CMS-4068-P-1302

Submitter : Mrs. Fran Visco **Date & Time:** 10/04/2004 09:10:45

Organization : National Breast Cancer Coalition

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See atttached file

CMS-4068-P-1302-Attach-1.doc

CMS-4068-P-1302-Attach-2.doc

NBCC

NATIONAL BREAST CANCER COALITION

grassroots advocacy in action

October 4, 2004

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

Re: Medicare Program: Medicare Prescription Drug Benefit, Proposed Rule, published in Federal Register Volume 69, August 3, 2004

Dear Dr. McClellan:

Thank you for the opportunity to comment on the Draft Model Guidelines for the Medicare Prescription Drug Benefit.

The National Breast Cancer Coalition is the leading grassroots organization committed to ending breast cancer. We represent over 600 organizations and 70,000 individual members. By empowering thousands of women affected by breast cancer to be effective activists and participants in all areas of breast cancer research and policy, NBCC has fundamentally changed the world of breast cancer and become one of the Nation's most effective and powerful advocacy groups.

NBCC's top legislative priority is *Guaranteed Access to Quality Health Care for All*. One of the key framing principles for this priority is: *patients must be able to access all the care they need, when they need it*. However, we strongly believe that health care must be grounded on high-level evidence and best practices, such as those recommended through the process used by the National Comprehensive Cancer Network. Our principle is in agreement with the CMS proposed Draft Model Guidelines first goal to: "assure beneficiary access to the drugs they need, preventing substantial discouragement from enrollment." Our fundamental request is that the final rule for the drugs covered under the Medicare Part D benefit offers women with breast cancer full access to oral medications that have proven safety and efficacy in treating breast cancer.

NBCC has some concerns about the Draft Model Guidelines as formulated by the United States Pharmacopeia Convention (USP):

- ·**Pharmacologic classes and subclasses**: While NBCC appreciates the need for simplification in defining therapeutic categories and pharmacological classes and subdivisions, we are also mindful that current research on targeted therapies for specific tumor types within breast (and other) cancer diagnoses will lead to discoveries that treatment efficacy will rely on ever-more specific drug selections. This will mean that agents that are currently understood to belong to the same pharmacologic class or subclass will be shown to be effective only in target

tumors with very specific molecular profiles. Because the specific target of such drugs or biologics will be tumor *profile* specific, rather than tumor *site* specific, the existing pharmacologic classes will prove insufficient to *guarantee that beneficiaries will have access to the drugs they need*. Examples that are already established are the proposed subdivision of Sex Hormones/Modifiers (within the Hormones Suppressant category) into Antiestrogen Agents/Modifiers and Antiandrogens, which may result in few or no options for patients who need these treatments. In the case of Antiestrogen Agents/Modifiers, these two represent distinct acting mechanisms that are appropriate to individual patient characteristics and therefore need to be further separated into distinct subclasses. Similarly, the Monoclonal Antibodies class (within the Antineoplastics Category) is too broad as these biologics target specific tumor profiles that distinguish one breast cancer from another. Therefore it is necessary to further subdivide the Monoclonal Antibody class in accordance to the biologic's specific target, which again is not tumor site specific but tumor profile specific.

- **Choice**: Within our evidence-based framework, we believe it is both important and feasible to ensure alternative treatment choices for breast cancer patients. This is particularly necessary as cancer patients frequently experience side effects from the medications they take, and may need to switch to an alternative drug within the same pharmaceutical class or subclass. Therefore, we discourage a narrow application of the "at least two" drugs guideline within a class. We urge CMS to use an evidence-based approach that allows all prescriptions that solidly meet this test to be included in the formularies for a class or subclass.

- **Need for Guidelines on off label use**: Lastly, NBCC recommends that CMS issue additional guidelines prohibiting the inclusion of off-label drugs in the Medicare Part D benefit, unless the drug is being used as part of a clinical trial designed to prove efficacy for a specific indication. This will protect patients from the use of unproven treatments, from serious and sometimes long-term side effects, and will conserve Medicare's resources by covering only interventions with proven efficacy for specific indications.

The National Breast Cancer Coalition believes that in addition to a well informed classification system, clear and evidence-based criteria need to be developed to guide the inclusion of specific drugs in the formularies. NBCC welcomes the opportunity to participate in the public process that CMS intends to conduct as it develops its approach for evaluating the formularies.

Thank you for your attention to our concerns. Should you require additional information, I, or Kimberly Love, Director of Government Relations and Public Policy, can be reached at (202) 296-7477.

Sincerely,

Fran Visco, J.D.
President

NBCC

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Sincerely,

Fran Visco, J.D.
President

CMS-4068-P-1303

Submitter : **Date & Time:** **10/04/2004 09:10:28**

Organization : **Consortium for Citizens with Disabilities**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

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Please see attached file from the Consortium for Citizens with Disabilities

CMS-4068-P-1303-Attach-1.doc

October 4, 2004

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

RE: Comments to the "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632, CMS File Code CMS-4068-P

To Whom It May Concern:

The Consortium for Citizens with Disabilities (CCD) submits the following comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit." CCD is a Washington-based coalition of national disability organizations that advocates on behalf of the 54 million people with disabilities and chronic conditions in the United States.

We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions to insure that they will have the following: 1) Adequate information and assistance in navigating the enrollment and plan selection process; 2) Access to an affordable benefit that provides the drugs they need; and, 3) Access to an exceptions and appeals system that permits them to easily resolve unfavorable plan decisions in a timely manner.

Many of the CCD organizations worked with the Medicare Consumers Working Group, a broad coalition of advocates for Medicare beneficiaries, who submitted comprehensive comments on the proposed rule. CCD believes that significant revisions in the proposed rule are needed in order to ensure that people with disabilities have access to a quality prescription drug benefit and to ensure that full benefit dual-eligible beneficiaries ("dual eligibles") are not disadvantaged further by inadequate access to needed care. However, rather than duplicating the Medicare Consumers Working Group's extensive effort and detailed comments, CCD is submitting comments on issues we have identified as priorities

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for Medicare beneficiaries with disabilities. We recommend that CMS take the following steps to protect the health of people with disabilities and chronic conditions:

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

CCD believes that in many ways the Preamble provides much better guidance than the proposed rule itself and that the specificity in the Preamble should be reviewed by CMS and included in any final rule. On the other hand, we are concerned that there are critical gaps in information in the Preamble that also should be expanded upon. This is an extremely complex law with life and death implications for people with disabilities and chronic conditions. Therefore we suggest that CMS support the delay of implementation of the law for dual-eligibles and publish a second NPRM that reflects the input CMS receives on these proposed rules.

SUBPART B—ELIGIBILITY AND ENROLLMENT

A successful implementation of the MMA will require strong regulatory protections to ensure that people with disabilities are adequately informed that they must enroll in the Part D program and select a private prescription drug plan. In addition, for many people with disabilities, Medicaid prescription drug coverage will end—dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) must be clearly informed of the need to take action to prevent interruptions in access to prescription drugs.

The final rule must ensure that the enrollment process takes into account the unique needs of people with disabilities and recognizes the exceptional challenges of appropriately educating, screening, and enrolling people with disabilities.

423.34(d)(1), Temporarily Extend Medicaid FFP for Full Benefit Dual Eligibles

CCD is deeply troubled by the very real possibility that CMS will not be able to implement the MMA under the current timeframe in a way that adequately responds to the needs of people with disabilities and that ensures that access to prescription drugs will not be interrupted for dual eligibles for whom drug coverage will transfer from Medicaid to a private Medicare Part D plan. Therefore, in the strongest possible terms, we request that CMS immediately indicate its support for legislation that would delay the implementation of the MMA for dual eligibles.

