiaries navigate the complicated new law?s provisions.

While SHIPs will be critical to education and enrollment efforts, other 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. Enrollment opportunities must come to these populations, or there is a very real risk that they will be left behind.

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.

GENERAL PROVISIONS

Subpart A ? General Provisions

Community Legal Services suggests that the definition of ?authorized representative? appear in this subpart to emphasize the uniform role that such agents have in every aspect of the Medicare drug benefit, from the very earliest stages of enrollment to the last stage of appeal.

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CMS-4068-P-959-Attach-1.doc

CMS-4068-P-960

Submitter : Mr. James Collins **Date & Time:** 10/04/2004 04:10:20

Organization : Medicaid Matters New York

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-4068-P-960-Attach-1.doc

Medicaid
Medicaid Matters New York
Matters

October 4, 2004

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

Medicaid Matters New York (MMNY) is a state-wide coalition of over 100 organizations that advocates on behalf of New York State's 3 million Medicaid recipients. As advocates, we are dismayed with the regulations CMS has proposed to implement the Medicare drug benefit in 2006. Clearly, far too little was done by CMS to protect all beneficiaries, particularly Medicare-Medicaid dual eligibles and others with low incomes.

We endorse and support the recommendations Families USA is submitting to CMS to improve the Part D benefit. In addition, we want to highlight the following provisions and recommendations that we feel are of particular importance to Medicaid recipients in New York State. We believe it is within the authority of CMS to issue regulations and request any corrective legislative changes needed to provide a more accessible and affordable drug benefit, particularly for Medicaid and other low-income beneficiaries.

Subpart,B, Eligibility and Enrollment

1. States are expected to eliminate full Medicaid drug coverage to dual eligibles on January 1, 2006. This will cause dual eligibles exercising their rights under §423.36 to lose up to 5 months of drug coverage. CMS must seek immediate legislative relief to allow states to provide full drug coverage with 100% federal match to all dual eligibles during their statutory enrollment period. This should apply on an on-going basis, not just January 2006, to cover all Medicaid eligibles when they become Medicare eligible, because of age or disability.

2. Provisions for outreach and education in § 423.48 must be strengthened. The regulations should outline actions CMS will undertake, and specify requirements for plans and states, to ensure that a concerted outreach and assistance campaign for dual eligibles takes place alerting potential recipients about the need to enroll in a Part D plan and helping them make appropriate choices. The states or CMS must involve

community-based organizations and providers that serve and work with dual eligibles in this enrollment process in order to ensure culturally appropriate outreach and assistance. In addition, drug plans should be required to include, in their bids, specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness.

3. The dual eligible need access to a meaningful range of plans. Individuals dually eligible for Medicare and Medicaid are the sickest and poorest Medicare beneficiaries and often have extensive prescription drug needs with 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.

§423.30 and §423.34 should be modified to allow dual eligible beneficiaries access to the full-range of plans in their area and not be limited to the plan(s) with the lowest or average premiums. 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 without an added premium.

4. In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. Without knowledge of the timing and frequency of the information flowing between CMS, the state and the drug plans, it is difficult to determine which agency is best suited to the task. The clear objective should be to maximize beneficiary choice and to minimize auto-enrollment.

State officials have more readily available data identifying dual eligibles and will be involved in the enrollment process already because they are required to perform low-income subsidy enrollment. However, we are concerned that the incentive states have to enroll dual eligibles in Medicare drug plans in order to avoid the increased utilization of other Medicaid services, will be offset by the "clawback" provision in Part D. We urge CMS to seek legislative change to eliminate the "clawback" provision. In the meantime, we urge CMS to reimburse the state for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.

5. We urge CMS to modify §423.780(c) to exempt individuals eligible for the low-income subsidy from the late enrollment penalty described in §423.46. In the alternative, CMS should delay implementation of the late enrollment penalty for two years. Many Medicare beneficiaries will need more than 6 months to understand how Part D coordinates with other drug coverage they may have, and then choose the drug plan that is right for them. Individuals eligible for the subsidy face the additional complexity of two different program applications and may not understand that they have to apply separately for the subsidy and a drug plan. Beneficiaries should not be penalized because of the program's complications.

6. Under § 423.48, we urge CMS to require that plans provide potential enrollees with a minimal amount of information, including premium amounts; benefit structure and comparative values of plans; copays on the formulary, and the negotiated prices upon which the copays are based; the formulary structure, and how the formulary can change during the year; participating pharmacies; and the appeal and grievance processes. In addition, due to the proposed differential cost-sharing between "preferred and "non-preferred" pharmacies (Subpart C, p. 46658), beneficiaries will need each plan's costs by pharmacy in order to make an informed choice between plans. This information must be provided by the plans and be available on the CMS website.) Note: the same principles apply to calls to 1-800-MEDICARE.

Individuals choosing plans should receive all the information required under §413.48 and under the dissemination provisions of §423.128 without having to make individual requests for each item. The regulation should specifically require dissemination of all the items when a potential enrollee requests any information about the plan. (p46664).

Subpart C Voluntary Prescription Drug Benefit and Beneficiary Protections

7. We urge several changes to §423.120 on formularies. Drug plans serving dual eligibles must be able to respond to a range of disabilities and conditions, including physical impairments and debilitating psychiatric conditions, and other serious conditions such as cancer, cerebral palsy, cystic fibrosis, Parkinson's disease, multiple sclerosis, autism and HIV/AIDS. The following requirements for are essential to a flexible and adequate formulary:

(a) § 423.120 should provide minimum timeframes for periodic evaluation and analysis of protocols and procedures for plan formularies, in order to ensure that the formularies keep abreast of advances in clinical management of disease.

(b) The regulation should strictly limit mid-year formulary changes and require plans to justify a decision to remove drugs from a formulary. The proposed rule prohibiting a plan from removing a covered drug from its formulary or changing the drug's cost-sharing status from the beginning of the annual election period to 30 days after the contract year (ie., Jan 31) provides too little protection. A person new to the plan or using the drug for the first time who filled a prescription for such a drug on January 5 would not receive the timely 30 day notice (p46661). Providing coverage for only one month out of the 12 months the beneficiary was expecting and needing would be cruelly unfair. §423.120(b)(6) should be modified to require plans to offer the described drugs and cost-sharing for a minimum of three months in the contract year, or the remainder of the contract year, whichever is longer.

(c) Plans should be required to provide notice, in writing, mailed directly to any beneficiary affected by a formulary change, 90 days prior to the change

informing the beneficiary of his or her right to request an exception and appeal the plan's decision.

(d) We appreciate that CMS recognizes that special populations do need protection from plans' tiered formularies and other cost-saving processes in order to meet their drug needs. (p46661) While we agree the groups mentioned merit protection, we urge CMS to extend protections to all low-income subsidy eligibles, institutionalized beneficiaries (see #16 below), and those with life-threatening or pharmaceutically complex medical conditions.

8. We have strong reservations about CMS allowing plans to impose 100% beneficiary cost-sharing for any drug. (p46654) If CMS does so, it must clearly exempt dual and other low-income subsidy eligibles.

9. CMS indicates it is considering suggesting an addendum to pharmacy-drug plan sponsor contracts for I/T/U and Federally Qualified Health Center pharmacies to waive or modify standard contract clauses that are impractical for those pharmacies. (p46657) We recommend CMS require an addendum to all contracts to require all pharmacies to waive co-pays by dual eligibles and others qualifying for the low income benefit. This would provide the dual-eligible beneficiaries protection similar to what they now have under the Medicaid regulations and extend this protection to other low income beneficiaries.

10. We strongly oppose the imposition of additional costs to the beneficiary when she (1) chooses to use her neighborhood instead of a mail-order pharmacy (p46659) or (2) must use an out-of-network pharmacy for the reasons specified at II.C.5 (p. 46662) At a minimum, these costs must not be applied to low-income beneficiaries who cannot afford them. Also, CMS needs to establish a process for enabling a low-income beneficiary, when necessary according to its own criteria, to access an out-of-network pharmacy without paying the full price of the prescription.

11. We agree with CMS that a Pharmaceutical and Therapeutics (P&T) committee's formulary decisions should be binding on the plan. In response to a question in the Preamble, we also strongly recommend that the P&Tcommittees should approve and oversee implementation of utilization management activities of health plans offering the Medicare drug benefit under § 423.153. With regard to the composition of the P&T committee (p46659), we recommend CMS require:

(a) a majority of the physicians be expert in the care of the aged and disabled. The Medicare drug benefit is solely for the aged & disabled for whom drugs' dosage, efficacy, and interactions frequently differ from younger populations. "Doctors in the United States are prescribing inappropriate and potentially harmful drugs to more than one in five older patients, according to a new study examining data from more than three-quarters of a million elders."

(*Aging Today*, Sept-Oct 2004, reporting on a study in *Annals of Internal Medicine*, Aug 9/23, 2004)

(b) all P&T members be independent and free of conflict with respect to pharmaceutical manufacturers. Otherwise, in everyday terms, CMS is letting the fox into the chicken coop.

(c) at least one-quarter of the P&T members be independent and free of conflict with respect to the sponsor and plan.

12. Patients receive prescriptions from hospital ER's 24 hours a day, including Saturdays, Sundays and holidays. Any problems they have finding a pharmacy or dealing with coverage problems demand immediate attention. 24/7 access to the plan is needed for both the beneficiary and the prescribing doctor. (p46664) §423.128(d)(1) should be modified accordingly.

13. We understand CMS's reluctance to tell plans what cost management tools they may employ, but they must not be given *carte blanche*. At a minimum, CMS must prohibit plans from limiting the number of prescriptions a beneficiary may fill except when a plan can document to CMS's satisfaction beneficiary fraud or abuse.

Subpart M, Grievance, Coverage Determinations and Appeals

14. We urge CMS to consider substantial revision to this subpart. We would first ask that the agency seek statutory changes in order to provide for an appeals process similar to Medicaid. In the meantime, we recommend that the regulation be clarified to provide a meaningful, fast-track, pre-termination review that will be accessible to enrollees in the program. While we refer you to the full discussion of the section contained in the Families USA comments, we wish to emphasize the following provisions:

(a) Section 423.566, describing coverage determinations, needs to clearly state that 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 the right to request a re-determination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless.

(b) Section 423.568, which currently places the responsibility for providing notice of a coverage determination on the plan sponsor, should be amended to address the reality of how beneficiaries will receive or experience denial of prescription drug services. In most situations, the pharmacy will tell 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.

(c) The regulations should require the plan sponsor to develop a notice explaining the right to seek a re-determination, and to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Any potential burden involved in requiring the pharmacy to give notice to the enrollee is reduced by the need Part D will create for maintaining 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.

(d) Under § 423.570 all coverage determinations and appeals concerning drugs should be treated as requests for expedited reviews. All requests for exceptions to exclusions from formularies in order to continue use of a prescribed drug should be automatically given expedited consideration. Plans should be required to process the request in 24 hours, with the enrollee receiving a 72-hour supply of the medicine, renewable if the plan decides to take longer processing the request.

Subparts P & S, Premiums and Cost Sharing Subsidies for Low-Income Individuals and Eligibility Determinations for Subsidies

15. The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs must ensure enrollment is as streamlined as possible. CMS should require state Medicaid agencies to follow the procedural guidelines the Social Security Administration (SSA) promulgates for its district offices to determine eligibility for the low-income subsidy. States should be required to offer applicants the opportunity to enroll during the initial screening visit. Documentation must be kept to a minimum, never to exceed documentation requirements promulgated by the SSA. CMS must not allow any state to put up its own procedural barriers to access to this federal benefit.

(a) §423.904(d)(3) should specify that states may require submission of statements from financial institutions only if the applicant is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information.

(b) § 423.904(d)(3)(ii) should be modified to permit states to use the verification process established by the SSA to verify income and assets of people who apply for a Part D subsidy through a state Medicaid agency.

(c) §423.774 should be amended to allow for presumptive eligibility and minimize the cost and disruption in service caused by frequent re-

determination through adoption of an annual, streamlined re-determination procedure that would require beneficiaries to respond only if any of their relevant information had changed over the year.

16. The definition CMS proposes (p46729) for the fully eligible dual eligible "institutionalized individual" who has no cost-sharing below the OOP threshold is unduly restrictive. It should apply to individuals in all congregate care facilities who are entitled to a personal needs allowance, as well as those eligible for home and community based services under a Medicaid waiver, since they are generally subjected to the same budgeting rules as recipients receiving coverage in an institution.

In conclusion, may we remind you the Medicare-Medicaid dual eligibles are the only Medicare beneficiaries for whom enrollment in Part D is ***involuntary***. CMS has a daunting ethical obligation to this particular population – those most ill and least health literate - to ***do no harm***. We urge you to keep this in mind as you consider our recommendations and those coming from Families USA.

Sincerely,

James Collins
For Medicaid Matters New York

Medicaid Matters

Medicaid Matters New York

Access to Independence of Cortland County
Action for a Better Community, Rochester NY
AIDS Treatment Data Network
AIDS Day Services Association
Alianza Dominicana
Alzheimer's Association, New York City Chapter
American Cancer Society
Aspire of Western New York
Bronx Health Link
Brooklyn-wide Interagency Council of the Aging
Brooklyn Perinatal Network
Cancer Care
Care for the Homeless
Catholic Charities AIDS Services, Albany NY
Center for Disability Rights, Rochester NY
Center for Independence of the Disabled, NY
Cerebral Palsy Associations of New York State
Chenango Health Network
Chinese-American Planning Council
Citizen Action of New York
Citizens' Committee for Children of New York
Coalition for the Homeless
Coalition of NYS Alzheimer's Association Chapters
Coalition of Voluntary Mental Health Agencies
Commission on the Public's Health System
Community Health Care Association of New York State
Community Healthcare Network
Community Service Society of New York
Consumers Union
Damian Family Care Center
Disabled in Action
District Council 37/AFSCME
District Council 37/Local 1549
East Harlem Community Health Committee
Family Planning Advocates of New York State
Federation of Protestant Welfare Agencies
Friends and Relatives of the Institutionalized Aged
Gay Men's Health Crisis
Goddard Riverside Community Center
Greater Rochester Interfaith Health Care Coalition
Greater Southern Brooklyn Health Coaltion
Greater Upstate Law Project
Harlem Interagency Council for the Aging
Health and Welfare Council of Long Island
Heritage Centers, Buffalo NY
Hispanic Senior Action Council
Hospice and Palliative Care Association of NYS
Housing Works
Hunger Action Network of New York State
Independent Living Center of the Hudson Valley
Institute for the Puerto Rican/Hispanic Elderly
JPAC for Older Adults
Legal Action Center
Long Island Association for AIDS Care
Long Island Minority AIDS Coalition
Lower East Side Health Care Coalition
Manhattan Boroughwide Interagency Council on Aging
Medical and Health Research Association of NYC
Medicare Rights Center
Mental Health Association of NYC and Westchester
Mental Health Association in New York State
Metro New York Health Care for All Campaign
Metropolitan Council on Jewish Poverty
Morris Heights Health Center, Bronx NY
Mothers & Babies Perinatal Network, Binghamton NY
NARAL Pro-Choice New York
National Association of Social Workers, New York State and New York City Chapters
National Multiple Sclerosis Society, NYC Chapter
New York AIDS Coalition
New York Association of Psychiatric Rehabilitation Services
New York Citizens' Committee on Aging
New York City AIDS Housing Network
New York City Providers of Health Care for the Homeless
New York City Task Force on Medicaid Managed Care
New York Immigration Coalition
New York Network for Action on Medicare and Social Security
New York State Association of Retarded Citizens
New York State Catholic Conference
New York State Council for Community Behavioral Healthcare
New York State Health Care Campaign
New York State Nurses Association
New York State Psychological Association
New York StateWide Senior Action Council
New Yorkers for Accessible Health Coverage
Northern Queens Health Coalition
Nurses United CWA Local 1168, Buffalo NY
Nursing Home Community Coalition of New York State
Planned Parenthood of Buffalo/Erie County
Planned Parenthood of New York City
Planned Parenthood of Rochester/Syracuse
Providers of Health Care for the Homeless
Public Health Association of New York City
Queens Center for Progress
Roberto Clemente Center
Schuyler Center for Analysis and Advocacy
Selfhelp Community Services
Services and Advocacy for Gay, Lesbian, Bisexual and Transgender Elders
Southern Tier AIDS Program
Staten Island Welfare Advocacy Network
The Children's Health Fund
The Floating Hospital
The Legal Aid Society
The National Alliance for the Mentally Ill – NY
The New York Forum for Child Health
United Neighborhood Houses
University Settlement

c/o 119 West 24th Street, 9th Floor, New York, NY 10011 Phone: (212) 367-1228

Urban Justice Center
Visiting Nurse Service of New York
Voices of Women of Color Against HIV/AIDS
Westchester Disabled on the Move
Westchester Health Action Coalition
Western New York Health Care Campaign
William F. Ryan Community Health Center
Women's City Club of New York

Submitter : Ms. Joy Donelson **Date & Time:** 10/04/2004 04:10:34

Organization : New Mexico Pharmaceutical Care Foundation

Category : Other

Issue Areas/Comments

Issues 1-10

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

New Mexico Pharmaceutical Care Foundation
4800 Zuni S.E.
Albuquerque, New Mexico 87108

October 3, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
www.cms.hhs.gov/regulations/ecomments

Re: CMS-4068-P

Dear Sir or Madam:

The purpose of this letter is to comment on the Medication Prescription Drug Improvement, and Modernization Act of 2003 (MMA), specifically the Medication Therapy Management Program.

The New Mexico Pharmaceutical Care Foundation was established to provide resources for pharmacy education, research, projects in pharmaceutical care and disease management, education for pharmacists, pharmacy technicians and the public, and community screening and public health projects related to pharmaceutical care.

Currently, under New Mexico law, pharmacists can have full prescriptive authority under the supervision of a physician to provide medication therapy management limited only to the scope of the physicians practice.

As the New Mexico Pharmaceutical Care Foundation, we make the following recommendations for successful implementation of the program, leading to improved patient care.

It is our position that CMS should include in the rules:
1. Rules to determine who is a qualified provider, and that pharmacists should be granted primary provider status within the regulations.
2. Under-use of medications often is as serious a drug-related problem as is over-use. Based upon this, targeted beneficiaries should not be limited, except to patients with at least one chronic disease condition.
3. Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas.
4. The patient must have freedom of choice of providers.
5. CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas.

Signed,

Joy Donelson, RPh President

CMS-4068-P-961-Attach-1.doc

New Mexico Pharmaceutical Care Foundation
4800 Zuni S.E.
Albuquerque, New Mexico 87108

October 3, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
www.cms.hhs.gov/regulations/ecomments

Re: CMS-4068-P

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3. Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas.
4. The patient must have freedom of choice of providers.
5. CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas.

Signed,

Joy Donelson, RPh President

CMS-4068-P-962

Submitter : Mrs. Valerie Rinkle **Date & Time:** 10/04/2004 04:10:53

Organization : Asante Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Asante
2650 Siskiyou Blvd.
Medford, OR 97504

October 4, 2004

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

Attn: CMS-4068-P
Medicare Prescription Drug Benefit ? Proposed Rule

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

Dear CMS:

Part D Coverage of Non-Covered Outpatient Hospital Self-Administered Drugs

Under Part B, self-administered drugs such as insulin and other prescription medications are non-covered. Patients who are outpatient hospital patients of the Emergency Department, provider-based clinics, outpatient surgery or observation patients are often administered these drugs under physician order for medically necessary conditions. These drugs are non-covered and are billed to patients as patient liability. Note that CMS has clearly instructed hospitals that they cannot routinely write-off these non-covered charges. Patients are very confused and outraged at having to pay for these drugs. Note that for patient safety and quality of care reasons, patients often cannot bring these medications into the hospitals and self-administer while they are treated for other conditions.