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

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit starting on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the likelihood that not all 6.4 million dual-eligibles will be identified, educated, and enrolled in six weeks (from November 15, 2005, the beginning of the enrollment period to January 1, 2006), we recommend that the transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. The statute requires auto-enrollment on a random basis for all dual eligibles not enrolled on January 1, 2006. CCD has grave concerns regarding how this process might occur for the following reasons:

- It is very likely that many, if not a majority, of dual eligibles will not be able to enroll by January 1, 2006. Existing caseworkers in non-profits, government offices, or SPAPs will not have sufficient time with all 6.4 million dual eligible beneficiaries to educate them on the myriad choices, finding new providers, counseling them on formularies, or shepherding them through a complex enrollment process.

- Assigning dual eligibles on a random basis will—by statute—steer dual eligible beneficiaries into the lowest-cost plan. As a result of being the lowest cost plan, beneficiaries will have significantly restricted access to medications currently being administered to dual eligible beneficiaries.

- Because many dual eligibles will be enrolled in plans not tailored specifically to their unique needs, many beneficiaries will be forced—within a short span of time—to switch critical medications, find a new network pharmacy, and, at worst, go without medications simply because they did not receive enrollment materials in time.

A delay in implementation is critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. The Congress is kidding itself to think that in 6 weeks this complex population will independently enroll in a new plan. Without a doubt, if the current implementation schedule occurs on time, ***some dual eligibles will go to the pharmacy in January 2006 and not come home with needed medication***.

We recognize that this may require a legislative change and hope that ***CMS will actively support such legislation***.

423.36(c)(4), Special Enrollment Periods and Dual Eligibles

The selection of an appropriate prescription drug plan for people with disabilities will be especially challenging given their extensive and complex needs. Moreover, individuals may find that despite their best efforts to evaluate their private plan options, they have selected a plan that does not meet their needs or, their needs may change. For these reasons, we support granting dual eligibles special enrollment periods.

It is critical that dual eligibles receive notice explaining their right to a special enrollment period when they enroll in a plan, and every time their PDP changes its plan in a way that directly affects them, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

423.44(d)(2), Disenrollment for Disruptive or Threatening Behavior

CCD is very concerned that the proposed rules would allow prescription drug plans to disenroll beneficiaries if their behavior is "disruptive, unruly, abusive, uncooperative or threatening." These provisions create great potential for discrimination against individuals with mental illness and cognitive disabilities.

The proposed provisions will be used purposefully to discriminate against persons with mental illness or other disabilities or will result in discrimination as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need. Therefore, plans must be required to develop mechanisms for accommodating the needs of beneficiaries with these disabilities, and CMS must provide safeguards to ensure that these individuals do not lose access to drug coverage. The provisions to allow involuntary disenrollment for disruptive behavior must not be included in the final rule.

Additionally, CCD particularly urges CMS not to include the proposed expedited disenrollment process in the final rule. This process is offensive and unnecessary - and could lead to abuse by private plans that do not have the cultural competence needed to serve some people with disabilities or who wish to avoid potentially high cost individuals who have significant mental health needs or other types of disabilities.

Alternatively, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals. Individuals most likely to be disenrolled for disruptive behavior do not have the resources to pay for needed medications out of pocket and would suffer great hardship from losing drug coverage for an extended period.

Section 423.46, Late Enrollment Penalty

CCD urges CMS to delay implementation of a late enrollee penalty for all enrollees for two years. The drug benefit is a new and particularly complex program, especially for many people with disabilities. In our view, many beneficiaries with disabilities will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. During the initial implementation process, people should not be penalized because of the complexity of the program.

After the first two years, CMS should require plans to allow individuals with disabilities a waiver or grace period if they miss an enrollment deadline. These individuals face additional challenges and may need additional time to select a plan and enroll. Furthermore, the rationale for imposing late penalties – i.e., to discourage healthier beneficiaries from waiting to enroll until later – is less likely to apply to people with disabilities who are likely to require on-going treatment for one or more conditions or illnesses.

In addition, after the first two years, implementation of the late enrollment penalty should be delayed for individuals eligible for the low-income subsidy. Again, individuals may not understand that they have to apply separately for the subsidy and a drug plan, and may think application for the subsidy is sufficient. CCD also recommends that the final rule allow enrollees to appeal late enrollment penalties.

Section 423.48, Information about Part D

CCD believes that people with disabilities must have access to information in order to make informed judgments about private plan options. The final rule (rather than guidance) should include binding and enforceable standards defining the information plans must provide to beneficiaries and how they must make this information available. CMS has important obligations to ensure that information is accessible to people with various types of disabilities and the proposed rule is inadequate in this regard.

CMS must require plans to make information available in accessible formats for people who are blind or have low-vision. Materials must also be available in "plain English" for individuals with cognitive disabilities or low-literacy. On request, plans must be required to provide information in Braille, large print, audio-tape or computer disc. In addition, CMS should require that PDPs' Internet web sites are accessible for individuals with vision impairments.

Information should also be provided in languages other than English to reflect the languages spoken in a plan's service area. This should include adequate information about drug plan options and should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and the appeals and exception processes.

Need for Targeted Outreach to Beneficiaries with Disabilities

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

The State Health Insurance Assistance Programs (SHIPs) are funded by CMS and are charged with being the local one-stop shop for all Medicare beneficiaries. CCD research on SHIPs finds that while they are well intentioned, they often do not understand the unique needs of individuals with disabilities; may not be physically accessible; and may not have information available in accessible format. We strongly recommend that the SHIPs mandate be clarified to ensure that they address the needs of individuals with disabilities, including non-elderly individuals. This could greatly improve education and outreach to this population.

SUBPART C- BENEFITS AND BENEFICIARY PROTECTIONS

No section of the proposed rule is more important to ensuring that the Part D program provides a prescription drug benefit that will meet the diverse needs of people with disabilities than subpart C. CCD is deeply concerned that the proposed rule fails to meet even minimal standards for ensuring that people with disabilities will be able to access Part D drug coverage that meets their needs.

Definition of "Long-Term Care Facility" to Explicitly Include ICF/MRs and Assisted Living Facilities

For people with disabilities residing in residential facilities, including intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities, it is necessary that Part D prescription drug coverage is compatible with the manner in which residential facilities deliver prescription drugs. The final rule must ensure that persons with disabilities residing in residential living facilities are not subject to additional cost-sharing, or out-of-network cost-sharing if they access prescription drugs through a long-term care (LTC) pharmacy.

For this reason, we recommend that the final rule include a definition of "long-term care facility" that explicitly includes ICF/MRs and assisted living facilities. We believe that many mid to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

423.104(e)(2)(ii), Establishing Limits on Tiered Copayments

CCD strongly opposes the provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit."

The final rule must place limits on the use of tiered cost-sharing, such as permitting no more than three cost-sharing tiers and requiring Part D plans to use the same tiers for all classes of drugs. Permitting unlimited cost-sharing tiers could allow a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate safeguards or standards to ensure a fair review of an individual's request for an exception to a Part D plan's non-preferred cost-sharing.

Moreover, allowing plans unlimited flexibility in establishing cost-sharing tiers increases their opportunity to discriminate against people who need costly medications or who need multiple medications. We also believe that permitting multiple cost-sharing tiers will greatly complicate the ability of CMS to determine actuarial equivalence and to determine that the design of a plan does not substantially discourage enrollment by certain eligible Part D individuals under the plan.

Section 423.120, Access to Covered Part D Drugs

Balancing Convenient Access with Appropriate Payment for Long-Term Care Pharmacies

CCD believes that CMS must propose a way to ensure that plan enrollees residing in long-term care facilities must have access to the LTC pharmacy in the facility where they reside. We could support one of two approaches for achieving an appropriate balance of convenient access with appropriate payment.

The first option is for the final rule to require PDPs to contract with all LTC pharmacies. Alternatively, the final rule could require PDPs to make available a standard contract to all LTC pharmacies. However, plan enrollees residing in facilities where the LTC pharmacy has elected not to contract with a prescription drug plan must be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

Further, we believe that there are overlapping responsibilities for the delivery of services between LTC facilities and prescription drug plans. To the extent that prescription drug plans are responsible for coordination and medication management, the final rule should encourage plans to contract with LTC pharmacies to provide these services to the plan's enrollees in long-term care facilities.

1860D-11(e)(2)(D) Authority to Review Plan Designs to Ensure that They Do Not Substantially Discourage Enrollment by Certain Part D Eligible Individuals

CCD is very concerned that plans will discourage enrollment of people with complex medical needs who will need access to a wide variety of medications. CMS must take advantage of every opportunity to ensure this does not happen.

We urge CMS to use the authority provided under section 1860D-11(e)(2)(D) to review plan designs, as part of the bid negotiation process, to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals.

CMS needs to analyze formularies, cost-sharing tiers and cost-sharing levels, and how cost-sharing (including both tiers and levels) is applied to assure that people with the most costly prescriptions are not required to pay a greater percentage of the cost of those drugs.

CMS also needs to assure that a variety of drugs are included in a formulary at the preferred cost-sharing tier to treat chronic conditions and conditions that require more costly treatments. Furthermore, as recommended previously, CMS must ensure that persons who utilize specialized pharmacies, such as LTC, I/T/U, FQHC, rural, or clinic-based pharmacies are not penalized through higher cost-sharing for non-preferred pharmacies or through high cost-sharing for out-of-network access.

423.120(b), Formulary Requirements

CCD has many concerns related to formulary requirements and urges CMS to release a final rule that strengthens the consumer protection requirements and requires special treatment for specific populations.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must be protected from tiered cost-sharing or burdensome prior authorization procedures that could create insurmountable access barriers.

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

Medicare beneficiaries with disabilities also require access to a broad range of medications. For example, people with spinal cord injuries or diseases of the spinal cord must have access to a broad range of antibiotics. Bacterial infection is a leading cause of hospitalization and death for these individuals. Because bacterial resistance to antibiotics is currently a very serious and growing issue CMS must ensure broad and timely access to a wide variety of

antibiotic medications. Bacterial resistance coupled with the common problem associated with individual beneficiary allergies make broad antibiotic access a matter of life and death for this population and the elderly.

Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects, making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance.

The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, as well as hospitalization or other types of costly medical interventions. It can also impact a person's decisions about work. The Ticket to Work and Work Incentives Improvement Act (TTWWIIA) expanded options for states to cover working people with disabilities under their Medicaid programs. Many of these individuals would already be Title II/Medicare eligible. Because of the state buy-in they have been able to access prescription drugs through Medicaid. If the Medicare formularies are limited for people with disabilities, an important purpose of TTWWIIA would be thwarted.

CCD recommends that the final rule provide for alternative, flexible formularies for special populations that would include coverage for all FDA-approved covered Part D drugs. Further, because of the clinical importance of providing access to the specific drugs prescribed, drugs prescribed to these defined populations must be made available at the preferred level of cost-sharing for each drug. We recommend that this treatment apply to the following overlapping special populations:

- **Dual Eligibles:** In enacting the MMA, Congress and the Administration both promised that dual eligibles (persons eligible both for Medicare and Medicaid) would be better off when coverage for prescription drugs is transitioned from Medicaid to Medicare Part D coverage. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment. Under federal law, states that elect to provide prescription drugs in their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products they purchase.

  Dual eligibles include people with disabilities and other serious conditions who need a wide variety of prescription drugs. Medicare prescription drug plans, as programs serving dual eligibles, must be able to respond to a range of disabilities and conditions, including physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as

cancer, cerebral palsy, cystic fibrosis, Down syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. If dual eligibles are not to be worse off when Part D prescription drug coverage begins, then they must have continued access to an alternative and flexible formulary that permits treating physicians to prescribe the full range of FDA-approved medications.

- **Institutionalized Populations:** Many, but not all, Medicare beneficiaries residing in nursing facilities and other residential facilities are dual eligibles. The same rationale provided for dual eligibles applies to providing institutionalized individuals access to flexible formularies on the basis of their complex and multiple prescription drug needs. Moreover, although we recommend that any alternative formulary include access to all FDA-approved medications, should the final rule permit a more restrictive alternative formulary, it must ensure that all drugs included on the formulary of participating LTC pharmacies are included on the plan's formulary, and drugs that are preferred by the LTC pharmacies' formularies must be treated by the plan as a preferred drug.

  Institutionalized individuals have limited capacity to pay cost-sharing for non-preferred drugs or to purchase drugs for which coverage has been denied. It is imperative that any alternative formulary provides strong protections that prevent individuals from being charged cost-sharing. For dual eligibles residing in institutions, a condition of eligibility requires them to pledge all, but a nominal personal needs allowance, to the cost of their care. For non-dual eligibles, the high cost of nursing home coverage leaves few remaining resources to pay non-preferred cost-sharing or to purchase drugs for which coverage has been denied.

- **Persons with Life-Threatening Conditions**: These are individuals with a diverse range, but limited number of conditions in which the absence of effective treatment would be life-threatening.

These individuals must have unrestricted and affordable access to the full range of available treatments. CCD believes that the MMA intended to ensure that beneficiaries will have access to all needed medications, including newly approved medications. Provisions in the proposed rule are inadequate for persons with life-threatening conditions for whom access to life-saving medications cannot be weighed against the financial interests of for-profit Part D plans. Therefore, these individuals must have immediate access to all FDA-approved medications.

- **Persons with Pharmacologically Complex Conditions:** Medications to treat many complex conditions are not generally interchangeable, including those with the same mechanism of action, and have fundamental differences that render them pharmacologically unique.

  In these circumstances, it is inappropriate to permit private plan formulary and cost-sharing policies to drive utilization to specific preferred drugs within a class. CCD recommends that the final rule require the Secretary to seek input from affected groups

and the general public and publish annually a list of conditions for which pharmaceutical management is complex and which have access to an affordable and flexible alternative formulary. This category should encompass.

- Persons with conditions that are recognized for their pharmacological complexity must include, at a minimum, conditions such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS;

- People who require multiple medications to treat many conditions—where drug-to-drug interactions are a critical challenge and where certain formulations might be needed to support adherence to treatment; and,

- Persons taking drugs with a narrow therapeutic index. These drugs are clinically effective and safe only at a narrow dosage range, and generally require blood level monitoring and highly individualized dosing requirements. To allow automatic substitution without physician approval can be deadly.

423.120(b)(1), Development and Revision by Pharmacy and Therapeutics (P&T) Committee

CCD strongly recommends that the final rule ensures that P&T committee decisions are binding on plans.