Hospitals need clarification regarding the following:

(1) Will the new Part D benefit for prescription medications apply to self-administered prescription drugs that are dispensed from hospital pharmacies?
(2) If yes, how will beneficiaries avail themselves of this benefit? Will hospitals have complex billing instructions to submit to various prescription plans? Hospital pharmacies are not equipped to bill drugs in the same manner as retail pharmacies.
(3) Alternatively, will hospitals have to provide drug coding and other detail on billing statements for beneficiaries that they submit to the prescription plan for reimbursement of their payment made to the hospital? If so, what is expected of hospitals?
(3) If Part D is not to cover these prescription drug expenses, how are hospitals to respond to beneficiaries who expect Medicare coverage of their prescription drugs under the new Part D benefit?

Hospitals respectfully request instructions on these questions and beneficiaries also need guidance.

Medication Therapy Management Performed by Hospitals

As discussed in the proposed rule, medication therapy management (MTM) is direct patient care. Many hospitals perform this service due to the needs of the Medicare beneficiary population and their complex prescription drug management issues. For example, in geriatric provider-based clinics, a pharmacist, based upon physician order, will assess the patient. The patient?s medication use, diet and medical history will be reviewed and the pharmacist will interview and assess the patient face-to-face. Often the pharmacist makes significant recommendations to the physician for medication adjustments. These visits are billed as a hospital visit under OPPS. At times, the service may be rendered as a pharmacy consult to an inpatient. Various hospitals, may or may not be separately billing this service when provided to inpatients.

Will hospitals lose the ability to perform this service under the MTM provisions for Part D? Will hospitals have to contract with the PDP or MA? Can this service continue to be rendered by the hospital separate from the MTM of the PDP or MA? If so, will this service be assigned a HCPCS code for separate tracking under OPPS? If the service meets the same medical necessity requirements for payment under OPPS, what is CMS? guidance on separate reporting of this service on inpatient claims paid under IPPS?

Thanks you for consideration of these comments.

Sincerely,

Valerie A. Rinkle
Revenue Cycle Director
Asante Health System

CMS-4068-P-963

Submitter : Dr. Jay Currie **Date & Time:** 10/04/2004 04:10:12

Organization : Individual

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

Subpart A - General Provisions

Beneficiaries of Medicare Part D Provider Plans will need assistance in making plan selection choices to best meet their needs. While this is an issue for all Part D beneficiaries, it will be of particular concern for individuals with additional coverage such as SPAP or private coverage, as they will need to assess the merged benefit of the PDP with additional coverage in making this decision. Beneficiaries do not have the knowledge base for making these decisions with only help regarding the financial side of the equation. Formulary coverage is of special concern and may be complicated depending on the PDP and any relevant additional coverage. Confusion in selection of a plan has resulting in many beneficiaries not enrolling for the current interim discount card coverage. Current education strategies to assist beneficiaries may not be adequate for appropriate decision-making when therapeutic decision making, and the need for health professional advice, is added as a variable. As was observed with the implementation of the current discount card system, it is anticipated that many beneficiaries will seek assistance from their pharmacists to help them assess individual plans. This process became burdensome to pharmacists with the discount card, and would be expected to occur again with implementation of Part D plans. Pharmacists who have knowledge of beneficiaries? medication needs, a working relationship with the beneficiaries? prescribers and experience working with third party payers should be seen as an asset in assisting individuals in making plan selection choices and facilitating enrollment. While in an excellent position to assist, pharmacists cannot be expected to provide this service without reimbursement. Many pharmacists would be willing to assist in the effort of helping beneficiaries assess the benefit of a plan for their health care needs. At least one national pharmacist association (The American Pharmacists Association) has proposed this solution in the past with the discount card.

Pharmacists will need training to assist beneficiaries in a method consistent with CMS guidelines on plan selection. CMS should expect that all providers of information to assist beneficiaries in making enrollment decisions will have adequate training to assure proper provision of this service. CMS working with national pharmacist associations could implement such training so as to allow interested pharmacists to assist beneficiaries to make these often difficult decisions regarding their medication-related health care. Pharmacists providing this consultative assistance to beneficiaries should upon providing necessary documentation be appropriately compensated for providing those services.

Recommendations:

1. Education Funds ? CMS should dedicate necessary funds to compensate pharmacists and others who help beneficiaries assess Part D plans.

2. CMS should work with national pharmacist associations and other appropriate entities to develop a process to:
a. prepare pharmacists and others to assist beneficiaries in assessing Part D plans,
b. document the provision of those services, and
c. compensate the service provider.

Submitter : Ms. Nancy Atkins **Date & Time:** 10/04/2004 04:10:00

Organization : APHSA/NASMD

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Attached is our submission of comments to the proposed Medicare Prescription Drug Benefit Regulations. We look forward to working with CMS on the implementation process. Thank you.

CMS-4068-P-964-Attach-1.doc

National Association of State Medicaid Directors

October 4, 2004

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

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

Dear Dr. McClellan:

The National Association of State Medicaid Directors **("NASMD")** respectfully submits the following comments regarding the proposed Medicare Prescription Drug Benefit Regulations, published in the Federal Register on August 3, 2004. (**the "Proposed Rule"**). NASMD, a non-partisan, professional nonprofit organization is the national representative of Medicaid Directors and their staffs in all 50 states, the District of Columbia and the territories. Since 1979, NASMD has been affiliated with the American Public Human Services Association (APHSA). The primary purposes of NASMD are to serve as a focal point of communication between the states and the federal government, and to provide an information network among the states on issues pertinent to the Medicaid program.

General Comments on the Proposed Rule

Our membership has raised significant questions and concerns to numerous aspects of the Proposed Rule. As you are aware, many of these issues raised by the Proposed Rule are highly technical in nature. NASMD applauds CMS and the Social Security Administration for establishing an open dialog with representatives from the states to address these myriad issues. The members of NASMD look forward to working closely with staff from both agencies while they review and prepare the final regulations to achieve the best possible implementation of the Medicare Modernization Act. **("the Act")**

Subpart B: Eligibility and Enrollment

Section 423.36: Enrollment Periods

Section 1860D-1(b)(1) of the Act requires the establishment of a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and change of enrollment rule for MA-PD plans under certain provisions of section 1851 of the Act. In accordance with section 1860D-1(b)(1)(C) of the Act, CMS is seeking to establish a process to automatically enroll full benefit dual-eligible individuals (as defined under section 1935(c)(6) of the Act) who has failed to enroll in a PDP or MA-PD plan by either the end of the individual's initial enrollment period or upon becoming dual

eligible after his/her initial enrollment period. For full benefit dual eligibles, this timeframe runs from 11/15/05 to 5/15/06. NASMD believes that the auto-enrollment process, for those who do not select a plan during their designated enrollment period, may present difficulties. Specifically, full benefit dual eligibles will lose their Medicaid prescription coverage effective January 1, 2006. Under Section 423.36 of the Proposed Rule, for 2006 dual eligibles may enroll or be enrolled in a PDP Part D plan until as late as May 15, 2006 at which time auto-enrollment would begin. That could leave many of them without prescription coverage for several months. The potential exists for this vulnerable population to either not fill necessary prescriptions, use emergency rooms or they may turn to a State Pharmaceutical Assistance Program **("SPAP")** in those states where they are available. Consequently, we recommend that Medicaid coverage, as well as federal financial participation in 2006 should not expire for dual eligibles until they have voluntarily enrolled in a Part D plan or until CMS or the State has automatically enrolled them in a plan.

Not only will full benefit dual eligibles not qualify for Part D benefits if unenrolled, but federal matching funds would also no longer be available to State Medicaid agencies as of January 1, 2006. In essence, the states would be paying 100% of the cost for these dual eligibles during this 6 month period of time. NASMD suggests two approaches to addressing the dual eligible issue. First, because of the myriad issues associated with determining eligibility for the low income subsidy, as well as ensuring that dual eligibles actually get enrolled into one of their available plan choices, we propose utilizing a phased in enrollment process for dual eligibles. Within this phased-in approach, states would still need to be able to draw down federal financial participation to cover the costs

of prescription drugs. We would also argue that these expenses should not be counted in the phased down state contribution calculation since that would result in states paying twice for the same beneficiary.

This phase-in period would allow the necessary outreach and education to take place. Furthermore, it would help ensure that beneficiaries would not lose drug coverage for any period. Under the Proposed Rule, states are unable to continue to provide drug benefits to any dual eligible beneficiary and receive federal financial participation. (See P. 46751 of the preamble to the Proposed Rule (**"the Preamble"**))**.** We believe that the January 1, 2006 cut-off potentially puts this already vulnerable population at increased risk.

NASMD's second approach is to treat all dual eligible individuals as a "special needs population" for at least the first year of Medicare Part D. Under the MMA, certain specialized Medicare Advantage plans can limit enrollment to special needs subgroups of the Medicare population in order to focus on ensuring that their needs are met as effectively as possible. This provision will encourage greater access to Medicare Advantage plans for special needs subgroups. We believe that the establishment of such special needs plans for dual eligible beneficiaries would allow for their unique health care needs to be better addressed. We have concerns that some broad-based Medicare Advantage plans may not be equipped to respond to the challenges posed by providing coverage to dual eligibles. One approach would be to allow states to enroll full-benefit dual eligibles into a preferred private prescription drug plan (PDP) of the State's selection similar to the process used for SPAPs (for those states that have them) and the Medicare discount card. Given the special needs of this population and the history the States have in managing their health care needs, it seems that auto-enrollment with a preferred PDP

would be the least disruptive way to allow the States to help dual eligibles select the appropriate prescription plan.

Automatic Enrollment Process: Section 423.34

In implementing the automatic enrollment process for full benefit dual eligible individuals, CMS is considering which entity is best suited to perform the automatic and random enrollment function. The options include CMS or the State performing this function, or a contracted entity or entities on their behalf. CMS notes in the Preamble that if states or their contracted entities performed this function that it "would be necessary for the proper and efficient administration of the State plan." The Preamble continues, "we would need to provide states with accurate and timely Part D data. States would be compensated for this effort through FFP in their administrative expenses or through contractual or other arrangements." We believe that if states were to manage the auto-enrollment process that federal financial participation is essential. In addition, such federal financial participation should be at the 100% level. However, NASMD's position is that states should have the option as to whether they would manage the auto-enrollment process. This sets up a scenario under which a state could determine, based upon various factors including existing infrastructure and data availability whether it would be feasible. Accordingly, NASMD does not believe that states should be required to manage the auto-enrollment process, but rather, that it should be at the option of individual states.

Finally, the auto-assignment provision Section 1860D-1(b)(1)(c) includes the use of the term "random" for the enrollment of full benefit dual eligibles. NASMD strongly believes that this process must include a detailed algorithm for auto-assignment.

NASMD would like to have input in the process of developing this algorithm. This may be a more significant issue in service areas that include existing PACE plans and special needs plans that could include full benefit dual eligibles. This may also be an issue for special populations such as those requiring care in nursing homes, HIV/AIDS populations, and those with serious mental illness because many of their drug costs will be out-of network. NASMD also believes that the Medicaid buy-in population, for those states that have established such programs, should be specifically acknowledged in the regulations under Subpart B.

Involuntary Disenrollment: Section 423.44

CMS provides under Sec. 423.44(d) of the Proposed Rule that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. According to the rule, an individual who is disenrolled for failure to pay monthly PDP premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided a Special Enrollment Period ("SEP") permitting him or her to enroll in another PDP. Since the individual generally will not be able to enroll in either a PDP or an MA-PD until the next annual coordinated election period, he or she may be subject to late enrollment penalties under Sec. 423.46 of the Proposed Rule. In the Preamble, CMS states that if the individual is prohibited from re-enrolling in each of the MA plans available in an area, original Medicare is always available to provide and deliver services to that individual. NASMD recommends that this approach be reassessed given the unique aspects of dual eligible individuals. Because Medicaid will no longer be able to receive federal financial participation for paying for prescription drugs, dual eligible

beneficiaries who are involuntarily disenrolled would face a significant hardship. In addition, many members of this population have mental health difficulties and other financial limitations that could make them more likely to face involuntary disenrollments than the Medicare Part D population at large. NASMD recommends that CMS develop a heightened standard for involuntary disenrollment for this vulnerable population. Furthermore, such disenrollment, if it occurs at all, should be contingent upon selection of another PDP or MA-PD plan to ensure there is no lapse in coverage. Finally, federal financial participation should be available for drug expenditures should the beneficiary decline participation; otherwise the individual is left without coverage. If these individuals are left without recourse, it could result in increases in caseloads in emergency rooms and nursing facilities providing these types of services. We believe there must be some fallback position here.

Subpart C: Benefits and Beneficiary Protections

Subpart C mandates that CMS provide certain Part D data to beneficiaries. NASMD believes that the Proposed Rule should be modified to include more detailed provision for furnishing Part D data to Medicaid programs regardless of whether the state has an active SPAP program. The absence of detailed Part D data will make it much more difficult to manage Medicaid programs for vulnerable dual eligibles.

Definition of Long-Term Care Facility: Section 423.100

CMS requested comments regarding the definition of the term long-term care facility in Sec. 423.100 of the Proposed Rule, which is interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Social Security Act, or a nursing facility, as defined in section 1919(a) of the Social Security Act. CMS expressed particular interest in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in Sec. 440.150 of the Proposed Rule, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. CMS stated that it understands that there are individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. The CMS proposed definition limits the definition to skilled nursing and nursing facilities because it is their understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, according to the Preamble, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, CMS stated that it would consider modifying this definition. NASMD recommends modifying this definition to include ICF/MR facilities and other types of long-term care facilities such as community-based facilities, as well as individuals covered under 1915(c) waivers. In some cases, they may contribute as much as half of their income to the cost of care and would not be able to afford significant out-of pocket costs for pharmaceuticals.

In the Preamble, CMS recognizes that LTC facilities generally contract with a single LTC pharmacy. So, to expect seniors in LTC facilities to access their Part D drugs at another pharmacy when the LTC pharmacy associated with their institution is not in a plan's network is unreasonable. CMS proposed two alternatives. CMS could use its authority to require plans to contract with some or all of the LTC pharmacies in their service area. Or CMS can strongly encourage plans to negotiate with and include LTC pharmacies in their network plan. NASMD shares CMS's concern about access to Part D drugs for seniors and disabled individuals in LTC facilities. These beneficiaries do not have the ability to go elsewhere to purchase their medications. NASMD recommends that CMS require the plans to contract with any willing LTC pharmacy.

Determination of Prescription Drug Plan Service Areas: Section 423.112

The Proposed Rule suggests that prescription drug plan service areas must be established for PDPs and the MA-PDs. The regions will be the basis for service areas in which participating MA regional plans and PDP plans will offer their products. The regions are also the basis for determining premiums, benefits and payments. A plan must serve an entire region and premiums cannot vary within the region. The Act requires that there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia, and at least one PDP region covering the US territories. PDP regions can be different than MA regions, but each should be created in a consistent manner. The deadline for establishing the regions is January 1, 2005, to become operational in January 2006. NASMD believes that the number of regions should be as close to one per state as possible. Multi-state regions will present challenges to Medicaid programs regarding

access to data, population characteristics, and ensuring adequate access to needed health care services. In addition, it should be noted that in border areas, MA-PD plans should be encouraged to contract with pharmacies in the adjacent states in accordance with historical patterns of beneficiaries access services from providers.

Tiered Pricing: Section 423.120(a)(5)

CMS interprets this provision as not restricting PDP sponsors and MA organizations from varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy's status within the plan's pharmacy network – in essence authorizing distinctions between "preferred" and "non-preferred" pharmacies. These distinctions within network are acceptable, despite the 'any willing provider' provision of the Proposed Rule at 423.120(a)(4)(i). CMS also stated that it recognizes the possibility that plans could effectively limit access in portions of their service area by using this flexibility to create a within-network subset of preferred pharmacies.

This tiered cost sharing based on within-network distinctions cannot increase the CMS payments to PDPs or MA-PDs according to the Proposed Rule. Thus, CMS proposes that the tiered cost sharing arrangements could be included in the plans' benefits subject to the same actuarial tests that apply for tiered cost-sharing structures applied to formularies. A reduction in cost sharing for preferred pharmacies could be offered through higher cost sharing for non-preferred pharmacies or as alternative prescription drug coverage.

In the Preamble, CMS recognizes the risk that plans will use this flexibility to discourage enrollees in certain areas from enrolling in that plan. CMS proposed that it will use its authority to review the bids submitted by plans so as to preclude the approval of any bids

that attempt to limit enrollment in certain service areas that are more difficult or costly to serve. The Proposed Rule at 423.120(a)(1) sets forth the access standards. We presume that CMS will apply these standards to a plan based on all network pharmacies submitted, not just the preferred pharmacies.

SPAPs are designed to serve low-income seniors on a statewide basis. NASMD is concerned that a plan could serve to price out some of these seniors by having a network of mostly non-preferred pharmacies. The higher cost-sharing for non-preferred pharmacies simply shifts the higher costs to the SPAPs that provide some cost-sharing, without any influence from the SPAP to the member as to which pharmacy will provide the better cost-sharing. Also, while CMS will review the plans to ensure the design does not discourage enrollment in certain less 'lucrative' areas, SPAP programs have expressed concern that this interpretation of access will cause an even greater disparity between the SPAP pharmacy network and the PDP network in the same service area. SPAPs have expressed concern with the CMS interpretation of "any willing provider" allowing a PDP or MA-PD to submit pharmacy access plans that include higher cost non-preferred in-network pharmacies. Even CMS acknowledges that this allowance presents risks that certain geographic areas and certain low-income seniors begin to be "costed out" of participation. The distinction between preferred-in-network and non-preferred-in-network is one of cost only and creates two-tiered in-network access that can lead to discrimination. This distinction also adds to confusion and complexity for seniors trying to enroll and understand the rules of a particular plan. This interpretation provides no advantages to seniors or SPAPs, rather it lends itself to potential discrimination and to access problems for enrollees.

Therefore, NASMD recommends that the access standards for pharmacies be revised to require PDPs and MA-PDs to meet the defined network access standards with preferred pharmacies.

Formulary Design

As provided under section 1860D-4(b)(3)(C)(ii) of the Act, CMS has requested that the U.S. Pharmacopeia (USP) develop a model set of guidelines that consists of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. CMS expects that the model categories and classes developed by USP will be defined so that each includes at least one drug that is approved by the FDA for the indication(s) in the category or class. That is, no category or class would be created for which there is no FDA approved drug and which would therefore have to include a drug based on its "off label" indication. While NASMD generally approves of the process being utilized by USP we point out an inherent flaw in the decision that, in some cases, only one drug approved in a given therapeutic class will be included in the formulary. In the case of many drugs that require lengthy periods to determine "stable" doses, abruptly changing a beneficiary's medicines in order to ensure reimbursement as a covered Part D drug could have serious consequences to that individual's health and welfare. Such negative outcomes are especially likely in the case of psychotropic compounds, HIV/AIDS medications, cardiac regimens, and anti-convulsants. Accordingly, we advocate that CMS creates transition period of at least 60-

90 days for these types of individuals during which a patient's current drugs would be covered regardless of their inclusion in the formulary. Generally, we also state that there are significant difficulties in determining whether a drug is actually used on an off-label basis. Furthermore, there are numerous legitimate off-label uses that represent an integral aspect of the practice of medicine.