P&T committees can provide important checks on the profit-seeking motives of private drug plans by bringing research findings and clinical experiences to bear on decisions that will restrict access to certain medications. P&T committees must be empowered to make policy decisions regarding formulary tiers and any clinical programs to encourage the use of preferred medications, including formulary tiers and any clinical programs to encourage the use of preferred medications including prior authorization, fail first and step therapy.

In order to fulfill these critical functions the P&T committees must be charged with a strong mission to promote and protect the health of the beneficiaries. In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs. The final regulations should require a majority of the members to be independent and free of conflicts.

The final rule must require P&T committees to have formalized contractual relationships to advise the P&T committee in decision making with respect to areas where the P&T committee does not have adequate clinical expertise. At a minimum, this must include current clinical expertise and current experience in the following areas of medicine: geriatric medicine, oncology, cardiology, neurology, infectious disease, mental illness, and rare disorders.

The final rule should also require P&T committees to do the following:

- Hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies.
- Specify that meetings of the P&T committee should be open to the public and occur at least quarterly.

In addition, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations, and a diverse range of organizations representing people with disabilities.

Ensuring the Adequacy of the USP Model Guidelines

We do not support the CMS position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class.

Further, we do not believe it is appropriate for physicians to be given the new burden to "document and justify off-label use in their Part D enrollees' clinical records."

CCD has written USP urging significant changes to the model guidelines to ensure that individuals have access to the medication they require. We are very concerned that in many cases two drugs per class will not provide a sufficient level of access to ensure a quality prescription drug benefit for individuals with disabilities. CMS must ensure that the model guidelines do not create access barriers to clinically appropriate off-label drugs or to newer, more effective medications within the classes.

We were also significantly concerned that the model guidelines did not have classes for the medications used to treat serious long term conditions like multiple sclerosis and that the classes for psychiatric medications and the anti-convulsants require significant revisions.

Standards for determining PDP/MA Formulary Discrimination

We strongly believe that any review standards developed by CMS must be published as legally enforceable regulations and not as guidelines. We urge CMS to develop criteria and standards that do not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. CMS needs to develop standards that can assess whether the formulary is directing utilization away from efficacious treatments and commonly recognized treatment protocols.

Providing a quality drug benefit to individuals with disabilities will require access to a broad range of medications including many of the newer drugs with fewer side effects. For example, a formulary that only included two anti-convulsants would clearly be discriminatory to people with seizures since epilepsy medications are not interchangeable. Different drugs control different types of seizures and the response to the medication is very

individualized. No one or two products of currently available anticonvulsants will be successful for all people with seizures. Access to the medication an individual requires to control their seizures can be a matter of life and death for people with epilepsy.

CMS must also ensure that the formularies do not exclude whole classes of drugs such as immunomodulating drug therapies used to treat multiple sclerosis. This is one of CCD's significant concerns with the USP model guidelines and must be addressed in order to avoid discrimination toward the people who rely on these medications.

Notification Requirements for Formulary Change

CCD believes that the proposed rule provides inadequate notification provisions regarding formulary changes. They are inadequate both for effectively notifying and protecting beneficiaries.

We recommend that if the final rule limits the notice requirements to persons directly affected by the change, then plans must be required to provide notice in writing, mailed directly to beneficiary, 90 days prior to the change, and the notice must inform the beneficiary of their right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary.

423.128 (d), Access to Call Centers

We believe that it is essential that the final rule require all plans to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call center.

The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

423.128(e), Required Information in the Explanation of Benefits

We support the inclusion in the final rule of provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by the following:

- **Appeals Rights and Processes:** Information about relevant requirements for accessing the exceptions process, the grievance process, and the appeals process.

- **Access for all Beneficiaries to Formulary Information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. (See our comments in Subpart B, Section 423.48, Information about Part D.)

- **Including Formulary in Explanation of Benefits**: While we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary, in isolation, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

- **Plan terminations:** 423.128(c)(iii) requires plans to tell all Part D eligible individuals that the part D plan has the right to terminate or not renew its contract, but only if the individuals request this information. Information about the potential for contract termination needs to be included in all plan descriptions and in all marketing materials, and not just if requested by an enrollee or Part D eligible individual.

  Based upon experience with the Medicare+Choice market, the drug plan market will experience volatility that results in adverse consequences to many beneficiaries. The Medicare+Choice model summary of benefits requires this information to be in the summary of benefits and in the evidence of coverage; the same rule should apply for Part D.

SUBPART D – COST CONTROL AND QUALITY IMPROVEMENTS REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Section 423.150, Scope

The need to limit and prohibit unacceptable cost containment strategies—CCD has serious concerns that the proposed rule contains no restrictions on the ability of plans to use cost-containment tools such as dispensing limits, or prior authorization.

Indeed, the preamble to the proposed rule appears to specifically encourage plans to use such cost management tools, without constraint, to limit the scope of the prescription drug benefit. We believe that this is completely inappropriate, and inconsistent with commitments made by CMS to the Congress and the public.

We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration, and scope of coverage for covered Part D drugs. Specifically, the final rule must prohibit plans from limiting access to covered Part D drugs through limits on the number of drugs that can be dispensed within a month, limiting the number of refills an individual can obtain for a specific drug, or by placing dollar limits on the amount of the prescription drug benefit. For example, research in the mental health field has demonstrated that fewer than six mental health medications per month seriously risks patient health.

CCD also strongly recommends that the final rule explicitly prohibit plans from requiring therapeutic substitution. While the MMA authorizes the use of formularies which could lead prescribers' practices to alter their practice in order to comply with standard Part D plan preferences for covered drugs within a class, we believe that the ultimate authority to decide which specific drug a Medicare beneficiary will receive must reside with the treating physician. Therefore, to protect patient safety and health, the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution without the advance knowledge and written concurrence of the treating physician. We are encouraged that the preamble to the proposed rule indicates that therapeutic substitution will be prohibited without the prescriber's approval, this prohibition must appear in the text of the final rule.

Further, the use of prior authorization has become a common practice in the private sector and Medicaid. For many Medicare beneficiary populations, the manner in which prior authorization and fail first (or step therapy) systems have been implemented in these other contexts has been clearly unworkable both from the perspective of beneficiaries and treating physicians. Prior authorization can delay necessary and appropriate treatment putting at risk the health and safety of individuals who depend on medications for the management of their conditions.

Prior authorization is particularly burdensome to people in group home settings and institutions where often there may not be a well-informed and aggressive advocate or health care professional to ensure that residents with disabilities get the medication they need.

The final rule must establish clear standards and requirements for Part D plans that elect to adopt prior authorization and fail first policies. In particular, the final rule must require plans to ensure that any system of prior authorization is easily accessible to beneficiaries and physicians, and must impose negligible burdens with respect to time needed to complete the prior authorization process, expense, and information documentation.

Most state Medicaid programs exempt certain types of prescription drugs from prior authorization/fail first policies because of the complexity of the underlying condition, the recognized need for physicians to have broad prescribing flexibility, and the grave clinical consequences that could result if necessary access to prescription drugs is denied. Medicaid experience also shows that when certain populations are not exempted from prior authorization, significant problems arise. We propose that the final rule require the Secretary to consult with the public and publish annually a list of conditions which will be exempted from prior authorization/fail first policies, and should include conditions such as mental

illness, epilepsy, HIV/AIDS, multiple sclerosis and cancer, that are widely acknowledged for the difficulty and complexity of pharmaceutical management.

Further, ***we strongly recommend that when prior authorization is imposed, whenever the prior authorization process has not been completed within 24 hours of the time that a prescription was first presented at a pharmacy, plans must be required to dispense a temporary supply of the prescribed drug pending the completion of the prior authorization process***, including any time needed to receive an exception process and appeal decision. The final rule must also provide for exigent circumstances when an emergency temporary supply of a prescription drug must be dispensed immediately, without allowing for a 24 hour prior authorization period.

Requiring beneficiaries who have been stabilized on a particular psychiatric or anti-convulsant medication to switch to another medication can be very dangerous for the beneficiary and is not fiscally prudent. It is very difficult to determine which medication will work best for an individual and most have to try many different kinds of medications. Moreover some of these medications stay in the system for a long time (e.g., up to six weeks) and modifications of drug therapy must be done very carefully to avoid dangerous drug interactions. Each failed trial results in suffering and possible worsening of a person's condition.

We recommend that the final rule require plans when enrolling new enrollees to continue for at least six month any prescription drug regimen for all individuals who have been stabilized on a course of treatment. Moreover, the plan must provide an organization determination within the first month of enrollment for all covered Part D drugs that are part of the treatment regimen and notify, in writing, the beneficiary whether each drug in the regimen is covered and the beneficiary's cost-sharing requirement. Should the plan determine that any drugs in the regimen are not covered, all individuals stabilized on a treatment regimen should be automatically eligible for an exception request, and plans should be prohibited from discontinuing access to all drugs in the regimen pending final resolution of the appeals process.

Cost management tools subject to P&T Committees—In response to a question in the preamble of the proposed rule, we strongly recommend that P&T committees should approve and oversee implementation of utilization management activities of health plans offering the Medicare drug benefit. These committees should be empowered to make policy decisions and be charged with a mission to promote and protect the health of beneficiaries. In overseeing utilization management activities, P&T committees must be empowered to ensure that beneficiaries have access to a variety of drugs that reflect current utilization patterns and current research and that take into account the efficacy and side effects of medications in each therapeutic class and the complex needs of an ethnically diverse, elderly, co-morbid, and medically complex population.

SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

Many people with disabilities who are dually-eligible for Medicaid and Medicare have cognitive or mental disabilities which make it more difficult for them to navigate a cumbersome and multi-step appeals process. The final rule must ensure that these individuals who currently receive their prescription drugs through Medicaid are not harmed by the enactment of the MMA. Additionally, for many individuals with a variety of physical and mental disabilities, access to appropriate medication is one of the major factors which allow them to live full and more independent lives in their communities. CMS must ensure that the final rule is consistent with the principles and goals of the President's New Freedom Initiative to ensure that all people with disabilities have the opportunity to live in the community where they belong.

The proposed rule fails to meet the requirements of the Due Process Clause of the Fifth Amendment to the Constitution.

CCD believes that the proposed rule fails to meet Constitutional due process requirements and fails to satisfy the requirements of the statute. As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid beneficiaries, whose prescription requests are not being honored, receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice and face-to-face hearings, pending an appeal if their request is denied and they file their appeal within a specified time frame. Currently, all state Medicaid appeals processes are completed more expeditiously than Medicare appeals. Based on this fact and on the fact that the majority of people with disabilities who are dually-eligible for Medicaid and Medicare, have major health care needs, CCD believes it is completely inappropriate for the proposed rule to expose these individuals to a weakened due process system.

The appeals process as described in Subpart M does not accord dually-eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights; with an adequate opportunity to a face-to-face hearing; with an adequate opportunity to have access to care/prescription drugs pending resolution of the appeal; or with a timely process for resolving disputes. While CCD recognizes that the most efficient means of protecting enrollees – which would be to amend the MMA to provide for an appeals process similar to Medicaid -- is beyond the authority of CMS, CCD does believe that CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that sponsors of Part D plans establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Section 1852 (f) & (g) of the Social Security Act. In addition, CMS – in the settlement of *Grijalva v. Shalala* and in the Medicare Plus Choice program – already has established the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review. CCD strongly

recommends that CMS incorporate a similar fast-track process for Part D, which would be more in keeping with due process requirements.

Require plans to have an expedited appeals and exceptions process and to dispense a temporary supply of drugs pending the resolution of an exception request or an appeal.

The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee that beneficiaries have access to needed medications. This is a major cause for concern for the CCD. For millions of individuals with disabilities such as epilepsy, mental illness, HIV, Multiple Sclerosis, and spinal cord injuries -- treatment interruptions can lead to serious short-term and long-term problems. For this reason, the CCD strongly recommends that the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

For people with HIV/AIDS, even temporary interruptions in treatment can spur the development of drug resistant strains of HIV that have broad implications for the public health, and seriously compromise the likelihood that an individual will continue to benefit from their current drug regimen and jeopardize treatment success with any of the available anti-HIV medications. Fifty to seventy percent of people living with AIDS develop drug resistance. Failure to prevent treatment interpretations by supplying a temporary drug supply will contribute to this statistic.

Many people with epilepsy depend on specific medication to control their seizures. A disruption in their medication regimen can cause breakthrough seizures, the consequences of which can be very severe and can include loss of driving privileges, absence from work and hospitalization. Access to a temporary supply of drugs is also critical for people with physical disabilities such as spinal cord injury (SCI). Urinary tract infections, a common secondary condition of SCI, can worsen quickly and result in kidney infections which can lead to autonomic dysreflexia, a life threatening condition.

For many people with mental illness, access to the one specific medication or the critical combination of specific drugs, is what helps them maintain their mental and physical health as well as their independence and the ability to live a full life in the community. Treatment interruptions for these individuals are just as dangerous to them as is a treatment interruption to a person with a physical disability such as epilepsy.

CCD concerns related to treatment interruptions are heightened due to the absence of any adequate protections to ensure that individuals can receive a timely resolution of an appeal. We are also extremely concerned about the lengthy period of time that is allowed to pass before an individual has access to a fair and independent review of their appeal by an independent decision maker at the Administrative Law Judge (ALJ) level. CCD recognizes that the expedited time-frames and the general 72-hour standard are a significant improvement over the standard time-frame of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of individuals with serious and complex health conditions and disabilities, 72 hours is an unacceptable delay.

CCD strongly recommends that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people with disabilities automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal.

Strengthen and improve the inadequate and unworkable exceptions and appeals processes by establishing clear standards; expediting decisions; minimizing evidence burdens on physicians; and ensuring that drugs provided through the exceptions process are made available at the "preferred drug" level of cost-sharing.

CCD is also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We are specifically concerned about the impact of such a burdensome process on individuals with cognitive and mental disabilities. We strongly recommend that CMS establish a simpler process that places a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. We also strongly recommend that the final rule include a truly expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal drug plan appeals that a beneficiary must navigate before receiving a truly independent review by an administrative law judge (ALJ) and the timeframes for plan decisions are unreasonably long.

CCD believes that the provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that -- if properly crafted through enforceable regulations -- could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. However, as structured in the proposed rule, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

CCD is particularly concerned that the proposed rule would require treating physicians to assert that an exceptions request is based on both clinical experience and scientific evidence. This is an inappropriate standard that most doctors could not meet because scientific experience is not always available to support the knowledge which they acquire through clinical experience treating people with a range of disabilities – from HIV to mental illness – to epilepsy – to cerebral palsy – to spinal cord injury – to MS. CCD recommends that this requirement be eliminated from the final rule.