Moreover, we believe that any established formulary exceptions criteria must be flexible enough to take into account the actual circumstances of a particular beneficiary. The Secretary should provide a guideline to MA-PD plans, as well as stand-alone PD plans that requires such flexibility.

Medicaid-Only Beneficiaries

Generally, CMS should also prepared to issue a state plan preprint that clearly articulates that the states can provide prescription drugs as an optional service to non-duals, but not to dual eligibles, without violating the provisions of equal amount, scope, and duration of benefits as contained in the applicable rules.

Subpart G: Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans

Low-income cost sharing subsidy payment amount: Section 423.329 (d)

Payments under this section are based on a method that CMS determines. SPAPs have expressed interest in setting up a process to pay premium costs for their beneficiaries.

For beneficiaries with incomes between 135%-150% FPL, CMS will pay premium costs

on a sliding scale basis. Some SPAPs want to supplement this premium subsidy so that their beneficiaries do not have to pay first and be reimbursed by the SPAP. We believe that Section 423.329 should include a requirement for plans to implement a process, similar to the Medicare Part B buy-in process, which will allow states to pay Medicare Part D premiums on behalf of SPAP beneficiaries. Since premiums will need to be paid before January 1, 2006, this process needs to be in place before program implementation.

Subpart J: Coordination Under Part D Plans With Other Prescription Drug Coverage

State Pharmaceutical Assistance Programs

CMS assumes in the Preamble that some SPAPs will pay Part D plans' premiums on behalf of enrollees. CMS also has stated that it expects that many SPAPs will choose to wraparound coverage rather than paying premiums. CMS proposes to include SPAP information in a coordination of benefits system. Thus, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan. It appears that existing SPAPs will be more likely to serve in a wraparound type function. NASMD believes that Section 1860D-23(b)(2) of the MMA should allow SPAPs to determine the scope of wraparound benefits. If a beneficiary chooses to enroll in another PDP or MA-PDP, the SPAP should not be held responsible for a level of coverage above the benchmark level of coverage of the SPAPs preferred provider(s). SPAPs should not be required to provide wraparound coverage over a standard benefit or for costs higher than those of the preferred PDP, thus providing the same coverage across all plans. In other

words, SPAPs should have adequate flexibility in setting up their benefit once the standard benefit level is met.

Out of Pocket Costs and AIDS Drug Assistance Programs

The proposed regulations explicitly state that expenses made on behalf of a beneficiary by AIDS Drug Assistance Programs (ADAPs) cannot count toward that beneficiary's true out of pocket costs. Not allowing ADAP funds to be spent on premiums, deductibles, cost-sharing or the amount spent filling in the "donut hole" may leave those people living with HIV/AIDS (and not currently on Medicaid) vulnerable to not receiving adequate care and potentially placing them on Medicaid with greatly deteriorated health care outcomes. This has implications for the medical management of their conditions, especially from the increased risk of the development of resistance to currently available HIV-related antiretroviral medications. We suggest that the final regulation provide for such expenditures to be counted.

Coordination with Managed Care Plans Section 423.464(a)

It is the experience of SPAPs, that are unwilling to deny claims based on poor data or other prescription coverage, to find other insurers to be uncooperative in coordinating benefits. The legislation and Proposed Rule say the plans must "permit" SPAPs to coordinate benefits with them. This assumes a proactive role by SPAPs, with a reactive one by plans that may prove difficult to enforce. NASMD believes that Part D Plans should be <u>required</u> to coordinate benefits with SPAPs, rather than simply be required to "permit" SPAPs to coordinate benefits with them. CMS should establish clear and detailed guidelines and requirements that plans must follow to support effective

coordination with participating SPAPs. This should include a requirement that Part D plans participate in retroactive recovery processing, using standard claim transaction formats, to properly reimburse SPAPs for claims inappropriately submitted to and paid by an SPAP as the primary payor. Additionally, pharmacies should not be held responsible for coordination problems. Reasonable time periods for recoveries should be defined, consistent with common timely filing requirements. Requiring this coordination process will likely foster greater participation by SPAPs and aid in providing more comprehensive benefits through the wraparound process. In addition, Medicare Advantage plans should also be required to coordinate benefits with existing Medicaid managed care plans.

General Comments Regarding Native American Populations

1. ***The Indian population should all be exempt from premiums, deductibles and copayments***. Imposing premiums and copayments will cause a lot of confusion for tribal elderly and often will result in much of the cost of prescription coverage being shifted from the PDP plans to the IHS, Tribal,Tribal Organization and Urban Indian Health Programs (I/T/Us) pharmacies as tribal elders decline to enroll in or disenroll from the plans. An exemption from premiums, deductible and copays is consistent with the federal trust responsibility that all federal agencies share, including CMS. The Indian population is different from other groups by virtue of the trust relationship with the federal government and the obligation of the federal government to provide health care separate and apart from any Medicaid and Medicare considerations.

2. ***The prohibition against I/T/Us paying toward incurred "out-of-pocket" costs should be reversed.*** I/T/Us are greatly underfunded and the cost of helping a small portion of the elderly and disabled tribal members with their out-of-pocket incurred costs would not be substantial as a percentage of overall expenditures. Denial of catastrophic coverage to Indian health program users is inappropriate and will deny many reimbursements currently available under Medicaid.

3. ***I/T/U Pharmacies should be included in the PDP pharmacy networks***, if they choose to be, to ensure that they are paid for the prescription drugs that they provide to PDP or MA-PD covered individuals.

4. ***I/T/Us should be assured 100% of their ITU rate of reimbursement***, similar to the protection for Federally Qualified Health Centers under proposed 422.316 and 422.527. I/T/Us need to be fully reimbursed for prescription drugs provided to individuals enrolled in a PDP or MA-PD.

5. ***I/T/U users should be allowed full benefit of Medicare Advantage*** program without losing free access to I/T/U services; Indian programs should be fully reimbursed and otherwise made part of MA planning.

PACE Program Waivers: Section 423.458

Sec. 423.458(d) of the Proposed Rule establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. Because many of the Part D requirements duplicate, conflict

with, or inhibit coordination of existing PACE requirements, CMS anticipate a significant number of waivers would be necessary for PACE organizations. CMS expressed concern about the potential burden this would place on PACE organizations and proposed to include a provision that would allow for CMS to identify all Part D provisions requiring waivers and waive these provisions on behalf of PACE organizations. In other words, CMS is considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule without a plan-specific application process. NASMD supports the automatic waiver of these requirements for PACE and other similar health plans such as social health maintenance organizations that also serve significant numbers of full benefit dual eligible individuals.

Subpart M: Grievances Coverage Reconsiderations and Appeals

The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, 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. NASMD urges CMS to consider an appeals process that is similar to Medicaid. Adequate notice and the opportunity for a speedy review of a denial or other plan action are essential to the dual eligible population.

Subpart S: Special Rules For States: Eligibility Determinations for Low-Income Subsidies and General Payment Provisions

Eligibility Determinations, Redeterminations and Applications: Section 423.774

According to the Preamble, based upon section 1860D-14(a)(3)(B)(i) of the Act, an application for subsidy assistance may be filed with either a State's Medicaid program office or SSA. Inquiries made by individuals to PDPs or MA-PDs concerning application or eligibility for the low-income subsidy could be referred to State agencies or SSA. Eligibility determinations would then be made by the State for applications filed with the State Medicaid agency or by the Commissioner of Social Security for those filed with SSA. NASMD applauds the extensive work of the Social Security Administration in putting together the application and process for determination of the low income subsidy for Part D benefits. Nevertheless, NASMD seeks clarification from CMS as to what the proper role of the state Medicaid programs should be in this process. We believe that the statute should be interpreted so as to allow states to make an assessment to determine whether they could participate. States, at a minimum, should serve an intake function, or at their individual discretion, should have the option to process the application themselves. We understand that a literal reading of the statute suggests that beneficiaries should have a choice as to whether to file their application through SSA or through the state Medicaid program. We are concerned, however, that this system may result in two competing processes. Moreover, we point out that even if states only handle a relative few of these applications, they would be required to develop whole new systems to do so. This would not be the best use of limited resources available for state Medicaid programs. Accordingly, NASMD seeks to achieve an understanding with CMS regarding state Medicaid program responsibilities under the Act with regard to the low income subsidy process.

Phased Down State Contribution to Medicare Part D Drug Benefit Costs: Section 423.908

Under the Proposed Rule, states would provide a phased down state contribution to Medicare Part D drug benefit costs. This amount is based on drug expenditures on covered Part D drugs during calendar year 2003. The Proposed Rule indicates that the prescription drug expenditures for the full-benefit dual eligible population in 2003 will be based on MSIS reported data as adjusted by the drug rebate benefits**.** We ask that CMS clarify how it will consider these drug rebate benefits. Simply utilizing a portion of the amounts reported on the CMS-64 reports for 2003 does not reflect that much of the rebate benefits for these drug expenditures are not reported until they are received by the states after the end of 2003 and that a portion of the rebate benefits recorded on the 2003 CMS-64 reports are related to drug expenditures incurred in 2002 (i.e. the lag factor). In addition, a number of states have implemented new laws and programs promoting cost containment in pharmaceutical expenses. Many of the benefits of these initiatives are not reflected in 2003 data but will ultimately result in lower overall drug costs. We encourage CMS to take this into account when considering modifications to the phased down state contribution to drug benefit costs. Moreover, we ask CMS to clarify which National Health Expenditure projection will be used for the phase-down calculation, e.g., national average, Medicaid expenditures or other. Furthermore we would like clarification as to whether there will be adjustments to the inflation factors included in the clawback calculation. The Preamble explains that "…and the estimated actuarial value of prescription drugs benefits provided under a capitated managed care plan for these

individuals in 2003." It is critical for CMS to issue guidance on the process for calculating the managed care portion of the phase-down calculation. It should also be noted that this may be a labor intensive process depending upon the existing Medicaid managed care penetration in a given state.

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

NASMD greatly appreciates the opportunity to submit comments on the Proposed Rule. We welcome the opportunity to discuss the comments with you and your staff. Should you have any questions, please contact Nancy Atkins or Elaine Ryan at (202) 682-0100.

Respectfully submitted,

Nancy Atkins, MSN, RNC, NP
Chair, NASMD

Jerry Friedman
Executive Director, APHSA

CMS-4068-P-965

Submitter : Mr. Ray Hanley **Date & Time:** 10/04/2004 04:10:09

Organization : EDS

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see comments in attached Word file. Thank you.

CMS-4068-P-965-Attach-1.doc

October 1, 2004

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

Thank you for an opportunity to comment on the proposed rule to implement the new Medicare Prescription Drug Benefit (CMS-4068-P). The passage of the new Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) is a landmark measure that dramatically changes the Medicare program. EDS has been delivering solutions to the healthcare market for over 40 years, including processing claims for Medicare, Medicaid, and our commercial clients. The largest provider of Medicaid and Medicare process management services, EDS administers healthcare benefits for more 40 million Medicare and Medicaid recipients. A seamless implementation of the MMA is a priority for the government, our corporation and our clients.

Our mission is to support our clients and help them achieve their business goals. As part of our commitment, EDS continues to work with our clients, our partners, and the Centers for Medicare and Medicaid Services to ensure that we, as an industry, are working together towards an efficient, timely and operational healthcare system.

EDS supports the goals of the MMA. We recognize that implementing MMA regulations will have a tremendous impact, both financially and operationally, on the healthcare industry and the lives of millions of Americans, and may ultimately reduce costs in the administrative and financial aspects of the Medicare and Medicaid programs. We are committed to helping our clients succeed in the implementation of the new Part D Medicare drug benefit as established in Title I of the MMA and the new Medicare-Advantage as established in Title II.

There are a number of provisions that we believe should be modified and clarified. We appreciate your consideration of our comments as you work toward finalizing the regulation.

Thank you for the opportunity to comment on the proposed rule and we look forward to the publication of the final rule in January of next year and the implementation of the new Part D benefit and the Medicare-Advantage plans.

Sincerely,

Ray Hanley

EDS Comments on Proposed Drug Rule

Part D of the Medicare Program

Definitions (Part 423, Subpart A)

- Section 423.100: EDS recommends that the definition of "institutionalized" include ICF-MR and HCBS eligible. 440.150 of the Proposed Rule, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. CMS stated that it understands that there are individuals residing in these facilities who are dually eligible for Medicaid and Medicare. In the Preamble, CMS recognizes that LTC facilities generally contract with a single LTC pharmacy. So, to expect seniors in LTC facilities to access their Part D drugs at another pharmacy when the LTC pharmacy associated with their institution is not in a plan's network is unreasonable. CMS proposed two alternatives. CMS could use its authority to require plans to contract with some or all of the LTC pharmacies in their service area. Or CMS can strongly encourage plans to negotiate with and include LTC pharmacies in their network plan. NASMD shares CMS's concern about access to Part D drugs for seniors and disabled individuals in LTC facilities. These beneficiaries do not have the ability to go elsewhere to purchase their medications. SPAPs recommend that CMS require the plans to contract with any willing LTC pharmacy.

- Dispensing Fees (Section 1860D or page 46647 of the **Federal Register**): The rule considers three different definitions or options of "dispensing fee." EDS recommends that CMS use Option 1 because it is the option most closely aligned with the current Medicaid program definition of "dispensing fee". Use of a different definition could result in the need for states to implement significant editing/auditing to ensure proper payment.

- Part D vs. Part B: It is important to ensure that the appropriate carrier pays for what they're responsible for, in particular take-home medication/injections. Not all of these services are identifiable as an NDC but instead are billed as a HCPCS code which makes matching to a formulary a challenging. Otherwise, significant editing/auditing will be required to determine if services are inappropriately applied to Medicaid (that would be covered under Part D dispensing fee).

Premiums

- Part D Premiums should be automatically withheld from Social Security checks like Part B premiums, or paid directly to PDP through electronic funds transfers by client.

Dual Eligible Coordination and Data sharing (s 423.772 (Subpart P)

- Section 1860D-1: Eligibility, Enrollment, and Information: States and CMS should be able to track dual eligible beneficiaries consistently across both Medicare and Medicaid programs. CMS should require data transfers to States from PDPs and CMS as well as States to CMS using specifications consistent with the MMIS and HIPAA requirements.

- Section 423.36: Full benefit dual eligibles will lose their Medicaid prescription coverage effective January 1, 2006. Under Section 423.36 of the Proposed Rule, for 2006 dual eligibles may enroll or be enrolled in a PDP Part D plan until as late as May 15, 2006 at which time auto-enrollment would begin. That could leave many of them without prescription coverage for several months. The potential exists for this vulnerable population to either not fill necessary prescriptions, use emergency rooms or they may turn to an SPAP in those states where they are available. Consequently, we recommend that Medicaid coverage in 2006 should not expire for dual eligibles until they have voluntarily enrolled in a Part D plan or until CMS/or the State has automatically enrolled them in a plan.

- Section 1860D-1: Eligibility, Enrollment, and Information : Because of the myriad issues associated with determining eligibility for the low income subsidy, as well as ensuring that dual eligibles actually get enrolled into one of their available plan choices, utilizing a phased in enrollment process for dual eligibles might be advisable. Within this phased-in approach, states would still need to be able to draw down federal financial participation to cover the costs of prescription drugs. This phase-in period would allow the necessary outreach and education to take place. In addition, treat all dual eligible individuals as a "special needs population" for at least the first year of Medicare Part D. One approach would be to allow states to enroll full-benefit dual eligibles into a preferred private prescription drug plan (PDP) of the State's selection similar to the process used for SPAPs and the Medicare discount card. Given the special needs of this population and the history the States have in managing their health care needs, it seems that auto-enrollment with a preferred PDP would be the least disruptive way to allow the States to help duals select the appropriate prescription plan.

Automatic Enrollment Process

- Section 1860D: In implementing the automatic enrollment process for full benefit dual eligible individuals, CMS is considering which entity is best suited to perform the automatic and random enrollment function. If states were to manage the auto-enrollment process that federal financial participation is essential. In addition, such federal financial participation should be at the 100% level. States should have the option as to whether they would manage the auto-enrollment process. This sets up a scenario whereby a state could determine, based upon

various factors including existing infrastructure and data availability whether it would be feasible.

- Finally, the auto-assignment provision Section 1860D-1(b)(1)(c) includes the use of the term "random" for the enrollment of full benefit dual eligibles. This process must include a detailed algorithm for auto-assignment**.**

Section 423.329 (d) Low-income cost sharing subsidy payment amount (2) Payment amount.

- Section 423.329: should include a requirement to implement a process, similar to the Medicare Part B Buy-in process, which will allow states to pay Medicare Part D premiums on behalf of SPAP beneficiaries. Since premiums will need to be paid before January 1, 2006, this process needs to be in place before program implementation.

Involuntary Disenrollment Section 423.44

- Sec. 423.44(d): PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. CMS should develop a heightened standard for involuntary disenrollment for this vulnerable population. Furthermore, such disenrollment, if it occurs at all, should be contingent upon selection of another PDP or MA-PD plan to ensure there is no lapse in coverage. Finally, federal financial participation should be available for drug expenditures should the beneficiary decline participation; otherwise the individual is left without coverage.

Coordination with Managed Care Plans Section 423.464(a)

- Part D Plans should be required to coordinate benefits with SPAPs, rather than simply be required to "permit" SPAPs to coordinate benefits with them. CMS should establish clear and detailed guidelines and requirements that plans must follow to support effective coordination with participating SPAPs. This should include a requirement that Part D plans participate in retroactive recovery processing, using standard claim transaction formats, to properly reimburse SPAPs for claims inappropriately submitted to and paid by an SPAP as the primary payor.
-

- If Part D enrollment and eligibility determination for subsidies is carried out by the States, then it should be an option of the beneficiary to do eligibility re-determination for this program. This would be consistent with their eligibility re-determination for Medicaid and ensure that the beneficiary completes the re-determination. This will limit the administrative effort on the beneficiary and government.
- The Termination of Prescription Drug Plans (PDPs): PDPs should be required to notify the State Medicaid Agency prior to or simultaneously with notifying Medicare enrollees.

PACE Program Waivers Section 423.458

- Sec. 423.458(d): Establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. CMS is considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule (see discussion in subpart T of the preamble) without a plan-specific application process. EDS supports the automatic waiver of these requirements for PACE and other similar health plans such as social health maintenance organizations that also serve significant numbers of full benefit dual eligible individuals.

Questions Regarding the Draft Rule

- Subpart F, 1860D-13: If a dual-eligible beneficiary enrolls in the Part D program late, will Medicaid be responsible and/or allowed to pay the late enrollment penalty?

- Will enhanced 90/10 or 100% FFP be available to States for system enhancements needed to support the new Part D program?
- The rule requires States to send data to Medicare Advantage (MA) plans and PDPs. However, the rule is not specific on the type of data that will be sent by the States to the MA plans and PDPs. EDS recommends that PDPs and MA plans be required to report back to States data on pharmacy claims for quality, fraud and abuse, utilization, duplication of payment and tracking Tracking True Out-of-Pocket (TrOOP) costs. We recommend that CMS include more detail in the requirement that the PDPs communicate with CMS “in a manner we prescribe”. This phrase needs to be defined to include CMSO and State Medicaid agencies (use of MMIS and MSIS need to be considered).

- If a Medicaid-only member becomes a dual eligible (due to age, disability, ESRD, or other reasons), is the Medicaid program required to generate a creditable coverage to this member?