CCD recommends that CMS revamp the exceptions process to:

1. Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
2. Minimize the time and evidence burdens on treating physicians; and

3. Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

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

432.772, Definitions

Institutionalized individual: The definition should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. § 1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICF/MRs and individuals in any institution in which they are entitled to a personal needs allowance.

423.782(a)(2)(iii), Dual eligible beneficiaries must not be denied medications for failure to pay co-payments.

Dual eligible beneficiaries will be required to pay $1 for generic drugs and $3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. Many people with disabilities depend on multiple medications including brand name medications. Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing.

CCD strongly recommends that in the final rule dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing.

423.782(a)(iv) and §423.782(b)(2), Low-income individuals should not be denied medications for failure to pay co-payments.

Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. Studies have demonstrated that even minimal levels of cost sharing restrict access to necessary medical care for individuals with low incomes. Individuals between 100% and 135% of FPL must pay $2 for generics and $5 for brand-name drugs. Those between 135% and 150% are required to pay a 15% co-insurance for their drugs. For individuals who require expensive treatments or multiple medications, this requirement will

impose an enormous financial burden on thousands of individuals who will be unable to pay out-of-pocket for these medications. Beneficiaries eligible for the full or partial low-income subsidy should not be denied a prescription for failure to pay a co-payment or other co-insurance.

CCD appreciates the opportunity to comment on these critical regulations which will have a profound impact on America's 13 million Medicare beneficiaries with disabilities.

For more information contact the CCD Health Task Force Co-Chairs: Kirsten Beronio (National Mental Health Association) 202-675-8413, Liz Savage (The Arc and United Cerebral Palsy) 202-783-2229, Kathy McGinley (National Association of Protection and Advocacy Systems) 202-408-9514), and Peter Thomas (American Medical Rehabilitation Providers Association) 202-466-6550.

On behalf of:

American Association on Mental Retardation
American Association of People with Disabilities
American Congress of Community Supports and Employment Services
American Congress of Rehabilitation Medicine
American Council of the Blind
American Diabetes Association
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Network of Community Options and Resources
American Therapeutic Recreation Association
APSE: The Network on Employment
Association of Academic Physiatrists
Association of University Centers on Disabilities
Bazelon Center for Mental Health Law
Center on Disability Issues and the Health Professions
Easter Seals
Epilepsy Foundation
Family Voices
Helen Keller National Center
Learning Disabilities Association of America
Lutheran Services in America
National Association for the Advancement of Orthotics and Prosthetics
National Association of County Behavioral Health Directors
National Association of Protection and Advocacy Systems
National Coalition on Deaf-Blindness
National Mental Health Association
National Multiple Sclerosis Society
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities

National Association of Social Workers
National Fragile X Foundation
National Law Center on Homelessness & Poverty
National Organization of Social Security Claimants' Representatives
National Respite Coalition
Paralyzed Veterans of America
Spina Bifida Association of America
TASH
The Arc of the United States
Title II Community AIDS National Network
United Cerebral Palsy
United Spinal Association
Volunteers of America
World Institute on Disability

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Submitter : Ms. Kathleen Means **Date & Time:** 10/04/2004 09:10:30

Organization : Patton Boggs LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4068-P-1304-Attach-2.doc

CMS-4068-P-1304-Attach-1.doc

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October 4, 2004

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Re: CMS-4068-P, Comments on the "Medicare Program; Medicare Prescription Drug Benefit; 69 Fed. Reg. 46631 (Proposed Rule, August 3, 2004)."

Patton Boggs LLP respectfully submits these comments in response to the proposed rule on the Medicare Prescription Drug Benefit as issued by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on August 3, 2004. Patton Boggs LLP, with offices in the United States and abroad, is a major law firm with a leading public policy and health care practice. The foregoing comments are relevant to the "General Provisions" section of the proposed regulations.

We respectfully recommend that CMS develop a process for manufacturer appeal of negative formulary decisions as part of the Agency's power to review plans for discriminatory effect.

Current Medicare Part D Appeals Process Fails to Adequately Protect Beneficiaries on a Plan-Wide Basis

The MMA and the proposed rule establishing the Medicare Prescription Drug Program are silent on manufacturer appeal of formulary decisions. Currently, the proposed regulations only establish procedures that PDP sponsors must follow to resolve grievances between the sponsor and enrollees.[1] While these procedures provide a modicum of protection for individual beneficiaries, the current framework lacks any mechanism for outside parties, particularly drug manufacturers, to engage in a plan-wide challenge of a PDP decision not to include a particular drug on its formulary.

The downfall of the current coverage appeals process is that it is a hind-sighted rather than foresighted approach to beneficiary protection. If a patient needs a drug that is not on the formulary, that patient must engage in a lengthy grievance process to obtain coverage for the non-formulary drug. An individual may very well obtain a favorable drug coverage determination from this process; however, the rest of the beneficiaries enrolled in that plan gain nothing from the extensive deliberative process that just occurred. It is not hard to imagine how this inability to force

[1] Social Security Act §1860D-4(g)(1) (2004).

PDPs to review formulary inclusion decisions on a plan-wide basis could be detrimental to enrollees. If a PDP chooses not to include a new, innovative drug that provides unique therapeutic advantages to a particular population, these enrollees would have to engage in multiple individual patient appeals in the hope of gaining much needed drug coverage. A more logical approach would be to encourage drug manufacturers to appeal negative formulary inclusion decisions at the outset when all enrollees under a PDP could benefit, thus addressing patient needs at the plan level and possibly avoiding the burden of repetitive individual coverage determinations.

Precedents Exist for Drug Manufacturer Appeal on Both the Federal and State Level

Providing manufacturer appeal for adverse formulary inclusion decisions would directly serve the ultimate purpose of the prescription drug benefit program: ensuring patient access to therapeutically appropriate pharmaceuticals without discriminating against any particular medical condition or subpopulation. According to the statute, the structure of prescription drug benefit plans should not be discriminatory.[2] The proposed rule further explains how CMS intends to ensure that individual plan formulary structures do not result in intended or unintended discriminatory effects: "In general, this means that [CMS] would review benefit plans for features that, when applied, have differential impacts on beneficiaries with particular medical conditions."[3] The regulations also lay out a set of factors CMS will look at when reviewing a plan for discriminatory structure: 1) the benefit design, including the initial coverage limit, tiered cost-sharing***, the use of categories and classes in formulary, and the choice of drug provided in each category***; 2) use of discriminatory limits or requirements; and 3) suspect supplemental benefits.[4] CMS' oversight role clearly extends beyond reviewing individual beneficiary needs to include judgment on how specific drugs treatment under a plan's formulary effects Medicare beneficiaries across the plan; however, neither the bill nor the regulations provide a mechanism capable of accomplishing this broader oversight goal.

Drug manufacturers, regardless of individual beneficiary claims, should have standing to request CMS review of a PDPs decision to exclude a drug from a formulary. Providing manufacturer access to agency review of coverage determinations is not new to the Medicare program. The Medicare Part B program allows outside parties to appeal to CMS for issuance of a National Coverage Determination (NCD) to clarify what the extent to which Medicare will cover particular services, procedures and technologies, including what medications are "reasonable and necessary" for different indications. These formal requests require a great deal of supplementary documentation, allowing CMS to have the most up-to-date therapeutic information on a drug in order to adequately assess the appropriateness of Medicare coverage. If CMS feels a coverage question requires greater clinical expertise than generally found at the agency, CMS may request review by the Medicare Coverage Advisory Committee (MCAC). The MCAC advises CMS on whether specific medical items and services are reasonable and necessary under Medicare law in order to ensure unbiased and contemporary consideration of "state of the art" technology and science. The MCAC is advisory in nature, with the final decision on all issues resting with CMS.