- Will Medicaid be required to disclose the creditable coverage status to CMS for each dual-eligible beneficiary, or will Medicaid be able to submit one response applicable to all dual eligible beneficiaries?

- How are State Medicaid programs compensated for the functions related to the disclosure of creditable coverage requirements to all Part D eligible beneficiaries?

- How will information about Part D formulary changes be relayed to Medicaid in a timely manner? Will Medicare implement logic that looks at the next drug and associates it with an existing match (i.e. therapeutic category, class, GCN)? At what level will CMS generate the Part D covered drug list (i.e. NDC, GCN, HICL)?

- The proposed rule indicates that CMS cannot charge user fees to State drug assistance programs; however, the proposed rule states that a user fee can be charged to prescription insurance plans for the data exchange of coordination of benefits information, except for state drug assistance programs. Will CMS charge State Medicaid programs for the exchange?

- Will the coordination of benefit information exchange be performed through a central repository (CMS) or with each individual PDP or MA-PD?

- If a pharmacy provider dispenses a drug that is non-covered under Part D and covered under Medicaid, does this provider submit a claim to the PDP or MA-PD first? (Will the PDP or MA-PD process and deny the claim and then send it on to Medicaid for adjudication?) Or, does the provider submit the claim directly to Medicaid?

- If Medicaid pays for a non-covered Part D drug, is the Medicaid program responsible for sending the claim adjudication information to the dual-eligible beneficiary's PDP or MA-PD (which would show any out-of-pocket costs)? How would this occur for the non-covered Part D drug that is applied to the member's spending down amount?

E-Prescribing

- We support CMS' efforts to work with State Boards of Pharmacies to remove the restrictions on e-prescribing, and we recommend that CMS work toward removing all restrictions such as the requirement that all Schedule II drugs be written on a paper prescription pad. In order to promote the use of e-prescribing, CMS should also ensure that the removal of restrictions apply to all drugs and not just Part D drugs.
- In addition, EDS recommends that systems costs for e-prescribing be eligible for 90/10 FFP or 100% FFP for both State systems and providers as incentives.

- Page 46819, 433.120 (c) Use of standardized technology: EDS recommends basing the card standards on NCPDP's "Pharmacy ID Card Standard". This

standard is based on the American National Standards Institute (ANSI) INCITS 284 standard titled Identification Card-Health care Identification Cards.

- Page 46821, 423.159 Electronic prescription program (a) Electronic Prescription standards: EDS recommends the use of the NCPDP SCRIPT standard except in the inpatient environment in which EDS recommends the use of the HL7 standard as the electronic prescription standard relating to covered Part D drugs. In addition, EDS recommends the use of a standardized sig in the standard transactions and supports the joint development underway of a sig standard. EDS recommends the use of the NPI.

Coverage

- Vaccines are typically purchased by the healthcare provider, administered to the Professional transaction using at J-code to denote drug and administration. Will the PDP or the MA-PD process this claim type/transaction? Also, if there are other services on the claim (i.e. E/M service), will the provider be required to split bill? Or, will the PDP or MA-PD be required to "crossover" these claims to the Medicaid program when applicable services are billed?

CMS-4068-P-966

Submitter : Dr. Stephen Eckel **Date & Time:** 10/04/2004 04:10:08

Organization : UNC Hospitals

Category : Individual

Issue Areas/Comments

Issues 1-10

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

Recognizing that patient's need MTM services to improve their health is a positive part of this legislation. I am extremely pleased that CMS recognizes that pharmacists will be the likely providers of this service, since we are the best trained in managing a patient's medication regimen. I am concerned though that by leaving the decision to the plans, there is a chance for them to choose less qualified people to provide MTM services - individuals who are either not trained for this or do not have the data to show that they can make a difference in delivering MTM services. This might seem like a more expensive option by utilizing pharmacists, but data from the North Carolina Asheville project demonstrates that the reduction of costs are seen downstream. When patients take the right medications and use them the right way, overall health care costs are reduced.

There are concerns though that I have with this proposed legislation. These are:
1. Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them of their choices of location (including a local pharmacy)
2. Once a beneficiary becomes eligible, they should remain eligible for the entire year.
3. Plans cannot prohibit pharmacists from providing MTM services to non-targeted beneficiaries. Since these plans do not provide a benefit for non-targeted beneficiaries, pharmacists should be able to bill directly for these services.
4. Plans must be required to pay the same fee for MTMS to all providers. Plans should not pay pharmacists at preferred pharmacies at a different rate than pharmacists at non-preferred pharmacies.
5. CMS must evaluate each plan's application for providing MTM services, looking to see that the proposed payment schedule is high enough to entice pharmacists to provide MTM services.

I urge CMS to continue to recognize the value that pharmacists play in MTM services and establish this regulation so that pharmacists can continue to demonstrate the high value of care they do provide.

CMS-4068-P-967

Submitter : Ms. Ana Oliveira **Date & Time:** 10/04/2004 04:10:14

Organization : Gay Men's Health Crisis

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-4068-P-967-Attach-1.doc

FIRST IN THE FIGHT AGAINST AIDS

GMHC

October 1, 2004

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

File Code: CMS-4068-P

Dear Dr. McClellan:

Gay Men's Health Crisis (GMHC) appreciates the opportunity to respond to the proposed rule for the implementation of the new Medicare prescription drug benefit. Individuals living with HIV/AIDS on Medicare will likely experience a dramatic change in the way they access prescription drugs due to the changes required by the Medicare Modernization Act of 2003. This is especially true for dual eligible individuals in New York State, who will lose their comprehensive Medicaid drug benefit in January 2006 and must acquire their drugs from Medicare. It is GMHC's highest priority to ensure that not one HIV-positive Medicare beneficiary is harmed by the implementation of the new law, and that all Medicare beneficiaries who are HIV-positive are able to access the drugs that they need, when they need them. With these goals in mind, I am pleased to submit the following comments to the proposed rule for your review.

About GMHC
Gay Men's Health Crisis (GMHC) is a not-for-profit, volunteer-supported and community-based organization committed to national leadership in the fight against AIDS. Our mission is to reduce the spread of HIV disease, help people with HIV maintain and improve their health and independence, and keep the prevention, treatment and cure of HIV an urgent national and local priority. GMHC serves one in every five persons diagnosed with AIDS in New York City. As the world's oldest AIDS service provider, GMHC helps over 15,000 men, women and children and their families each year, offering a wide range of comprehensive client services, including hot meals, benefits/entitlements advocacy, health care advocacy, case management, legal assistance, HIV counseling and testing, individual and group counseling services, prevention education, home-based support, and mental health services.

Medicare and HIV
GMHC has seen the number of clients who are enrolled in Medicare grow over the last several years because people with HIV/AIDS are living longer and are eligible for Medicare because of disability, and/or they enroll in Medicare once they turn 65. As the second largest source of HIV/AIDS funding, Medicare currently provides HIV-positive individuals with doctor and hospital coverage. As the quality and effectiveness of AIDS care improves, more people with the disease will be living longer and turning to Medicare for hospital care, outpatient medical visits, and prescription drugs. In fact:

- Nationally almost 20% of people with HIV/AIDS in care have Medicare.
- Spending for HIV care in Medicare has doubled over the past 7 years to $2.1 billion.
- Between 11% and 15% of people with AIDS are over age 50.
- In New York City, approximately 15,000 people with HIV/AIDS rely on Medicare for their primary health coverage.

Comments on the Proposed Rule

1. **<u>Subpart B – Eligibility and Enrollment</u>**

   A. §423.30(D)(1) Dual eligible beneficiaries must not be limited to an "average cost plan."
   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 eligible individuals without meaningful access to the full range of prescription drug plans in their area. Dual eligible beneficiaries 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.

2. **<u>Subpart C – Benefits and Beneficiary Protections</u>**

   A. §423.120 People living with HIV/AIDS should be designated a "special population" and require special treatment and access to an open formulary.
   GMHC strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with HIV/AIDS be defined as a special population. We believe 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.

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 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 available at the lowest cost-sharing tier. We encourage CMS to grant serious consideration to the numerous studies that demonstrate that even modest levels of cost sharing result in low-income individuals, people with chronic illnesses and seniors being deprived of medically necessary prescription drugs.

B. AIDS Drug Assistance Program (ADAP) subsidies should be counted as incurred costs for Medicare beneficiaries.
GMHC believes that ADAP subsidies, like those from State Pharmaceutical Assistance Programs, should be allowed to count towards a beneficiary's out-of-pocket costs. 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. New York State's ADAP program is an integral component of the safety net for people living with HIV/AIDS in our state and has a long history of filling gaps left by other programs, including Medicaid and Medicare. We strongly recommend that the final rule count cost-sharing subsidies from ADAPs as incurred costs.

C. Require plans to cover drugs for off-label use.
GMHC strongly recommends strengthening the language regarding coverage of drugs for off-label uses. We believe it is necessary that prescription drug plans be required to cover medically accepted uses of drugs for off-label uses that are standard practice in the medical community. For HIV disease, as with many complex conditions, actual clinical use frequently runs ahead of label indications as practicing 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.

D. Require plans to cover new anti-HIV drug therapies.
GMHC strongly recommends 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 changes rapidly and many Medicare beneficiaries with 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.

3. <u>Subpart M – Grievances, Coverage Determinations, and Appeals</u>

A. 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.
CMS must 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) in its final rule. 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.

GMHC's concern over treatment interruptions are heightened due to the absence of adequate protections that ensure that individuals can receive a timely resolution of an appeal, and the 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 (ALJ) level. We recognize that the expedited timeframes and the general 72-hour standard are a significant improvement over the standard timeframe of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of the clinical management of HIV infection, 72 hours is an unacceptable delay. We strongly recommend that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people living with HIV/AIDS automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal in all cases of emergency, including all cases involving people living with HIV/AIDS.

4. <u>Subpart P –Premiums and Cost Sharing Subsidies for Low-Income Individuals</u>

A. §423.782(a)(2)(iii) Dual eligible beneficiaries must not be denied medications for failure to pay co-payments.
Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. 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. [423.782(a)(iiii)]

B. §423.782(a)(iv) and §423.782(b)(2) Low-income individuals should not be denied medications for failure to pay co-payments.
Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. 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.

GMHC strongly encourages CMS to issue a second notice of proposed rulemaking to provide us the opportunity to comment on the decisions made by CMS regarding the above issues. Thank you, and please contact me with any questions at (212) 367-1362.

Sincerely,

Ana Oliveira
Executive Director

CMS-4068-P-968

Submitter : Ms. Angie Thompson **Date & Time:** 10/04/2004 04:10:04

Organization : Mental Health Association of Middle TN

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the Mental Health Association of Middle Tennessee, I am writing regarding the proposed rule recently published by the Centers for Medicare and Medicaid Services (CMS) for the new Medicare prescription drug benefit.

As advocates for nearly sixty years on behalf of people with or at risk of mental illness, our organization recognizes that access to psychiatric medications is a critical component of community-based care, and deem it critical that the Medicare drug benefit provide coverage for all medically necessary mental health medications. We appreciate the enormous challenges associated with implementing this new benefit, but urge that CMS substantially revise the proposed rule in accordance with these comments to ensure adequate access to mental health medications for the many Medicare beneficiaries who need them. As Congress itself recognized in the conference report on the Medicare Modernization Act, Medicare beneficiaries with or at risk of mental illness have unique, compelling needs that must be given special consideration in implementing this important new benefit.

Many Medicare beneficiaries face mental illness. Research has shown that some 37% of seniors show signs of depression when they visit their primary care physician. Yet most are not receiving the mental health services they need. In fact, seniors have the highest rate of suicide of any age group in the country. It is estimated that only half of older adults who acknowledge mental health problems actually are treated by either mental health professionals or primary care physicians (US DHHS, 2001).Beneficiaries who qualify for Medicare based on a disability also frequently experience mental illness and studies have shown that over half of all under-65 disabled beneficiaries have problems with mental functioning (Kaiser Family Foundation, 1999).

We are in accord with the National Mental Health Association?s recommendations on the proposed rule which have been presented to CMS. We strongly encourage you to address these concerns in your deliberations on this matter. We believe that the concerns brought forth by the NMHA must be addressed in order to ensure access to mental health medications under the Part D drug benefit for the many Medicare beneficiaries who need them.

Thank you for consideration of these comments.

CMS-4068-P-968-Attach-1.wpd

CMS-4068-P-968-Attach-2.doc

CMS-4068-P-969

Submitter : Mr. Kevin Costello **Date & Time:** 10/04/2004 04:10:01

Organization : Community Legal Services

Category : Attorney/Law Firm

Issue Areas/Comments

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Please see attached document for extensive comments on Subpart M.

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

Please see attached document for comments on Subpart P.

SPECIAL RULES FOR STATES

Please see attached document for comments on Subpart S.

CMS-4068-P-969-Attach-1.doc

CMS-4068-P-969-Attach-1.doc

CMS-4068-P-969-Attach-1.doc

Comments to the Proposed Medicare Prescription Drug Regulations
Prepared by Community Legal Services, Inc.
Philadelphia, Pennsylvania
October 4, 2004

Subpart M – Grievances, Coverage Determinations and Appeals

Community Legal Services has grave concerns that the proposed regulations under this subpart are at odds with the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution as well as the Medicare Modernization Act itself. As interpreted by a long and distinguished line of U.S. Supreme Court jurisprudence, due process requires adequate notice and hearing when public benefits are terminated or denied. Under current law, Medicaid recipients whose prescription requests are turned down are provided with a 72 hour supply of medications pending adjudication of 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 a timely appeal. 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 for a face to face hearing with an impartial trier of fact, a reasonable opportunity to submit evidence and confront witnesses against them, as well as access to care pending resolution of the dispute in a timely manner. While we recognize that it is beyond the ability of CMS to amend the MMA to provide for an appeals process similar to Medicaid, there are several steps CMS can make in the proposed regulations to bring the Part D appeals process up to constitutional standards. These improvements are particularly significant for the population of dual eligibles that Community Legal Services serves, as the absence of a meaningful appeals process will likely necessitate long stretches of time without any access to life-sustaining medication whatsoever.

In accordance with Section 1852(c), it is of paramount importance that CMS add into the proposed regulations a pre-termination, fast-track review process as was put in place after the Grijalva v. Shalala case. Sections 1860D-4(f), (g) and (h) require that Part D plan sponsors establish grievance, coverage determination, reconsideration and appeals processes in accordance with the Social Security Act. As the proposed regulations are currently written, they fail to meet this requirement. In addition to the absence of the fast-track, pre-termination review process, the proposed regulations also fail in the following ways:

--There is almost no deadline for review and decision that must be adhered to by the drug plan. The plan is allowed to obtain an extension for review, even in expedited cases, causing further harm and uncertainty for the member.

--There are no requirements as to who within the drug plan can make initial

coverage determinations. At a minimum, the requirements regarding who may make redeterminations should also apply to the initial decision. Pennsylvania's requirement that the decisionmaker be a physician of the same specialty as the prescribing physician would be an appropriate safeguard in this regard. Otherwise, there is a risk that prescribing specialists will see their medical decisions overturned by plan officials without the same expertise.

--This Subpart is glaringly ignorant to the needs of limited English proficient communities, as well as visually or hearing impaired beneficiaries who may need notices and communication avenues not required in the proposed regulations. Experience with M+C organizations in Philadelphia has shown that the needs of these populations cannot be left up to the grace of the plans. It must be mandated if the needs of these populations are to be met and federal discrimination law upheld.

The rules as to when a plan may extend deadlines on coverage determinations should be further defined. Plans should be prohibited from extending their own deadline to make a coverage determination in an expedited appeals process. To permit such an extension would defeat the beneficiary's right to a timely determination and render the expedited provisions meaningless.

The final rules must do more than allow for beneficiaries to *request* expedited coverage determinations and exception decisions, as the proposed regulations do. The final rules should clarify that the beneficiaries have an actual right to receive these processes.

Section 423.564 Grievance Procedures

The proposed regulations should allow a beneficiary and / or her representative to choose whether their complaint will be treated as a grievance or an appeal, or to dispute the Plan's decision in this regard.

Fundamental due process principles require written decisions and an ability to appeal beyond the initial level, both of which are absent from the proposed regulations. In accordance with the federal law governing Medicare managed care, PDPs must be required to issue written decisions within 30 days of receiving a grievance and allow for review of this initial decision through subsequent levels of appeal. Most importantly, the grievance process should include some review or report to an independent reviewing entity that will track the Plan's treatment of these complaints. Likewise, it should be required that all grievances concerning quality of care be forwarded to the appropriate Quality Improvement Organization (QIO). The proposed regulations allow such complaints to be sent to either the Plan or the QIO. This provision should be clarified to make one uniform process through the QIO, regardless of where the complaint is first received.

Beneficiaries must be able to obtain an expedited coverage determination even when they have purchased the drug out-of-pocket. The proposed regulations all of for the enrollee to get a grievance decision within 24 hours only if the complaint is about the

plan's decision to extend or refuse a coverage determination or redetermination and the enrollee has not purchased or gotten the drug. This condition will prevent reimbursement where a beneficiary acted in desperation for their own health instead of waiting for a plan's bureaucracy to run its course. Low-income beneficiaries do not have the luxury of paying for a medication in such circumstances without the opportunity to gain reimbursement through an appeal. Moreover, this condition creates a disincentive to obtain immediate medication in a health emergency.

The proposed regulations should have stronger requirements for plan recordkeeping of grievances, including the details of the complaints received, the notification to the enrollee, the outcome and what information was considered. Plans should also be accountable for the method by which they communicate their cumulative grievance information to CMS.

Section 423.560 Definitions

The definition of "Appeals" should be broadened to include any situation in which a delay in providing or approving coverage *may* adversely affect the health of the beneficiary. As it is currently written ("*would*"), an appeal would require prescribing doctors to speculate in a manner that they may be unwilling to do. Moreover, this definition excludes the grievance and exception processes laid out in this subpart and in concert with the "authorized representative" definition in this section would prohibit plan members from the benefit of a representative in these processes. Whether by amending the "appeals" definition or the "authorized representative" definition, this oversight should be corrected to allow for the participation of representatives in the grievance and exceptions processes.

The reference to state law notwithstanding, the definition of "authorized representative" should include reference to a standard authorization form created by CMS to accomplish this appointment. Such a form should be written to conform to HIPAA standards and allow the beneficiary to permit disclosure of private medical information to their representative. When a medication is denied by a managed care plan, it is a time of crisis for many low-income beneficiaries. Too often, these beneficiaries are denied the opportunity to a speedy resolution of this emergency because their signature does not appear on the correct form and the plan's policies are steadfast in the face of federal privacy law. One standard, HIPAA-compliant PDP authorization form will greatly reduce this concern and also allow greater efficiency for advocates who represent beneficiaries in many different PDPs.

Section 423.562 General Provisions

This section precludes a beneficiary from appealing a coverage determination if she has no further liability to pay for the drug. This section should state that an enrollee may appeal a coverage decision even in the absence of co-payment responsibility. The same holds true for drugs obtained at an out-of-network pharmacy. Both no-liability prescriptions and drugs obtained from a non-network pharmacy are vitally important to

those who need them and these prescriptions should not be irrationally excluded from the appeals process.

Section 423.566 Coverage Determinations

This subsection needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations the decision by a PDP that a drug is not covered. An enrollee should be entitled to appeal and determine whether a drug that is allegedly uncovered is in fact not covered. In addition, the regulations should allow for denials of enrollment, involuntary disenrollment and imposition of a late enrollment penalty as coverage determinations subject to the appeals process.