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[2] Id. at §1860D-11(e)(2)(D)(i).

[3] Medicare Program; Medicare Prescription Drug Benefit, 69 Fed. Reg. 46,631, 46,680 (proposed August 3, 2004).

[4] Id. (emphasis added).

A similar model used in the State of California uses even more proactive measures to ensure that decisions by state-contracted drug benefit providers to remove or exclude coverage for a drug are made with sufficient information and stakeholder comment to determine the true effect on plan beneficiaries. In California, a manufacturer, physician or pharmacist may request a drug petition review for any drug that would be dispensed to fee-for-service Medi-Cal beneficiaries and billed by pharmacy providers. This process centers on the input of drug manufacturers – manufacturers supply a wide range of clinical information to allow the Department of Managed Health Care to determine the appropriateness of coverage for the state's beneficiaries. It should be noted that the State of California has taken significant measures to protect its ability to review drug coverage determinations, including passage legislation in 2002 that reinforced the authority of the Department of Health Care to review plan decisions excluding certain drugs and to ensure compliance with state laws regarding coverage of prescription drugs.[5]

The review provisions supplied by the State of California are particularly useful in protecting patient access to medication by addressing the need for timely inclusion of innovator drugs and promoting extensive evaluation of decisions to remove a drug from the list of contract drugs. A manufacturer of a new single-source drug may formally request inclusion of the innovator drug on the list of contract drugs when negotiations for drugs in the relevant therapeutic class were completed prior to approval by the FDA.[6] In brief, this process requires the Department of Managed Health Care to evaluate the request within a reasonable timeframe and seek outside review clinical review of the drug, as detailed in the following excerpt[7]:

"(d) (1) A ***manufacturer of single-source drugs denied a contract pursuant to this section or Section 14105.33 or 14105.37, may file an appeal of that decision*** *with the director within 30 calendar days of the department's written decision. (2) Within 30 calendar days of the manufacturer's appeal, the director shall request a recommendation regarding the appeal from the* ***Medi-Cal*** *Contract Drug Advisory Committee. The committee shall provide its recommendation in writing, within 30 calendar days of the director's request. (3) The director shall issue a final decision on the appeal within 30 calendar days of the recommendation. (e) Deletions made to the list of contract drugs, including those made pursuant to Section 14105.37, shall become effective no sooner than 30 days after publication of the changes in provider bulletins. (f) A manufacturer of a drug deleted from, or not added to, the list of contract drugs may request inclusion of the drug on the list of preferred prior authorization drugs that is hereby established as a subset of the list of contract drugs. To ensure that the health needs of* ***Medi-Cal*** *beneficiaries are met, the department shall evaluate the request pursuant to subdivision (c). The department shall give preference for prior authorization drugs based on the medical need or continuing care of the beneficiary. The department may contract with manufacturers of drugs on the list of preferred prior authorization drugs. Contracts executed pursuant to this subdivision are subject to Section 14105.33. (g) Changes made to the list of contract drugs under this or any other section are exempt from the requirements of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government* ***Code****), and shall not be subject to the review and approval of the Office of Administrative Law."*

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[5] 2002 Cal. Stat. S.B. 842.

[6] Cal. Welf. & Inst. §14105(a)(1) (2003).

[7] Id. at §14105.39.

In instances where the Department of Managed Health Care determines that a drug should be deleted from the list of contract drugs, the department is required to notify the manufacturer of the determination and conduct a public hearing in order to receive comment on the impact of the decision to remove the drug.[8] These two provisions act in concert to ensure that the latest, most effective, clinically-proven treatments are available to health plan beneficiaries.

Much like the MCAC in the federal program, California also utilizes an outside entity to provide impartial, clinically-based review of the appropriateness of a formulary removal or exclusion decision. California has established a Medi-Cal Contract Drug Advisory Committee (MCDAC) that evaluates the drugs in question and makes recommendations to the department as to the addition or deletion of any drug from the Medi-Cal List of Contract Drugs. The criteria used by the MCDAC for evaluating coverage of a drug is as follows: 1) the safety of the drug; 2) the effectiveness of the drug; 3) the essential need for the drug; 4) the potential for misuse of the drug; and 5) the cost of the drug.[9] As mentioned above, in order to give the MCDAC the information necessary to make appropriate therapeutic decisions, drug manufacturers are encouraged to provide the Department with detailed therapeutic and cost information, including clinical studies and other appropriate data.

Recommendations to CMS

1) CMS should establish a drug manufacturer appeal process to evaluate the discriminatory effect of a PDP negative formulary inclusion decision

The most effective means of ensuring adequate formulary review and protecting beneficiaries plan-wide from discriminatory formulary determinations would be for CMS to act as the adjudicator of appeals of negative PDP negative formulary inclusion decisions or decisions to remove a drug from the formulary. We would recommend development of a proactive system similar to that seen in California. If a drug manufacturer were to receive an adverse formulary inclusion determination by a PDP, a drug manufacturer could appeal that decision to CMS if inclusion of the drug is necessary to adequately protect the health of a plan's enrollees. This drug manufacturer appeal should be guaranteed in cases involving new, innovative drugs and decisions to remove a previously covered drug. In addition to proactive review mechanisms, we would also stress the need for outside clinical review of the drug as considered appropriate by CMS. Adequate clinical review of the value of a drug is essential to properly ensure the non-discriminatory nature of a formulary. If establishing the clinical benefit of a medication requires a technical assessment of the drug, CMS could request such assessment and subsequent recommendation from the United States Phamacopeia (USP). This outside review would be comparable to the input CMS receives from the MCAC under Part B or the State of California receives from its MDCAC.

2) CMS should require PDPs to develop a meaningful drug manufacturer appeal process to review negative formulary inclusion decisions

If CMS chooses not to develop a formal agency appeal process for drug manufacturers, CMS should at a minimum require plans to establishes a manufacturer's appeal process under criteria specified in the final rule and/or in the RFP standards governing the bidding process. The

[8] Id. at §14105.38(a)

[9] Id. at §14105.39(d)(1). These criteria are further defined in Cal. Code Regs. tit. 22 §51313.6 (2003).

MMA gives plans a significant amount of power in determining the form and content of their formularies. The MMA does not require plans to follow the model formulary guidelines developed by the USP, only providing plans "safe harbor" from charges of discriminatory practice if plans comply with the guidelines.[10] In fact, the MMA specifically prohibits CMS from "interfering" with plan formulary structures.[11] A negative determination from a plan's P&T Committee could indefinitely restrict a drug's inclusion from a PDP with no avenue for reevaluation or additional input from outside parties. If CMS is going to provide wide latitude to PDPs in regards to development and administration of their individual formularies, then CMS should also require plans to establish a meaningful appeals process that includes clinical input from the drug manufacturer.