The regulations should also state that the presentation of a prescription to a pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, the request should be deemed denied and the enrollee should be entitled to notice and a redetermination. Without such an allowance, enrollees will not be informed of their rights and the appeals process will become meaningless in those circumstances.

The standard for defining a coverage determination due to a delay that *would* adversely affect the health of the enrollee should be changed. If this standard were that an enrollee's health may or could be affected, the supporting opinion of a doctor would be far less speculative.

Section 423.568 Standard Timeframes and Notice Requirements for Coverage Determinations

Section 423.568(a) of the proposed regulations should require the plan to provide oral notice as son as it determines that it will extend the deadline for considering whether it will cover the drug, including notice of the right to request an expedited grievance. This oral explanation should be followed by a timely written notice within 24 hours. It is impossible to overstate the importance of a swift resolution of coverage problems when medications are at stake.

Section 423.568(b) should be eliminated in an effort to make the appeals process more easily understood by beneficiaries, to make the entire program more uniform and to avoid time-wasting confusion. An enrollee who is requesting reimbursement for a drug should not be subjected to a different process than one is has yet to receive their medication.

Section 423.568(c) presents a problem similar to that of "demand billing" in M+C organizations. This section puts the responsibility to issue notices regarding coverage determinations solely on the plan. For most beneficiaries, the news of denied coverage will more frequently be received from the pharmacist than from the plan itself. If the pharmacy is not included in the requirement to issue notice of coverage denials, such a requirement has the potential to become largely meaningless. Under the proposed

regulations, a beneficiary would have to have demand that the pharmacy submit the request anyway, in order to receive a denial notice and start the appeal process, whether that be through an expedited consideration or an exception. Nor will they understand the limitation on receiving expedited consideration if they do pay for the drug out of pocket. The regulations should require plans to develop notices that explain the right to redetermination and expedited review. The plans should be required to work with their network pharmacies to require that these notices are given at the point of contact by the pharmacist when the non-covered request is made. Experience with Medicare managed care illustrates that notices serve the purpose for which they are intended only when they are required to come directly from their point of contact when the decision is made.

The proposed regulations are far too vague in their requirements of the content of the notice. Simply requiring the notice to be in a readable and understandable form is not sufficient. To begin, notices must be made available in alternative formats and languages, especially in areas where portions of the Medicare population are known to be limited English proficient. Community Legal Services supports the August 2000 HHS OCR guidance on how programs can meet their Title VI obligations as a good platform from which PDP plans should be required to launch their accommodation of LEP communities. Moreover, CMS should monitor the content of notices with the interests of simplicity in mind for those beneficiaries with literacy or cognitive impairments.

Rather than just "state the specific reason for the denial," notices should be required to include the scientific or clinical basis for denial. Such a requirement will greatly assist beneficiaries and their doctors in preparing appeals, which is the reason for notice in the first place. Without this requirement, plans may list the reason for denial as: "not appropriate," or some similarly vague rationale.

The notice should also explain to beneficiaries what steps to take to resolve the issues that triggered the rejection, as well as how they can go about receiving medication coverage pending the appeal. Similar requirements were deemed essential to the due process issues that arose in Hernandez v. Meadows in the Southern District of Florida in 2003.

This section of the proposed regulations also fails to include a mandate of who may make a coverage determination. Like the redetermination process in section 423.590, only doctors with appropriate qualifications should be permitted to make these critical decisions.

When an adverse coverage determination is made, the regulations should also require that the prescribing doctor be copied on the denial notice. Too often, doctors are unaware of their patients' plights regarding obtaining the drug that they have prescribed. Given the difficulty of enrollees contacting their doctor directly, such a gap in information can be easily addressed by copying the denial notice to the prescribing doctor.

Section 423.570 Expedited Consideration

The regulations should explicitly allow for authorized representatives to request expedited coverage determinations. The ability to request expedited consideration should be the same for beneficiaries with representatives as those without such agents. This will especially be important in emergency medication situations for mentally ill and incapacitated persons.

All coverage appeals concerning drugs, including those in which the enrollee has paid for the drug out of pocket, should be treated as requests for expedited review. The consequences of waiting for a decision are simply too grave, as many beneficiaries will simply go without the medication during this period. The concern is parallel in situations where the beneficiary has found the money to pay for the drug up front. Waiting for reimbursement may cause beneficiaries to go without other basic sustenance, such as food or utilities.

Requests for exceptions should automatically be given expedited consideration. This is particularly important where a request is made to continue a drug that has been removed from the formulary. Such a request should be processed within 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's health requires. In the meantime, the enrollee should be allowed a 72 hour supply of medication pending the decision, which may be reviewed if the process is not complete within 72 hours. At the very least, the regulations should direct the plan to consider a doctor's request for expedited review and the request for an exception to be one and the same.

The standard for approving an expedited request should be amended in two distinct ways. First, the requirement that the jeopardy to an enrollee's health or life be serious should be removed. Advocates gathering evidence and prescribing physicians should not be forced to interpret such vague standards when such important decisions are at stake. Second, the requirement that such a decision is necessary to regain maximum function should be amended to allow for situations in which the decision must occur in order to maintain current function. The maintenance of maximum function and the prevention of decline are just as important as regaining lost functionality. Such a standard has worked well in Pennsylvania's Medicaid managed care program.

<u>Section 423.572</u> <u>Time Frames & Notice Requirements for Expedited Consideration</u>

All of the comments above regarding notice are also relevant to this section.

The extension of the 72 timeframe should be required where it is in the *best* interest of the enrollee, rather than just where it is in the beneficiary's interest. These interests should be defined to include those situations in which the enrollee needs time to gather supporting evidence. The enrollee should be notified of such an extension immediately, both orally and in writing. Also, here should be no extension allowed in situations where the drug has already been obtained by the beneficiary. As previously stated, beneficiaries awaiting reimbursement in these situations may be forced to forego

other staples of sustenance while they await payment.

The proposed regulations should be clarified as to the notice requirements when no oral notice is provided of an expedited decision. Section 423.572(c) provides a timeframe for written notice of an expedited decision when oral notice has been given. This section should be clarified to require that written notice must be sent on the same day the decision is made if the plan does not provide oral notice.

The final regulations should deem the failure of the plan to provide timely notice as an approval and name this failure as an appealable action itself. The plan should not be able to benefit from its failure to provide timely notice. Moreover, plans must have a meaningful incentive to meet their notice obligations.

Section 423.578 Exceptions Process

At the outset it must be emphasized that this section meets neither the statutory requirements nor the fundamental tenets of constitutional due process.

The only notice requirement concerning changes to the formulary is at 423.120(b) and this is inadequate. The proposed regulations do not explain how an individual beneficiary will receive notice about the exceptions process nor do they explain how one receives information that a certain drug is not included on the formulary.

In order to meet basic due process requirements concerning the termination of public benefits, the notice must be in writing sent directly to the beneficiary and must include an explanation of how to use the exceptions process, including the requirements of a doctor's certificate, the right to a hearing, and the reasons why a drug is not included on or has been removed from the formulary or why its status has been changed, and an explanation of the evidence required to be granted an exception.

Moreover, the 30 days proposed in section 423.120(b) in wholly insufficient. Within this timeframe, the beneficiary will be expected to receive and process the notice's information, perhaps seek out legal advice or advocacy, obtain an appointment with their prescribing physician, which in some cases may require a referral, have the doctor's appointment, which may sometimes require a new medical evaluation and lastly, get a new prescription. The final regulations should require 90 days written notice directly to the beneficiary when a drug's formulary status is going to be changed.

In addition, this section should include notice requirements that refers to section 423.120(b) and requires PDPs to develop exceptions process notices. Such notices should explain the exceptions process, the situations in which someone can seek an exception, and the information that is necessary to support an exception request. This notice should be given to the beneficiary by the pharmacy when a prescription is presented for a non-formulary drug or a request is made for a lower cost-sharing amount.

The allowance of plan discretion in section 423.578(a)(2) violates the statute. In

this regard, the statute requires that the Secretary establish criteria that the plans must follow. It does not make an allowance for plans to set their own criteria for an exceptions process. The fact that they are permitted to shape a tiered structure is a separate consideration from the beneficiary's right to request an exception to that structure. Indeed, the flexibility granted plans in shaping their plans is precisely the reason why beneficiaries need strong protections in the exception process. There must be one uniform standard for medical necessity that plans must be required to employ in making exceptions decisions. The lack of such a standard in the proposed regulations is a critical oversight that must be fixed. Without such a uniform standard, plans will enjoy unbridled discretion in responding to exceptions requests and have the option to deny such requests regardless of what information the enrollee provides. The risk that plans may make these decisions based on cost-saving concerns rather than the best interest of their enrollee is simply too great to allow the proposed regulations to stand as is. A uniform standard would also provide a level playing field for all plans and allow some certainty for beneficiaries as to whether a particular request will be approved.

Independent Review Entities must be given the authority to rule on the validity of the plan's exceptions criteria and formulary. The proposed regulations only allow IREs to review whether a plan properly applied its own criteria correctly and not about the validity of the exceptions criteria or the formulary itself. Without this oversight, beneficiaries with claims that are not appropriate for ALJ review (i.e. claim is for less than $100) will be without any recourse whatsoever for unreasonable or illegal exceptions criteria or formularies. Regulations, wherever practicable, must include enforcement and oversight mechanisms, lest they become meaningless.

The final regulations cannot allow for any exceptions process criteria that are beyond the scope of the statute. The proposed regulations include a "limited number of elements that must be included in any sponsor's exception criteria." This list, however, includes criteria that do not apply based on the statutory provision that states that 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 plans should not be permitted to include this factor in their exception criteria;

--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% to 125% of the medication be the same to be "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 prescribers take into account. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the exception process criteria used.

--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, is not relevant to the determination of the prescribing physician that the drug is needed.

The proposed regulations are in conflict with the statute by subjecting beneficiaries to a "fail first" requirement, i.e., the statement in the preamble that plans could require an enrollee to first try the preferred drug. The statute's mandate states that the prescribing doctor need only certify that the preferred drug *would* not be as effective or *would* cause adverse effects. Had the statute been drafted to allow for a fail first requirement, it would have provided that a doctor must certify that the preferred drug *is* not as effective or *has* caused adverse effects.

The proposed regulations state that the PDP "*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 effects, or both, plans are going to require some kind of written statement. However, the final regulation should limit this written statement to the statutory standard. The final regulation should thus state that the PDP "may only require the doctor's written certification to include the following information."

The final regulation should require that the lowest co-pay that applies is imposed on drugs for which a beneficiary has won an exception to the tiered cost-sharing structure. If the enrollee is able to show that none of the covered medications covered are as effective as the requested drug, or that they may cause harm, equity demands an entitlement to the lowest co-pay tier. Because the drug has been determined to be medically necessary and no on-formulary drug is suitable, the exception likewise meets the criteria for an exception to the tier structure.

In addition, the final regulation should include a rule permitting continued access to a drug at a given price when there is a mid-year formulary change. To do otherwise provides an opportunity for plans to engage in 'bait and switch' tactics with enrollees who are locked into their plans for the duration of the year. Enrollees should also be afforded the opportunity to request exceptions to the plan's tiered cost-sharing structure other than on a case-by-case basis.

CMS must establish specific criteria for the review process used to evaluate plan formularies and tier structures. These criteria should be guided by the principle of simplicity and with the interests of special-needs population in mind.

The proposed regulation providing that the cost of drugs obtained through an exception should count toward a beneficiary's out-of-pocket threshold.

As written in the proposed regulations, the definition of formulary use in Section 423.578(b) contradicts the statute. Formulary use includes not just dose restriction, but the format of the dosage (liquid v. capsule) and packaging.

The criteria in 423.578(b) must be rewritten so that it is not potentially impossible to gain an exception. The preamble to the proposed regulations lays out CMS's wish to have a transparent exceptions process (p. 46720). The discretion left to each plan to form their own exceptions criteria absolutely overwhelms this stated goal. CMS should establish uniform exceptions process criteria to be used in evaluating enrollee requests. Without such uniformity, a beneficiary's right to receive their Medicare benefits will become contingent upon which plan they join. Further, without uniform certificates and requirements, prescribers will face an unreasonable burden in seeing their orders followed and the health of their patients upheld.

The regulations should likewise establish standard criteria that plans must use in evaluating a prescribing doctor's determination that the preferred drug would have adverse effects or not be as effective. Independent review entities should be charged with reviewing plan criteria to ensure that they comply with these federal requirements and that the plan is adhering to the statutory standard.

The requirement that doctors produce clinical, medical and scientific evidence to meet the exceptions standard can be interpreted as to create an impossibly high bar. Scientific evidence, such as clinical trial results, is not always available for older people and those with disabilities. A prescribing doctor may have unique experience in dealing with these populations and conditions and that should be given at least equal weight in making exceptions determinations. Indeed, the statutory language suggests that deference to the doctor's opinion in whether the preferred drug would not be effective or likely to cause an adverse reaction is the correct standard.

In a similar vein, the proposed regulations authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed, including a catchall requirement for "anything other information reasonably necessary." This authorization allows plans to create bureaucratic and burdensome processes that all but the most determined doctor and beneficiary will be unable to meet. The requirements for certification should be standardized to facilitate use of the exceptions process by doctors and their patients. Such a step would help CMS to achieve its goal of a transparent exceptions process.

Community Legal Services strenuously urges that the burden must be placed on the plan to show why the prescribing doctor's decision is not determinative in meeting the statutory standard for the exceptions process.

For dosing exceptions, the proposed regulations set the standard as requiring a showing that the number of doses available under a dose restriction has been ineffective or based on both sound clinical evidence and medical and scientific evidence show that the regimen is likely to be ineffective or adversely affect effectiveness or patient compliance. The standard should include "or cause an adverse reaction or other harm to the enrollee."

The final regulation must provide for the right to continuing drug coverage pending the outcome of the appeal. As written, the regulations provide for a one month supply of the drug, but this is only if the plan does not act timely upon an exceptions determination. If the exceptions request is denied expedited treatment, the plan can take up to two weeks to make its decision, a time period during which the enrollee would be without their medication. Even if the request is given expedited treatment, the plan has up to 72 hours to decide, contingent on the beneficiary's medical condition. Refilling prescriptions is most frequently done on the last day of the prescription period, often by rule. Continuing a beneficiary's coverage should be a matter of procedural due process that is available to enrollees any time they are challenging the withdrawal of a medication, or restriction on access to a medication and have appealed in a timely fashion such that a final decision on the matter has not been rendered. Continuing ongoing drug coverage is of paramount importance, especially to pharmaceutically complex patients whose regimen is delicately balanced by their doctors. Patients with HIV/AIDS and mental illness also suffer extraordinarily adverse health consequences from interruption in medication.

Community Legal Services supports the provision in section 423.578 that prohibits a plan from continuing to require exception approval following the initial award. The indefinite continuance of this drug should be further defined to only end upon a finding by the FDA that the drug is unsafe for the treatment of the beneficiary's specific condition.

Like the timeframes for plan determinations commented on above, the timeframes in the exceptions process are far too long in the proposed regulations. For similar reasons, these timeframes should be the same for enrollees who are awaiting coverage before receiving their medication and those who pay out of pocket and appeal to gain reimbursement. The provision for an emergency supply of drugs during the exception request is not sufficient as it may still involve significant time periods where the enrollee will be without their medication. Concerning extensions to the standard exceptions time frame, plans should be required to show that such an extension is in the best interests of the beneficiary. Plans should be required to make exceptions determinations within 24 hours as required under Medicaid for determinations regarding prior authorization requests. 42 U.S.C. 1396r-8(d)(5)(A).

Section 423.580- Section 423.590 Redeterminations

All redetermination requests should be treated as expedited. The proposed regulations indicate that if a prescribing doctor determines that applying the standard timeframe for redeterminations may seriously jeopardize the enrollee's health or ability to regain maximum function, the plan must expedite the decision. As with the parallel exceptions and coverage determination standards, this is far too stringent. Either all redetermination requests should be expedited or this standard should be changed to require expedited redetermination when the doctor determines that the standard timeframe may jeopardize the enrollee's health or ability to *maintain* maximum function. This is the appropriate standard and has worked well for many years in Pennsylvania's

Medicaid managed care system.

The final regulations should expressly allow a beneficiary's authorized representative to request a redetermination or an expedited redetermination and to represent the beneficiary throughout the appeals process. Once appointed, the final regulations should expressly state that an authorized representative stands in the shoes of the beneficiary and is authorized to complete any action to which the beneficiary herself would be entitled, on that beneficiary's behalf. Outlining the powers of the authorized representative in the definition section should be paralleled with specific grants of authority in the regulations governing the particular appeals stages.

Once again, the notice provisions for standard and expedited redeterminations must be made much clearer. The regulations should establish clear criteria for informing the enrollee and her doctor that she can submit evidence in person as well as procedures for an in-person redetermination review via an acknowledgement notice. Parties to the redetermination should be afforded at least 15 days before the review occurs to gather and submit evidence. Such an opportunity should expressly be allowed to be submitted either by telephone, in person or in writing. Enrollees should be given the right to appear in person at the redetermination review and to be represented at this stage. Plans should be required to accommodate enrollees in the scheduling and holding of the review and enrollees should have the right to review any information that the plan uses in making their redetermination decision.

The regulations should state the content of redetermination outcome notices, including how to achieve further review of the plan's action, the reason for the denial, including medical and scientific evidence relied upon, and the timeframes of further review. This is especially important given that review by the IRE is not automatic.

Plans should only be permitted to extend the timeframes laid out in section 423.590 if it is shown to be in the *best* interests of the enrollee. For example, if the plan can show that additional time is necessary to gather evidence in support of the enrollee's request, an extension may be made. In expedited redeterminations, plans should not be granted an extension at all, given the threat to the enrollee's health.

The provision in section 423.590 allowing for a deemed redetermination denial, appealable to the IRE, if the plan does not issue a timely decision does beneficiaries a disservice. This section creates a disincentive for plans to actually provide a meaningful redetermination process and it denies the enrollee a further substantive decision to respond to later in the appeals process. The final regulations should be amended to provide for the converse outcome; if a plan does not issue a timely redetermination decision, the beneficiary's appeal will be sustained and coverage granted. This method provides a strong incentive for the plan to provide a full and meaningful redetermination stage.

<u>Section 423.600</u> <u>Reconsideration by the IRE</u>

The final regulations should clearly explain that the role of the IRE is to provide independent, de novo review of the plan's decision. Language in the preamble to the proposed regulations suggests otherwise. The IRE should consider all the evidence and issue a decision based on its own independent analysis and not be subject to the reasoning of the plan's decision. To allow otherwise would be a patent violation of the enrollee's due process rights.

Independent Review Entities must be given the authority to rule on the validity of the plan's exceptions criteria and formulary. The proposed regulations only allow IREs to review whether a plan properly applied its own criteria correctly and not about the validity of the exceptions criteria or the formulary itself. Without this oversight, beneficiaries with claims that are not appropriate for ALJ review (i.e. claim is for less than $100) will be without any recourse whatsoever for unreasonable or illegal exceptions criteria or formularies. Regulations, wherever practicable, must include enforcement and oversight mechanisms, lest they become meaningless.

The final regulations should expressly allow a beneficiary's authorized representative to request a redetermination by the IRE.

The enrollee should be permitted to request IRE reconsideration orally, particularly in the case of an expedited review.

There should be an automatic referral to the IRE when a redetermination is adverse to an enrollee, as occurs in Medicare managed care. The rationale that automatic IRE review should not occur because often small amounts of money will be in dispute is wholly inadequate. Cases involving small amounts in controversy are prohibited from being reviewed at the ALJ stage. IRE review is the only independent and external review stage for these common circumstances and all reasonable effort must be made to ensure that these cases do not fall through the cracks due to confused beneficiaries who fail to pursue their further appeal rights. If plans are to be held accountable to the regulations, an adverse redetermination should trigger automatic IRE review.

The proposed regulations provide that the IRE should solicit the view of the prescribing physician. This is an important inclusion, but the regulations fail to state how this should occur. This communication should be in writing, copied to the beneficiary and her representative, to ensure participation in the process and a decision made on all available evidence. The plan should be required to submit all evidence that it considered in its decision and provide a list describing this evidence to the beneficiary and her representative. The IRE's decision should describe all the evidence considered and be sent to not just the enrollee, but also the authorized representative and the prescribing physician. In addition, the IRE should include in its decision a determination of the amount in controversy and inform the enrollee of her further appeal rights, the amount in controversy requirement and the potential to aggregate claims. In addition, the notice should remind an enrollee of their right to be represented in the appeal process and provide the number of the state's SHIP, which may be able to refer them to available legal services in the enrollee's area.

There should be a clear timeframe enunciated in the final regulations for IRE review. An appropriate timeframe would be 60 days from the date that the IRE receives the request for review. If the IRE fails to act within this timeframe, the enrollee should be permitted to appeal directly to the ALJ.

Section 423.610 Right to an ALJ Hearing

Community Legal Services strongly urges CMS to provide exceptions to the ALJ amount in controversy requirement for those beneficiaries who receive the low-income-subsidy. Even small coinsurance amounts take on disproportionate importance to those surviving close to the poverty level. In creating the low-income subsidy, Congress recognized that this population is entitled to special consideration. A reasonable accommodation would be to deem the amount in controversy to be the amount that would be in controversy if the enrollee was a non-subsidy eligible individual receiving the standard benefit. Otherwise, those on the low-income subsidy will qualify for ALJ review in far fewer circumstances than their counterparts in the standard benefit.

The standard in section 423.610 must be clarified for when enrollees can join together and combine their appeals to meet the amount in controversy requirement. As written, section 423.610(c) is unclear. The final regulation should clarify that an enrollee should be able to add up the annual cost of the medicine, if it is used to treat an ongoing chronic condition, or for the number of refills allowed, if the condition is not chronic, in order to meet the jurisdictional requirement. It should also be clarified whether the 60-day filing requirement means that none of the reconsideration decision can be more than 60 days old. Likewise, the standard for when two or more enrollees may aggregate their claims should be clarified.

Section 423.612 Request for an ALJ Hearing

The final regulations should specify timeframes following an enrollee request for an ALJ hearing. If such a request is made to the PDP, the plan should be required to transmit it to the IRE within 24 hours and the IRE should be required to retransmit it to the ALJ office within the next 24 hours. Without set timeframes, the processing of such information could create undue delay. Confirmation should be sent to the enrollee that the ALJ request has been received and that the IRE has forwarded all of the information and documentation in its file to the ALJ. These requirements will ensure that the ALJ has all available information available to use in making her decision.

Sections 423.634 & Section 423.638

These sections allow PDPs to take up to 60 days to effectuate a reversal of their decision from the latter staged of the appeal process. There is no justifiable reason for this delay. Once coverage has been approved, it should be put into place within 72 hours, just as it is in the initial stages of the appeals process.

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

Section 432.772, Definitions

Family size: We support defining family members as relatives in the household receiving at least half of their support from the applicant or applicant's spouse. In order to minimize burdens on beneficiaries, the regulations should specify that applicants will be able self-attest to the status of dependents, without providing further documentation.

Full subsidy eligible individual: The definition of full subsidy eligible individual should refer to the language of 423.773(b) *and* (c), in order to avoid ambiguity.

Income: The definition of income should make clear that income not actually owned by the applicant, even if his or her name is on the check, should not be counted.

Institutionalized individual: The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICFs-MR and individuals in any institution in which they are entitled to a personal needs allowance.

The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

Personal representative: The portion of the definition that permits an individual "acting responsibly" on behalf of an applicant needs further clarification as to who would determine that the individual is acting responsibly and what circumstances would constitute a per se conflict of interest. Moreover, it should be made clear that this individual may be authorized by the same process that is provided for under the "authorized representative" sections of Subparts B, C and M.

Resources: We support the proposed regulation's limitation of countable resources to liquid assets only. However the definitions of liquid assets and what it means to be able to be converted into cash in 20 days need to be clarified. The final rule should include a specific list of countable resources to promote clarity for state and beneficiaries. Resources should not include burial plots, burial funds or life insurance of any value, nor should it include any officially designated retirement account, such as an IRA, 401(k),

403(b) etc. Alternatively, the respective exclusions for the value of life insurance and burial funds should be increased to a reasonable amount, such as $10,000 per asset. Most potential low-income beneficiaries have assets below this level.

Excluding these resources will ease the application process for consumers and eligibility workers, as well as reduce administrative costs by reducing the time and effort required to verify assets. This is consistent with both Congress's and CMS's intent (see Preamble at 46,726). Resource assessments should not include any consideration of transferred assets, as would otherwise be required under SSI rules.

We note that a current draft of the SSA application for the low-income subsidy inquires whether an applicant has life insurance with a face value of $1,500 or more. As noted above, life insurance should not count towards assets, and this question should be eliminated.

Section 423.773, Requirements for Eligibility

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 a low-income beneficiary 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 209(b) states and non-1634 states must coordinate with the Social Security Administration to determine how to provide notice to SSI recipients who are not receiving Medicaid and who therefore do not appear on the state's Medicaid rolls.

Section 423.773 of the proposed regulations 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.

We support the decision reflected in proposed regulation 423.773(c) to deem Medicare Savings Program ("MSP") beneficiaries automatically eligible for the low-income subsidy. We are concerned, however, that inequities and confusion among beneficiaries may result because SSA will not apply the more generous income and asset MSP eligibility rules in place in some states (for example, Alabama, Arizona, Delaware, and Mississippi, which have eliminated consideration of assets for MSPs). Eligibility requirements should be the same for all subsidy-eligible individuals in a state, regardless of where and how they apply. Under the proposed rules, in states that have adopted less restrictive income and asset methodology, people whose assets or income are slightly above the limits set in § 423.773 would be enrolled in a less generous subsidy, or have their application rejected entirely, if they apply directly through SSA, because SSA will apply the national guidelines proposed in § 423.773. However, the same people would have their application accepted if they applied through their states' Medicaid offices, were screened and then enrolled in an MSP, and were then automatically eligible for the

low-income subsidy.

To resolve this problem, we propose that SSA should apply state-specific income and asset eligibility rules in determining eligibility for the low-income subsidy, an option discussed, though rejected, in the preamble at page 46,727. This means that for applicants from states that have eliminated the asset test or increased disregards under 1902(r)(2) for MSP eligibility, SSA should apply the state's rules to determine eligibility. This option is permitted under Section 1860D-14(a)(3)(E)(iv) of the statute.

Alternatively, the regulations should provide that subsidy applicants who appear to have excess assets or incomes would either be screened by SSA for eligibility in an MSP program, or have their applications forwarded to the state Medicaid agency to be screened for MSP eligibility. States would be precluded from requiring beneficiaries to resubmit information, such as income and asset levels, that they have already provided to SSA. Applicants would be enrolled in the appropriate MSP program, and then be enrolled in the appropriate low-income subsidy under proposed § 423.773(c). Adopting this policy, which is not precluded by statute, will ensure that all subsidy applicants are treated equitably, as well as increase participation in MSPs.

As part of this alternative policy, the low-income subsidy application should allow an applicant to opt out of screening and enrollment for an MSP, as some applicants may not wish to participate in an MSP. Under Section 1860D-14(a)(3)(v)(II) of the statute, beneficiaries who are determined eligible for MSPs may be enrolled in the low-income subsidy. There is no requirement that beneficiaries actually enroll in an MSP. Therefore, applicants who meet eligibility requirements for an MSP, but who decline to enroll in the program, should still be automatically eligible for the low-income subsidy.

Because enrollment in an MSP can affect the amount of assistance a beneficiary may receive through other public assistance program, such as Section 8 housing vouchers or food stamps, there will be a profound need for beneficiary counseling during the enrollment process. We recommend that CMS plan for this need by making funds available to local agencies, including state health insurance assistance programs (SHIPs), and other community-based organizations.

In addition, we suggest that states not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective, but can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP. We include the same suggestion in our comments to section 423.904(c).

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.

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) 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 an individual being determined eligible for the subsidy.

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. 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

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.

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) 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.

423.782 Cost-sharing subsidy

This rule should specify that plans cannot use an alternative benefit design to charge cost sharing to low-income beneficiaries that exceeds the amounts set out by the statute. This applies to both the co-payments established in section 423.782(a) and the co-payments and co-insurance established in section 423.783(b).

Section 423.800, Administration of Subsidy

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.

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 423.902 Definitions

"Full benefit dual eligible" is defined, for 2003, to be those individuals having Medicaid drug benefit coverage and Medicare Part A or Part B. This definition appears to include some individuals not receiving full Medicaid benefits, but receiving drug coverage under a Pharmacy Plus waiver. The preamble does not discuss this definition; it is unclear what the intention of the language is.

Section 423.904, Eligibility determinations for low-income subsidies

Section 423.904(a) 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) 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.

The proposed regulation regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, proposed § 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential.

As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen and enroll provision included in the new Section 1935(a)(3) established in Section 103(a) of the statute. Instead, as proposed in our comments to Subpart P, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

Because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are

aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be confusing beyond repair for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Finally, 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.

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.

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.

CMS-4068-P-970

Submitter : Jon Sherwood **Date & Time:** 10/04/2004 04:10:39

Organization : Alaska Department of Health and Social Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attached File

CMS-4068-P-970-Attach-1.doc

STATE OF ALASKA

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October 4, 2004

Mark B. McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-40680P,
P.O. Box 8014, Baltimore, MD 21244-8014

RE: File Code CMS-4068-P
Comments on 42 CFR Parts 403, 411, 417, and 423; Medicare Program;
Medicare Prescription Drug Benefit; Proposed Rule

SUBMITTED ELECTRONICALLY: http://www.cms.hhs.gov/regulations/ecomments

Dear Dr. McClellan:

The comments of the State of Alaska Department of Health and Social Services are provided below. Thank you for the opportunity to submit comments on the proposed Medicare Part D regulations.

Subpart B—Eligibility and Enrollment

Automatic Enrollment of Dual Eligibles

Under 42 CFR 423.30(d), full benefit dual eligible individuals who fail to enroll in a PDP or a MA-PD will be automatically enrolled into a PDP or a MA-PD on a random basis. The regulation is silent as to what agency or entity is responsible for autoenrollment. States should not be required to perform automatic enrollment of dual eligibles; states should be given the option. While some states may be able to be more responsive to the needs of their dual eligibles, other states lack the capacity to perform auto-enrollment and will be unlikely to develop such capacity in the short time remaining until the start-up of Part D. Requiring states to perform autoenrollment would impose an enormous administrative burden on states; and if states failed to meet this burden, it would have disastrous consequences on low-income beneficiaries dependent on stable drug therapy.

This regulation also provides for the automatic enrollment of current full dual eligibles to take place after the end of the initial enrollment period. This would mean that a full dual eligible who

failed to enroll in a Part D plan would lose Medicaid drug coverage on January 1, 2006 and would not be enrolled in a Part D plan until May 16, 2006 at the earliest. We believe that full dual eligibles who have not enrolled in a Part D plan prior to the start of Part D should be automatically enrolled in a plan with sufficient time before January 1, 2006 that they can be informed of their enrollment. This is necessary to ensure the continuity of medication therapy.

Disenrollment

Under 42 CFR 423.44, PDPs can disenroll clients for failure to pay premiums. No time limit for arrearages is given. The effective date of disenrollment is the first day of the month following PDP giving notice of disenrollment. That could be as little as one day later.

Aged and disabled individuals may become unable to pay bills temporarily because of a health crisis, loss of competency, or financial reversals. In such cases, there must be adequate protections to ensure that Part D recipients do not lose coverage unnecessarily. It can take time for an individual to recover from illness, obtain a guardian or conservator, or take financial actions necessary to resume payment of premiums.

While the poorest Part D beneficiaries will have subsidized premiums, those with incomes just above subsidy level (or who have chosen not to apply for subsidies) could experience adverse health consequences from the loss of prescription drug coverage, driving up Part A and B costs. Such adverse health consequences could also increase the need for long term care services, driving up the cost to Medicaid under Medically Needy or special income groups for institutional and HCB services.

We believe that notice provisions must allow beneficiaries sufficient time to respond, and that there should be adequate provision for good cause exceptions, such as when a beneficiary becomes physically or mentally unable to pay a premium, rather than simply unwilling.

The proposed regulation also allows for disenrollment for disruptive behavior and provides some definition of what constitutes disruptive behavior under (d)(2), but this section falls short of a comprehensive definition, and leaves open the possibility that individuals could be disenrolled for less egregious behavior.

Nor does the regulation address what obligation the PDP sponsor has to provide accommodation to individuals with disabilities. Some of the behavior described in (d)(2) could easily be associated with a beneficiary's disability, including disabilities for which the beneficiary receives drug treatment. The proposed regulation would require PDP sponsors to make a good faith effort to resolve problems with disruptive clients, including use of the grievance process, but we do not believe this is adequate. Addressing similar situations, the State of Alaska has required providers to demonstrate that they have exhausted all possible reasonable accommodations prior to client discharge. CMS should make it clear that PDP sponsors will need the capacity to serve potentially disruptive clients and provide for a variety of accommodations for disruptive behaviors commonly associated with some disabilities.

Also, 42 CFR 423.44 allows for disenrollment if an individual no longer resides in the PDP's service area. The regulations need to provide an adequate mechanism for individuals who reside in different parts of the country at different times of the year to maintain their Part D enrollment in either location. Alaska is one of many states that have a significant number of part-year residents, sometime called snowbirds. The problems inherent in switching drug coverage repeatedly would almost surely impact the health of these individuals. Medicare prescription drug coverage should not unreasonably impede the ability of these people to maintain their lifestyle. We question whether a durational limit absence from the service area is even necessary if beneficiaries can provide proof that they maintain residence in a service area. Why not let the beneficiary decide whether the convenience of being enrolled with a plan in their current service area exceeds the inconvenience of frequent enrollment and disenrollment?

Creditable Coverage

We are unclear on the intent of 42 CFR 423.56(b), which requires Medicaid to disclose whether or not it provides creditable coverage to Part D recipient. Aren't Part D recipients ineligible for Medicaid drug coverage? Is it intended that Medicaid provide such information to individuals who become newly eligible for Part D?

Also, more generally, we would prefer that regulations and CMS referred to creditable coverage under Medicare Part D as creditable drug coverage to help avoid confusion with the meaning of creditable coverage under HIPAA. It will be easy for individuals seeking one form of proof of creditable coverage to inadvertently pursue the wrong kind. Using different terminology from the start of the program will help to avoid confusion.

We support treating IHS coverage as creditable drug coverage.

Subpart C—Benefits and Beneficiary Protections

IHS beneficiaries and out-of-pocket expenses

We have concerns about the discussion of the proposed 42 CFR 423.104 that indicates that IHS drug expenditures would not count as incurred costs toward meeting beneficiaries' out-of-pocket threshold. The described policy seems to break with the long-standing policy of IHS being the payor of last resort with regard to Medicaid and Medicare. This policy poses several problems.

First, as described in this discussion, IHS drug expenditures are treated differently when applying the Part D deductible than when determining out of pocket expenses. We fail to see the basis for this distinction.

Second, this policy would seem to eliminate Part D coverage as a source of payment for drug coverage above the initial coverage limit, at least for those individuals who rely on IHS or tribal

facilities for their medications. In many Alaska communities, IHS or tribal facilities are the only health facilities available. This result seems inequitable, as such individuals would be subject to the same premiums as other Part D eligible individuals. In locations where there are other sources for drugs, denying Medicare payment might lead IHS beneficiaries with high drug costs to leave the tribal health system to obtain their drugs, fracturing health care delivery for the individuals who would most benefit from coordinated care.

Third, the discussion implies, but does not state explicitly, that low-income subsidy eligible beneficiaries would not be subject to the same treatment without clearly stating how they would be treated. We support tribal pharmacies receiving reimbursement for low-income subsidy beneficiaries; however, it is not clear why other IHS/Medicare beneficiaries should be prevented for access Part D to pay for their catastrophic drug expenses. Their access to adequate medical care depends on adequate funding of tribal health facilities. For many years, such tribal facilities have had to depend on Medicare, Medicaid, and other third-party coverage for its beneficiaries to fund their operations.

If it is not the intention to provide full Medicare Part D reimbursement for low-income subsidy eligible individuals served at tribal facilities, tribal facilities would lose revenues, as most low-income subsidy eligible individuals will be full benefit dual eligibles, for whom Medicaid covers the cost of drugs currently. States will not be in a position to make it up under the proposed regulations, as they will be required to make the same phasedown contribution on behalf of these IHS beneficiaries as for any other full benefit dual eligible.

The State of Alaska sees tribal health facilities as an essential component of the state's health care delivery system and opposes any measure that would prevent IHS and tribal facilities from taking full advantage of Medicare Part D as source of third part coverage for IHS beneficiaries. Although Medicare Part D coverage may be viewed by CMS as a new source of coverage, it should be remember that for full dual eligibles, it is a replacement of existing coverage; for some others, Medicare Part D may supplant retirement-based third party drug coverage.

Service Areas/PDP regions

42 CFR 423.112 calls for CMS to establish PDP regions consistent with the requirements of MA regions. We are concerned that if Part D service areas are large, participating PDPs could meet the pharmacy access standards for the region without offering meaningful access in Alaska. Given our state's small number of Medicare beneficiaries, if Alaska was combined with one or more states with larger populations, the plans might be able to meet the access standards without a single pharmacy in Alaska's suburban or rural areas.

When CMS establishes the service area for PDPs, Alaska should be in an area of its own, as there are many challenges from its extreme rural nature and differential pricing that make it unlike other states. In addition, the Alaska has a large number of I/T/U (IHS) pharmacies that will need to be taken into account. If CMS chooses to use multi-state regions, it should require PDPs to meet access standards by state, and the regulations should include this provision.

Another reason for having service areas coincide with state boundaries it that PDP sponsors may want to tailor their benefits and formulary so as best to serve individuals transitioning from Medicaid or an SPAP. As noted above, there may be substantial health benefits and costs savings to the larger health system if this transition minimizes the disruption of individual's drug therapy. If the PDP must serve areas larger than a single state, it would be virtually impossible to tailor the plan to achieve this positive outcome.

Pharmacy Access Standards

The supplementary information provided by CMS invites comment on assuring access to I/T/U pharmacies. We believe that the first approach described by CMS, requiring PDP sponsors and MA organizations to offer any I/T/U pharmacy at least the same terms available under the plan's standard pharmacy contract, is the better of the two approaches outlined. CMS notes that these pharmacies are the only facilities capable for providing medication therapy management services due to language and cultural barriers. We would add that in many part of Alaska, geographical barriers also apply. We concur that certain contract provisions would have to be waived and that CMS should provide a model addendum for PDP sponsors.

Tribal health providers are a critical component of the state's health care delivery system. In many parts of the state, they are the only health care provider. Many of the Alaska Natives and American Indian seniors or disabled that these providers serve are full benefit dual eligibles, and providers already receive payment for drugs under Medicaid. Tribal providers should have access to Medicare Part D payments to make up for the loss of Medicaid payment for these individuals.

Formulary

It is essential that people with serious chronic illness have access to an adequate range of therapeutic options to manage their diseases. We appreciate that CMS recognizes the need to prohibit plans that substantially discourage enrollment by certain categories of Part D individuals. However, we worry that some classes of individuals, e.g., the chronically mentally ill, may need to be able to choose from more than two of drugs in a therapeutic class. While the proposed regulations address the appeal process, we believe that CMS should elaborate on the appeal rights for individuals seeking coverage of drugs not on their PDP sponsor's formulary. For example, should individuals have the right to obtain coverage of a non-formulary drug because it is the only one that has efficacy?

Also, explicit provisions should be made to address the transition to the Medicare Part D PDP formularies. For many beneficiaries, removing them from a stable drug therapy to take advantage of a new formula is a delicate proposition at best, and sometimes better avoided. These regulations leave open the question of what obligation PDP sponsors have to minimize the potential dangers of transitioning to their formulary.

Dispensing Fees

The Supplementary Information published with the proposed regulations invite comments on three options for defining dispensing fees. We offer the following comments. In general the dispensing fee should not include any accommodation for Medication Therapy Management since this is a separate service to be provided to those with chronic illness.

For option 1 – The dispensing fee definition should indicate this is payment for any and all Drug Utilization Review activities such as counseling, interaction checking, etc. as outlined in the CFR under Drug Utilization Review for Medicaid.

Under option 2, the administration activities of home infusion therapy should be included in the administration fee since these activities are completed after the drug is compounded in a pharmacy. There should not be a dispensing fee for supplies since these are submitted under the 837P standard and these items are covered under Medicare Part B at Part B rates. Under the current pharmacy billing standard (NCPDP 5.1), supplies and DME are not billable. Therefore, any supplies and DME must be billed with the 837P. Due to coverage under Part B, any coverage under Part D may duplicate payments.

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

Medication Therapy Management

42 CFR 423.153(d) states that medication therapy management program must be provided for targeted group: multiple chronic diseases taking multiple covered drugs, likely to exceed CMS determined cost. The regulation should not be included in the dispensing fee and, as the regulation now indicates a separate service. The reimbursement should follow the reimbursement for physician services using a RBRVS type, at a reduced percentage.

Electronic Prescribing

Under 42 CFR 423.159 (b), a Medicare Advantage organization may provide a separate or differential payment to a participating physician that prescribes Part D drugs. If Medicare provides incentives for physicians who purchase software and send prescriptions electronically, they should provide incentives to pharmacies to receive prescriptions by this method, as the increase in drug safety from advance DUR will enhance savings in the medical system.

Subpart J—Coordination Under Part D with Other Prescription Drug Coverage

SPAP definition

The proposed regulation at 42 CFR 423.464(e) lists the criteria for qualifying as a state pharmaceutical assistance program (SPAP). One of these criteria is that SPAPs must "provide assistance to all Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." While we do not disagree with the basic concept, the regulation should clearly state that discrimination is limited to the provision of financial assistance inequitably.

SPAPs and other state agencies constitute a critical source of outreach, information, and counseling to Part D beneficiaries, especially those who are transitioning out of Medicaid or SPAP drug coverage. As such, SPAP personnel must be able to provide beneficiaries with honest evaluations of how the choice of Part D plans will affect the beneficiaries. For example, it should not be considered discrimination for an SPAP to identify which Part D plans have formularies that closely resemble the state's SPAP or Medicaid formulary, or what difference in beneficiaries' combined Part D/SPAP out-of-pocket expenses will be if they choose one PDP over another.

Coordination of Benefits with Medicaid

While this may not be the appropriate place to comment, we found no provisions for situations where the state Medicaid program is not informed of an individual's Part D eligibility until after the Part D eligibility begins. Would Medicaid drug expenditures for such individuals be eligible for FFP? Would such payments be considered an error under the new PERM regulations? Could Medicaid recover its expenditures for drugs covered under the beneficiary's PDP?

Subpart K—Application Procedures and Contracts with PDP Sponsors

Notification of Contract Nonrenewal

The notification requirement under 42 CFR 423.507 may not be practical if interpreted too literally. There may not be newspapers of general circulation in each community (Alaska does not have counties, and its closest equivalent, boroughs, do not encompass all communities within the state). CMS may need to identify alternate means for PDP sponsors to inform the general public, such as publishing the notice in one or more newspapers of general circulation with statewide distribution.

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

Unique income definition

Under 42 CFR 423.772, income is defined differently from Medicaid in two ways: 1) it does not include any of the more liberal methodologies used under 1902(r)(2); and 2) it is applied at the "family" level, in other words, it includes dependents, and is not limited to a household size of

one (individual) or 2 (couple). If states have to make eligibility determinations, then they have to make completely separate determinations of income and resources for Medicare Part D subsidy than for Medicaid. See our comments at 42 CFR 423.774 below.

Institutionalized Individuals

We believe that the definition of institutionalized individuals under 42 CFR 423.772 should clearly include individuals with long term stays in hospitals, nursing homes, ICF/MRs, residential psychiatric facilities, and individuals receiving Medicaid home and community-based waiver services. It is important that Part D not provide perverse incentives for people to stay in institutions. While out-of-pocket copayments may not be high for low-income subsidy individuals, these individuals typically have very little discretionary funds, and if they are taking several medications, even $20/month could make a difference in their placement decision. Furthermore, for HCB waiver individuals, expenditures on Medicare cost sharing is a deduction from their cost of care obligation. As states already subsidize this population through the state phase-down contribution, this would have the affect of charging states twice for a portion of the cost.

300 Percent Standard

Under 42 CFR 423.773, all SSI recipients and deemed full benefit dual eligibles qualify as full subsidy low income Part D recipients, even if they have countable income in excess of 135% of FPL. Our state's waiver and nursing home residents can have up to $347 per month more than 135%FPL. Has any analysis been done to determine whether desire for the low income subsidy tied to Medicaid eligibility will lead to increased use of qualifying income (Miller) trusts?

QMB, SLMB, and QI

We support the inclusion of QMB, SLMB, and QI categories as individuals treated as full benefit dual eligibles under 42 CFR 423.773(c).

State Eligibility Determinations

Under 42 CFR 423.774(a), we believe that states should be allowed to meet their statutory obligation by receiving applications and passing the Medicare Part D subsidy eligibility determination to SSA; states should not be required to make a separate determination. This will ensure that all applicants are reviewed by the same agency and standards are applied consistently.

Outside of the regulations process, CMS staff has indicated that it is hoped most individuals will use a streamlined application process through SSA. While this would reduce the burden on states of doing a separate determination, we believe that the assumption that Medicare recipients will choose to apply through SSA may be wrong, at least in some states. SSA only has three offices in Alaska, with limited access. Individuals have access to apply through the State of

Alaska Medicaid application process through about 20 assistance offices and in hundreds of communities through private fee agents funded by the state. Medical providers and pharmacies have established relationships with state public assistance offices and are likely to feel more comfortable referring people to these offices to pursue the Part D subsidy. We believe that CMS must assume that, if states are required to maintain a full eligibility determination process separate from SSA, a large number of applicants will use the state system to access the low-income subsidy.

Accepting and performing the determination for a significant percentage of all subsidy applications will constitute a substantial workload, and will require states to train workers in new eligibility rules. Furthermore, automation of the determination is unlikely, as Alaska (and possibly other states) has a legacy eligibility system that cannot be adapted to take on new programs without considerable time and expense. And even though this is not a state program, states must pay 50 percent of the cost of eligibility determinations that they must perform. Imposing a significant responsibility on Medicaid agencies would result in another under-funded federal mandate.

States may lack a practical way to determine whether applicants have also applied through SSA. If SSA and state agencies make separate determinations that do not agree, some form of resolution process will be needed. This will further complicate processing and add to administrative burden and costs.

Requiring state agencies provide separate determinations would also provide applicants and recipients access to two separate hearings/appeals process. This could result in beneficiaries shopping for the most favorable treatment.

Also, as described, SSA would use a simplified verification process. Many states may not be able to adopt such practices, as they will also need to consider applicants' eligibility for Medicaid or state supplement payments. Some might argue that states could address this issue by relaxing verification standards for Medicaid and state supplement programs. However, we believe that for CMS to suggest that states weaken their verification requirements at the same time that CMS is implementing the PERM process is hypocritical.

The regulations are also unclear about state duty to notify CMS about subsidy status. Because income and resource definitions are not aligned with Medicaid, notifying CMS about someone's Medicaid eligibility status will not unambiguously indicate which level of cost sharing subsidy they are entitled to, (e.g., whether their income is over or under 100%FPL by Part D standards). (42 CFR 423.782) We believe that states should be responsible for providing the additional information needed to determine subsidy status.

Subpart S—Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions

Low Income Subsidies

The regulations do not specify what obligation states doing intake or eligibility determination have to determine premium subsidies or late enrollment penalties as described in 42 CFR 423.780. States should not have to make these calculations. Also, states should not have to assume the responsibility of tracking changes in the beneficiaries' circumstances that could affect their subsidy amounts once they are determined eligible.

State Phase-Down Contributions

The formula presents in 42 CFR 423.908 is not well defined. For example, there is no explanation of whether calendar year 2003 gross per capita Medicaid expenditures is determined using an unduplicated annual count of eligible beneficiaries or a monthly average of enrolled beneficiaries (we would want the unduplicated count). This would make a significant difference in the resulting figure. In general, we are uncomfortable with the practice of adopting a formula by "illustrative calculation." This would seem to leave the possibility open for reinterpretation or modification without going through the regulation process. The regulation should state the formula and define the component variables with their sources.

Alaska, like other states, will be adversely affected by the way the 2003 per capita formula ignores rebates collected after March 31, 2004 report, other costs saving measures implemented in 2003 but not producing reductions until 2004, and the likely indirect impact of reducing Medicaid drug purchasing volume: reducing Medicaid per unit supplemental rebate/PDL savings. The regulations account for none of these changes, nor would the regulations provide relief to any state that chose to eliminate its prescription drug coverage, which is an optional service. This has the effect of making the state financing of prescription drug coverage mandatory for dual eligibles. We believe that the regulations should allow states to seek adjustments to their base year costs to reflect legitimate program changes initiated prior to the end of 2003. We also believe that states should have a mechanism to adjust their base any time they make global changes to their Medicaid optional prescription drug coverage.

As published, the phase-down formula implies that standard FMAP rate will be used in the phase-down payment calculation. This formula does not account for the impact of I/T/U pharmacy billings on state Medicaid drug spending. A fair formula would adjust for 2003 drug expenditures for IHS beneficiaries who received drugs through their tribal providers. These expenditures are 100% federally reimbursable. The simplest way to accomplish this might be to simply remove such expenditures from the 2003 calculation. However, it might be more

accurate to make adjustments to the FMAP rate used in the calculation based on the number of IHS eligible dual-beneficiaries in the state Medicaid program.

Sincerely,

Jerry Fuller
Medicaid Director
Alaska Department of Health and Social Services

Submitter : Valerie Rinkle **Date & Time:** 10/04/2004 04:10:48

Organization : Asante

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-4068-P-971-Attach-1.doc

CMS-4068-P-972

Submitter : Mr. Kevin Costello **Date & Time:** 10/04/2004 04:10:45

Organization : Community Legal Services

Category : Attorney/Law Firm

Issue Areas/Comments

Issues 1-10

BACKGROUND

Please see attached document for comments on the background.

BENEFITS AND BENEFICIARY PROTECTIONS

Please see attached document for comments on Subpart C.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Please see attached document for comments on Subpart B

GENERAL PROVISIONS

Please see attached document for comments on Subpart A.

CMS-4068-P-972-Attach-1.doc

CMS-4068-P-972-Attach-1.doc

CMS-4068-P-972-Attach-1.doc

CMS-4068-P-972-Attach-1.doc

CMS-4068-P-973

Submitter : Mr. Craig Scott **Date & Time:** 10/04/2004 05:10:21

Organization : Catalina Health Resource

Category : Private Industry

Issue Areas/Comments

Issues 1-10

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

Comment is attached in Word format.

CMS-4068-P-973-Attach-1.doc

Submitter : Mr. David Seaver **Date & Time:** 10/04/2004 05:10:36

Organization : Mass Soc of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-974-Attach-1.doc

Submitter : Mr. DuWayne Schlittenhard **Date & Time:** 10/04/2004 06:10:24

Organization : St. Alexius Medical Center

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

PHARMACY ACCESS STANDARDS:

In order to serve the patients who come to our medical center and expect the same services in the outpatient areas and they do in the inpatient setting, we must have the same pharmacy requirements as the the TRICARE standards required by the Department of Defense. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.

Allowing anything less than that by averaging the service areas would provide patients with less than fair access to their pharmacy which would violate a promise made by Congress that CMS should honor.

ANY WILLING PROVIDER:

Plans are required to permit any pharmacy willing to accept the plan's terms and conditions to participate in their pharmacy network. However, the proposed regulation allows plans to make distinctions and designate pharmacies within the network as preferred and non-preferred. The plan could reduce a beneficiary's co-pay at preferred pharmacies.

This would affect my ability to continue to serve my patients. It could also drive patient 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 the full benefit in a rural area like North Dakota. Access is not access if our patients are forced to use other pharmacies.

LEVEL PLANING FIELD:

Plans must allow beneficiaries to obtain the same benefits at a community pharmacy that they can access at a mail service pharmacy. 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 product. Congressional intent as identified by 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

Medication Therapy Management Program:

I would ask that CMS designate pharmacists as the primary providers of MTM services due to the vast knowledge we have in drug therapy management. The following should be targeted beneficiaries:

- Patients who have two or more chronic diseases and two or more drugs should qualify for MTMS.
- Patients who 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 MTMS for the entire year.
- CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non targeted beneficiaries. If the non-targeted beneficiaries require MTMS pharmacists should be able to provide the services and bill patients directly for those services.

PROVIDER:

Pharmacists are the medication experts on the health care team and 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. Plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.

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 nonn-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 entire pharmacists to provide MTMS.

SERVICES:

MTM services are independent of, but can ocur in conjunctioin with, the provisioni 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.

CMS-4068-P-975-Attach-1.doc

CMS-4068-P-975-Attach-1.doc

Submitter : Miss. Tran Tran **Date & Time:** 10/04/2004 05:10:39

Organization : UNC CH School of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Congress supports providing patients with fair access to pharmacies. The best way to ensure that congress?s intentions are fully met is to amend the pharmacy access standards to require plans to meet TRICARE requirements on a local level in lieu of on an overall service level. Making the standards stricter ensures that patients? best interest will be observed in terms of availability of pharmacies in their area.

The regulation allows plans to distinguish pharmacies as preferred versus non-preferred yet allows plans to consider both in meeting the requirements to mandate fair access to local pharmacies for all patients. This leaves room for plans to coerce patients into using pharmacies that they designate as preferred over other non-preferred pharmacies that may be closer and more convenient. Preferred pharmacies may provide more affordable co-pays to patients forcing them to drive many miles which defeats the purpose of having a regulation that is intended to provide patients with better access to pharmacies. Allowing plans to include preferred and non-preferred pharmacies to meet the aforementioned requirements does not count as fair access for the patient because the pharmacies they have to select from are not providing equal benefits. The standards should apply only to preferred pharmacies ensuring that the patient has convenient access to all pharmacies regardless of how they are categorized.

Subpart D: Cost control & Quality Improvement Requirements for Prescription Drug Plans
CMS should replace the term ?multiple? which would leave room for interpretation with the more precise term ?two or more? in reference to the amount of chronic diseases and medications that would describe the targeted beneficiaries. Plans should be required to identify new targeted beneficiaries on a monthly basis since those that may benefit from MTM will change. In order to best serve patients, pharmacists should be notified of whom is eligible for these services. Beneficiaries should also remain eligible for the entire year to optimize the success of the services they are receiving. Pharmacists should not be limited to provide these services only to those eligible but also to those who desire these services regardless of eligibility. CMS must allow patients to receive MTM services from the pharmacy of their choice in order to protect patient-pharmacists relationships previously formed. All pharmacies regardless of whether they are preferred or non-preferred should be paid the same fee to ensure once again that patients have fair access to any MTMS provider. CMS recognizes the value of MTM services to patients in optimizing drug therapy and thus must ensure that pharmacists receive an adequate fee to support their provision of these services. In order to maximize the benefit of MTM services, these services should be carried out in person whenever possible.

Many chronic disease states such as high blood pressure, high cholesterol, or high blood glucose levels present little symptoms to the patient. Although clinical trials prove to us as professionals the importance of controlling these levels, these benefits may not be fully realized by the patients, especially since sometimes the medications may have more side effects than the disease itself. It is tough enough for patients to justify making a trip to the pharmacy, standing in lines, and paying the high costs of medications. Exacerbating this situation by not ensuring that patients? have access to local pharmacies with comparative costs and services may provoke patients to avoid getting their medications altogether. The only way to aid patients in understanding the significance of their medications is to educate, provide good service, and make it easy for them to attain these services. Pharmacists are in the best position to make this happen. Revising this regulation will also ensure that pharmacists are able to provide these necessary services.

CMS-4068-P-976-Attach-1.doc

CMS-4068-P-977

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

Organization : Brigham and Women's Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

10/4/2004

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

Re: CMS-4068-P

CMS-4068-P-977-Attach-1.doc

CMS-4068-P-978

Submitter : Ms. Michelle White **Date & Time:** 10/04/2004 05:10:04

Organization : Ms. Michelle White

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am responding to the proposed rule ?Medicare Program; Medicare Prescription Drug Benefit,? 69 FR 46632. I am concerned that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit. On a broader note, I am also quite concerned about the move to privatize a public program given the detrimental effects this change is sure to have.

CMS must designate people living with HIV/AIDS as a ?special population? and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines. The current plan promises to create disruptions in drug regimens for people living with HIV who are dually eligible for Medicaid and Medicare. Disruption in drug regimes means creation of drug-resistance, which is dangerous for everyone.

The Medicare Modernization Act promises to reduce coverage for people with HIV/AIDS who cannot afford health care services. The provision that allows prescription drug plans to rely on Pharmacy and Therapeutics Committees to determine formularies nearly guarantees that some beneficiaries will go without needed medications. All plans should be required to include all FDA-approved medications. Furthermore, the current plan does not even make clear that beneficiaries would have clear information available for making an informed decision about enrolling in a plan. This must be changed to ensure full information is made available to consumers before they make important decisions about plan enrollment. Finally the appeals process is unacceptable. The MMA plan must include provisions for an expedited appeals process in the case of an emergency, which exists when a drug must be dispensed to avoid a treatment interruption for HIV-related therapies.

Regarding the underlying drive of the MMA to privatize Medicare plans, I am appalled. With 42 million people in this country uncovered by health insurance, I would have imagined that we would have recognized the failures of health care privatization by now. We are already throwing away needed private health care dollars into the pockets of big business CEOs. Under the MMA, we will do the same with public dollars. When will we learn? Health care was meant to be a right, not a privilege for those who can afford it, and it is the government?s responsibility to ensure that health care dollars be spent most efficiently to reach the greatest number of people. The MMA will fail to do this. Rather than reserving precious tax dollars to pay for healthcare, it will sink a great percentage of these dollars into the ?administrative costs? of paying HMO executive?s high salaries. I know we can do better.

Thank you for considering my comments as you finalize the regulations.

Sincerely,

Michelle White
150 Cony Street
Augusta, ME 04330

CMS-4068-P-979

Submitter : Mr. Carl Schmid **Date & Time:** 10/04/2004 05:10:31

Organization : The AIDS Institute

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See Attached file

CMS-4068-P-979-Attach-1.doc

Submitter : Dr. Jennifer Davis **Date & Time:** 10/04/2004 05:10:47

Organization : Grady Health System

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

As Program Manager for Medicare Drug Card Services at Grady Health System ? Atlanta, Georgia (GHS), I would like to first thank you for the opportunity to submit comments on the proposed regulation to implement the Medicare prescription drug benefit. At Grady Health System, our mission is to improve the health of the community by providing quality, comprehensive health care in a compassionate, culturally competent, ethical and fiscally responsible manner. Grady maintains its commitment to the underserved of Fulton and DeKalb counties, while also providing care for residents of metro Atlanta and Georgia. Grady provides leadership to the healthcare community through its clinical excellence, innovative research and progressive medical education and training.

Recently, the Centers for Medicare & Medicaid Services published comment regarding the deeply discounted prices available to 340B disproportionate share hospitals (DSH) and health systems that are dispensing outpatient prescriptions to largely indigent and underserved populations. This allows 340B entities to extend affordable drug coverage to their patients, many of whom are Medicare beneficiaries without other insurance.

BENEFITS AND BENEFICIARY PROTECTIONS

Medicare Approved plan sponsors should not be allowed to require beneficiaries to use mail order pharmacies, nor should they be allowed to promote such pharmacies if they have an ownership interest. There are not only safety concerns, but medication management and compliance are hard to address when the patient?s profile is not easily accessible. Since DSH institutions are able to provide prescription medications at a reduced cost, mail order should only be offered as an additional benefit without a co-payment incentive.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

CMS discusses permitting State Pharmaceutical Assistance Programs (SPAPs) and other drug plans, such as Medicaid, group health plans, federal employee and military health plans to coordinate coverage with private and Medicare Advantage prescription drug plans (PDP and MA-PD), but again makes no concession for DSH institutions. DSH institutions generally provide care to Medicare beneficiaries at reduced out of pocket costs, including prescription medications. There is no wording in the proposed guidelines encouraging PDPs and MA-PDs to allow DSH institutions as part of the pharmacy network, which disrupts the continuity and high quality patient care we are currently providing. Currently, there are only two Medicare Drug Card approved sponsors that will work with DSH institutions, limiting our options to participate to an almost discriminatory level.

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

I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. At Grady Health System, we currently provide clinical pharmacy services for patients in our Geriatrics, Diabetes, Hepatitis C, HIV / Infectious Disease, Urgent Care, and General Medicine Clinics. Plans should be encouraged to continue to use our services and to help our patients make the best use of their medications.

Pharmacists are also the ideal health care professionals to identify Medicare beneficiaries with multiple disease states and chronic care issues that need medication management for their drug therapies. CMS needs to ensure that referral for MTM is not limited by the plan. CMS also needs to guarantee that pharmacy service providers are not limited to licensed pharmacies, nor tied to a specific pharmacy or a written prescription. Due to the clinical nature of pharmacy services offered by many institutions and health systems, MTM services should be able to be administered with or

without filling a prescription.

CMS should include guidelines for plan sponsors for minimum requirements for MTM services. To further ensure quality care, CMS should consider a program to accredit plans offering MTM services to meet basic knowledge competencies. This will help to lower costs and offer quality care by a pharmacist. Programs at minimum should include: diabetes management and education, anticoagulation services, asthma education, cholesterol monitoring, HIV therapy management and education, osteoporosis screening, and pharmacotherapy programs for chronic diseases.

I believe it is important for CMS to allow for all pharmacists to be considered providers of MTM services, and that plans should be directed to allow for such services, regardless of the practice setting. CMS should also guarantee that providers of MTM services are reimbursed at the same rate, regardless of provider status. Pharmacists are an integral part of the healthcare team that can make certain appropriate drug therapies are used and conditions are treated properly.

GENERAL PROVISIONS

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies; with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. It also alienates a subset of pharmacies providing care for the most vulnerable patients. CMS has failed to consider the unique situation of 340B ?Safety Net? healthcare organizations that represent five percent of the nation?s hospitals, and treat close to two million Medicare beneficiaries each year, in many cases, providing pharmaceutical coverage at substantially discounted prices. Incompatibilities with such institutions could limit, even cut-off, the very small number of approved Medicare Card vendors willing to participate with DSH institutions. CMS should require plans to offer a standard contract to all pharmacies and provide wording to require private prescription drug plans to contract with ?Safety Net? hospitals providing outpatient prescriptions.

CMS must act responsibly by assuring that the dispensing fees are not discriminatory against DSH institutions. Because such institutions are able to access 340B pricing, average wholesale pricing is not used as part of our billing equations, thus putting us at a disadvantage if the dispensing fee is limited. If an institution is billing at actual acquisition, a dispensing fee structure should be provided such that overhead costs are covered.

CMS-4068-P-980-Attach-1.doc

CMS-4068-P-980-Attach-1.doc

CMS-4068-P-980-Attach-1.doc

CMS-4068-P-980-Attach-1.doc

CMS-4068-P-980-Attach-1.doc

Submitter : Miss. Erika Bivins **Date & Time:** 10/04/2004 05:10:11

Organization : VA Medical Center Memphis, TN

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:
Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plans overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.
Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. Plans should be encouraged to use my services to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to require plans to meet the TRICARE pharmacy access requirements on a local level, CMS should require plans to offer a standard contract to all pharmacies, and plans should be encouraged to use services offered by pharmacist.

Thank you for considering my view.

Sincerely,
Erika Bivins
Pharmacy Practice Resident
Veterans Affairs Medical Center
Memphis, TN 38104
Office: (901) 523-8990 extension 6730
Pager: (901) 577-7288 #301

CMS-4068-P-982

Submitter : Ms. Rev. Carolyn R Palmer **Date & Time:** 10/04/2004 05:10:28

Organization : Special Concerns Ministries

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from Special Concerns Ministries

CMS-4068-P-982-Attach-2.doc

CMS-4068-P-982-Attach-1.doc

CMS-4068-P-982-Attach-3.doc

CMS-4068-P-983

Submitter : Ms. Lucinda Long **Date & Time:** 10/04/2004 06:10:37

Organization : Wyeth Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Wyeth Pharmaceuticals welcomes the opportunity to comment on the proposed rule to implement the Medicare Prescription Drug Benefit (CMS-4068-P). Please see the attached word file with our formal comments.

CMS-4068-P-983-Attach-1.doc

CMS-4068-P-984

Submitter : Jay Norberg **Date & Time:** 10/04/2004 05:10:44

Organization : Jay Norberg

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

The way the proposed law is worded could greatly limit the access that people would have to getting prescriptions covered by Medicare. The law clearly states that "any willing provider" may participate but it also says later on that the PBM's that will be administering the program will be able to choose, and limit, the providers in a certain geographic area. This means that the PBM's will, basically, be auctioning off prescription drug participation to the lowest bidder for them (the PBM's). The PBM's will choose the lowest bidder so that they can keep the most money for themselves. This will result in a decrease in overall healthcare availability which, in turn, will result in a decrease in overall health of the participants (aka taxpayers) and an increase in the cost of healthcare in general. Since Medicare is already in financial trouble how can they afford to increase the expenditures? PBM's have never been shown to save any healthplan money. PERIOD. They have shown without a doubt to increase the cost of healthcare and prescriptions in general. Until the politicians who are proposing these laws, and trying to get them passed under our noses, start listening to the people that deal with these problems on a daily basis (Pharmacists, Doctors, Nurses, Patients, etc.) and not to the PBM's, HMO's, Drug Manufacturers, etc. nothing goo will come out of any proposed legislations. All these companies are just paying the polititions off to get something that will benefit them only and couldn't care less about the people involved. They know that the people will be there because the people will be forced into a program that isn't the best for them and will cost them more. We, as taxpayers, deserve an elected official that will listen to the voters and not to the jingle in their pockets or their re-election campaign funds from these companies.

CMS-4068-P-985

Submitter : Dr. Daphne Smith **Date & Time:** 10/04/2004 05:10:58

Organization : University of Illinois at Chicago

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Pharmacists who provide medication therapy management should be allowed to bill those patients. The services help to enhance compliance and improve management of various disease states. The pharmacist can stress the importance of adherence to medication, as well as monitor for side effects and drug interactions. The time spent providing these services is valuable to the patient and health care team. Hospital admissions due to improper use of medication can be decreased. Therefore, the pharmacist should be compensated for these services.

CMS-4068-P-986

Submitter : Ms. Lori Arnold **Date & Time:** 10/04/2004 05:10:33

Organization : UT College of Pharmacy

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.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

The proposed regulation also allows plans to create 'preferred' pharmacies and 'non-preferred' pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one 'preferred' pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only 'preferred' pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

CMS-4068-P-987

Submitter : Dr. Jason Greene **Date & Time:** 10/04/2004 05:10:11

Organization : Reeves Sain Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to express my concern as a pharmacist to assure:
1. Any willing provider--that all patients have access to the pharmacy of his/her choice which would include any retail pharmacy.
2. Level playing field--all retail pharmacies have the same opportunity to fill prescriptions at the same reimbursement and days supply of medication offered (e.g.90 day supply allowed at retail and mail order settings)
3. Pharmacy access standards

CMS-4068-P-988

Submitter : Dr. Larry Ereshefsky **Date & Time:** 10/04/2004 05:10:17

Organization : College of Psychiatric

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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

ELIGIBILITY, ELECTION, AND ENROLLMENT

PAYMENTS TO PDP AND MA-PD PLANS

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

CMS-4068-P-989

Submitter : Mrs. DeLorna Strong **Date & Time:** 10/04/2004 05:10:40

Organization : Apache Tribe Vocational Rehabilitation Program

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

Submitter : Miss. Tabitha Cross **Date & Time:** 10/04/2004 05:10:58

Organization : IPA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

September ___, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.

? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice _____. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

? In conclusion, I urge CMS to revise the regulation to _____
[briefly recap all of your recommendations to CMS in list form].

? Thank you for considering my view.

Sincerely,
[Name]
[Contact Information]

Submitter : Dr. Janice Bopp **Date & Time:** 10/04/2004 05:10:23

Organization : Mar-Main Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SAMPLE LETTER TO CMS

October 10, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.

? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: diabetes education & monitoring, hyperlipidemia education & counseling, smoking cessation counseling, hormone replacement consultation, blood pressure monitoring, medication reviews (?brown bag review?). Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

? In conclusion, I urge CMS to revise the regulation to allow pharmacists to get reimbursement compensatory to the type & quality of service provided, and amount of reimbursement not be determined by PBM?s unless on equal terms.
Thank you for considering my view. Janice Bopp PharmD Mar-Main Pharmacy
574-234-3184, 800-439-2466, janbopp@hotmail.com

CMS-4068-P-992

Submitter : Mr. Larry Downey **Date & Time:** 10/04/2004 05:10:35

Organization : Teva Neuroscience, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See attached letter

CMS-4068-P-992-Attach-1.doc

CMS-4068-P-992-Attach-1.doc

CMS-4068-P-993

Submitter : Ms. Nancy Davidson **Date & Time:** 10/04/2004 05:10:15

Organization : Lash Group Healthcare Consultants

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

It is with great pleasure that Lash Group Healthcare consultants present comments to the Medicare Program; Medicare Prescription Drug Benefit [CMS-4068-P] Fed. Reg. 46632 (August 3, 2004). We appreciate CMS' efforts to move forward with this historic addition to the Medicare Program. Please feel free to contact us if you have any comments or concers about our attached comment letter.

Sincerely,

Nancy J. Davidson

CMS-4068-P-993-Attach-1.wpd

CMS-4068-P-994

Submitter : Mrs. Joyce Gleason **Date & Time:** 10/04/2004 05:10:54

Organization : NH DHHS, Division of Family Assistance

Category : State Government

Issue Areas/Comments

Issues 11-20

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

Section 423.773(c)(3) requires States to notify individuals who are full dual eligibles that the individuals are eligible for a full subsidy of Part D premiums and deductibles and must either enroll with a PDP or MA-PD or be randomly assigned to a PDP or MA-PD.

? The draft regulation does not specify what agency (the State or the Social Security Administration) is financially responsible for the notices. Section 1860D-14(a)(3)(B)(i) states ?There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.? Does this mean that the Social Security Administration must subsequently provide States with funding to enable States to comply with this notification requirement? If that is the intent, we feel that the regulations should specifically state that the Social Security Administration will provide an appropriation to each State to enable States to provide notice to dual eligibles as specified in the draft rules. The regulations should also specify the amount of funding that will be provided to states.

? The draft regulation requires States to notify its dual eligibles that they are eligible for a full subsidy of Part D premiums, etc., but the draft regulations are silent as to responsibility for explaining to dual eligibles how the PDPs and MA-PDs work or how their prescription coverage will differ from the coverage they had through the Medicaid program. With what agency does this responsibility lie?

Section 423.774(a) Determination of whether an individual is a subsidy eligible individual. This section states that eligibility for subsidies are made either ?by the State under its State plan under title XIX if the individual applies with the Medicaid agency, or if the individual applies with SSA, the Commissioner of Social Security in accordance with the requirements of section 1860D-14(a)(3) of the Act.?

? In our opinion, having two separate agencies responsible for determining eligibility will be confusing for individuals applying for subsidies. Application forms may differ, as well as the procedures for determining eligibility.

? It is our understanding the SSA is already developing a simple application form to be used in their offices and that they plan on determining eligibility using self-declaration of income and resources rather than by verification of income and resources. In determining eligibility, NH would rely on its current methods for determining eligibility, which includes having the individual verify certain key items such as Medicare, income and resources.

? We recommend that one agency be delegated the responsibility for determining eligibility for subsidies. Since SSA is being given funding to determine eligibility, it should be SSA that makes all decisions regarding non-dual eligible subsidies. States should be given the responsibility of providing low-income subsidy applications to individuals, assisting individuals in completing the applications, and forwarding the completed applications to SSA for the formal eligibility determination.

Section 423.774(b) Effective date of initial eligibility. This section states that ?(E)eligibility determinations are effective beginning with the first day of the month in which the individual applies or January 1, 2006 if the application was taken in advance of that date?.? If eligibility is effective beginning with the first day of the month in which the individual applies, how will situations of applications for retroactive assistance be handled? Currently, an individual may request Medicaid eligibility for the three months prior to the month of application. Will retroactive eligibility for prescription coverage through Part D Medicare be allowed for dual eligibles? If so, shouldn?t the regulations specifically allow for that possibility?

Section 423.782 pertains to the cost-sharing subsidy.

? (a)(ii) specifically pertains to ?

SPECIAL RULES FOR STATES

Section 423.904 General Rule. This regulation requires the State agency to make eligibility determinations and redeterminations for low-income

premium and cost-sharing subsidies.

? Please see the comment for Section 423.774 pertaining to having both the Social Security Administration and the State agency making eligibility determinations for the same group of individuals.

? If the decision is made that both the Social Security Administration and the State agency must make eligibility determinations and redeterminations, how is the State agency going to be reimbursed for the administrative costs associated with making such determinations? 423.774(a) references Title XIX. Does that mean that States will be reimbursed at their Title XIX federal matching rate? This would be another unfunded federal mandate.

o Having the State agency make the eligibility determinations in effect results in the creation of a new eligibility group. There will be significant costs to the State agency just to add this new eligibility group to its existing eligibility determination system.

o There will be additional costs for application development, assuming that the State does not use the application form currently being developed by CMS and the Social Security Administration. It is also unclear as to what agency is responsible for developing informational materials that will explain Part D Medicare. States are not equipped to understand or present such complex information to individuals regarding a program that is not technically part of Medicaid.

o We don?t know what to expect as far as numbers of individuals who will be applying for subsidies, but it is anticipated that additional staff may be needed to process the applications. NH has received informal information that the Social Security Administration will be hiring additional staff to help with the new program. How are States expected to fund their need for additional positions?

Section 423.904(c) Screening for eligibility for Medicare cost-sharing and enrollment under the State Plan. This section requires the State agency to screen individuals who apply for subsidies for eligibility for Medicare Savings Plans (Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, and Qualified Individuals). There doesn?t appear to be any requirement for the Social Security Administration to do the same screen. Does this mean that only individuals who apply for the Part D subsidy through the State agency will be screened for potential Medicare Savings Plan eligibility and that individuals who happen to apply for the Part D subsidy through the Social Security Administration will not be screened for such eligibility? If so, it would appear that the regulations will ultimately result in the inequitable treatment of individuals who are potentially eligible for Medicare Savings Plans based solely on where they apply for assistance.

Section 423.904(d) Application form and process.

? This section requires that no later than July 1, 2005 States must make the low-income subsidy application available to individuals. If the State agency decides to use the application being developed by CMS and the Social Security Administration, what are the timeframes for the application form to be provided to the State agencies? Why have the State agencies not been involved in the application development process?

? This section also requires the State agency to provide ?information on the nature of, and eligibility requirements for, the subsidies under this section.? Does this requirement mean that States must provide written information to individuals, or does it mean that States must provide written material as well as counseling individuals regarding their choices? Apart from our opinion that it is not appropriate for States to be required to provide such detailed information about a program that is not even part of the Medicaid program (and in fact bears almost no

CMS-4068-P-994-Attach-1.doc

CMS-4068-P-994-Attach-1.doc

CMS-4068-P-995

Submitter : Mrs. Rachel Brewer **Date & Time:** 10/04/2004 05:10:33

Organization : Mrs. Rachel Brewer

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pharmacists play a crucial role in the health care of many individuals. Please keep this role accessible to the public and allow this community of professionals to operate at their full potential in managing the pharmacotherapy of their patients.

Thank you.

CMS-4068-P-996

Submitter : joseph guagliano **Date & Time:** 10/04/2004 07:10:32

Organization : joseph guagliano

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-996-Attach-1.doc

Submitter : Ms. Karen Fiumara **Date & Time:** 10/04/2004 05:10:34

Organization : Brigham and Women's Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

10/4/2004

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

Re: CMS-4068-P

CMS-4068-P-997-Attach-1.doc

CMS-4068-P-997-Attach-2.doc

CMS-4068-P-998

Submitter : Lina Matta **Date & Time:** 10/04/2004 05:10:46

Organization : Brigham and Women's Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-4068-P

CMS-4068-P-998-Attach-1.doc

CMS-4068-P-999

Submitter : Mr. Steven E. Wojcik **Date & Time:** 10/04/2004 05:10:00

Organization : National Business Group on Health

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comment letter from the National Business Group on Health. Thank you.

CMS-4068-P-1000

Submitter : Brian Bamberger **Date & Time:** 10/04/2004 05:10:11

Organization : MediMedia USA, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Attached are our comments for the NPRM.

CMS-4068-P-1000-Attach-1.doc

October 1, 2004

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

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

Dear Centers for Medicare and Medicaid Services:

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

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

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

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

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

General Comments:
Subpart B. Eligibility and Enrollment

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

… We propose building on our experience in implementing the drug discount care price comparison Web site as we develop requirements for the Part D price comparison Web site, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But that's only a first step.

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

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

c. Use of Standardized Technology (FR 46662)

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

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

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

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

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

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

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

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

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

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

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

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

Recommendations:

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

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

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

Prior Authorization

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

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

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

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

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

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

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

Recommendations:

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

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

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

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

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

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

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

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

Recommendations:

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

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

Sincerely,

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