We would suggest that as part of any mandatory plan-based review process, CMS establish an ombudsmen position to ensure that internal appeal processes are conducted in a fair manner and in compliance with CMS requirements. The Medicare program already uses ombudsmen to assist enrollees in resolving problems and to act as a neutral party during conflicts among various Medicare stakeholders. Providing access to an ombudsmen specifically designated to assist in formulary disputes would not only protect beneficiary interests, but also act as a preemptive remedial agent to accomplish CMS' non-discrimination policy goal. A natural location for this position would be through the Council on Technology and Innovation. According to CMS, this council was developed to "provide the Agency with improved methods for developing practical information about the clinical benefits or new medical technologies resulting in faster and more efficient coverage and payments of thee medical technologies."[12] Since the purpose of most drug manufacturer appeals will center around the clinical benefits of the new and innovative pharmaceuticals, an ombudsmen associated with the Council would be best suited to assist in such specialized evaluations and assessments.

The USP Should Also Develop Processes to Ensure Incorporation of Innovative Drugs

Our comments regarding the Medicare Part D Drug Benefit closely parallel the concerns and recommendations discussed in our comments submitted to USP regarding the draft Model Guidelines for Medicare Part D prescription drug plans ("PDP") formularies. We are equally concerned about the USP establishing a timely, efficient and transparent process for updating the model formulary guidelines. As discussed above, the new prescription drug benefit must be capable of integrating use of new pharmaceutical and biological products launched in the United States to adequately protect the health of Medicare beneficiaries. The USP Model Guidelines in particular, as an integral part of the Part D benefit structure, must have processes in place to incorporate innovative, novel, "first-in-class" therapeutic approaches that promise significant medical benefit to the Medicare population. We have attached a copy of those comments for your reference.

[10] Social Security Act §1860D-11(e)(2)(D)(ii) (2004).

[11] Id. at §1860D-11(h)(i).

[12] News Release, Centers for Medicare and Medicaid Services, CMS Launches Council to Improve Timely Access to New Medical Technologies (August 12, 2004).

Conclusion

We appreciate this opportunity to submit comments to CMS regarding its Proposed Rule on the Medicare Prescription Drug Benefit, and we look forward to working with CMS as implementation of this new Medicare benefit progresses. If you have any questions about these comments, please feel free to contact me at 202-457-6328.

Sincerely,

Kathleen E. Means

Attachment

PATTON BOGGS LLP
ATTORNEYS AT LAW

2550 M Street NW
Washington DC 20037
(202) 457-6000

September 17, 2004

United States Pharmacopeia
Attn: Lynn Lang
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790

Re: Comments to the Draft Medicare Part D Model Guidelines

To the Model Guidelines Expert Committee:

Introduction

Patton Boggs LLP respectfully submits these comments in response to the United States Pharmacopeia's ("USP") draft Model Guidelines for Medicare Part D prescription drug plans ("PDP") formularies mandated under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Patton Boggs LLP, with offices in the United States and abroad, is a major law firm with a leading public policy and health care practice.

We commend the United States Pharmacopeia in the detailed and thoughtful steps it has taken thus far to discharge the very important responsibility it was granted under the MMA to develop model formulary guidelines to be available to PDPs. As you fully understand, the driving force and purpose behind enactment of the Medicare Part D drug benefit was to grant Medicare beneficiaries meaningful coverage of and access to prescription drugs and the therapeutic benefits they bring to treating acute and chronic illnesses of the aged and disabled. The Model Guidelines are intrinsic to meeting these objectives and must be designed to help ensure they are met. While it is true these are voluntary only, they perform an important role for PDPs under the Medicare law and we would suggest, will have an impact extending even beyond the Medicare program to formularies plans develop for their commercial health insurance business.

In that spirit, we offer the following comments suggesting important additional areas of consideration not fully addressed in the first round of USP's proposal. The following comments focus exclusively on the issue of ensuring that the USP further refine the Model Guidelines, building on its initial efforts, to discharge its significant responsibilities under the MMA in a manner that maintains a fair, transparent, and predictable process in the finalization of the initial model guidelines due in December 2004. Most importantly, we also request that the USP establish such processes going forward with particular attention to *timely and effective* recognition in the Model

Guidelines of new pharmaceutical and biological products being launched in the United States that represent innovative, novel, "first-in-class" therapeutic approaches that promise significant medical benefit to the Medicare population.

Updating the Model Guidelines

In this regard, we strongly urge the USP to add a well-developed process for updating the Model to incorporate new pharmaceutical categories and classes. These categories and classes should include but not be limited to chemical entities that are the first to target a specific receptor. Similarly, we urge USP to add a process for updating the Model to incorporate new uses for existing pharmaceuticals. This is consistent with the Congressional intent expressed in Section 1 of the MMA and which requires that the Model be updated.[1]

The MMA, by effectively creating a "safe harbor" for PDPs that use the USP Model as their formulary, makes it imperative that the USP establish an ongoing, public process for frequently updating the Model Guidelines to ensure that beneficiaries enrolled in PDPs that follow the Model Guidelines receive the benefit of access to the latest therapies on a timely basis. This is especially critical for truly innovative, first-in-class products which will be offering genuine therapeutic alternatives to existing therapies based on significant scientific and clinical differentiation.

USP has stated that it will be submitting to CMS a "final report," in December 2004, which will contain a plan for providing revisions to the Model Guidelines over time. Given the critical nature of the process for revising the Model Guidelines, USP should quickly establish an open and clearly structured process for making these decisions.

In terms of the process that should be used by USP to revise the Model Guidelines, we support assignment of responsibility for this task to the Model Guidelines Expert Committee (MGEC). The MGEC is appointed by USP's Council of Experts (COE) which is USP's scientific decision-making body. Its members include nationally and internationally recognized scientists and practitioners in medicine, pharmacy, the pharmaceutical sciences, and many other healthcare professions. We understand that, in all, the COE and its 62 Expert Committees include over 650 distinguished expert volunteers from all around the world. Thirty-one of the 62 Expert Committees in the Council of Experts are devoted to drug information topics. We also suggest that the professional backgrounds of members of the MGEC be evaluated and structures to ensure a broad base of scientific and clinical expertise and be closely aligned with the pharmacy and therapeutics (P&T) committee composition specified under the MMA.

Most importantly, we also strongly urge that USP take steps to ensure (routinely require) that the right kind of scientific and clinical training is represented in the expert reviewers

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[1] MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopoeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and *to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.* (emphasis added).

relative to the specific categories, classes and specific products under review.

In revising the Model Guidelines, the USP should specify the process for not only adding new products to the Model Guidelines, but also for the process of making revisions to the framework of the Model Guidelines. Regardless of where the USP assigns responsibility for this ongoing work, the USP should specify and publish the processes for changing the categories, classes and subdivisions based on new product development, new uses of existing products and developments in treatment protocols.

We recommend that such changes occur on a quarterly basis. In this regard, we agree with the leading trade organizations representing the life sciences industry in supporting quarterly review. A regular schedule would ensure the greatest opportunity for beneficiaries and plans to benefit from new developments, while offering PDPs a predictable schedule for minimum formulary modifications. This also happens to comport with CMS's own processes under Medicare Part B for updating coding for new drugs and devices being covered under the Medicare program.

Further, the MMA requires that revisions to the Model Guidelines *as well as* the Model be developed in consultation with interested parties. We commend the USP on its efforts and process in developing the Model Guidelines under a very tight timeframe. USP had a formal comment period, a public forum and numerous consultations. Revisions to the Model Guidelines should follow the same or similar process.

In closing, we suggest that the USP consider the connection of the Model Guidelines to other actions of the Centers for Medicare and Medicaid Services (CMS) that have a bearing on access to drugs for Medicare beneficiaries, and positive process models that CMS has adopted for other tasks under the MMA. The former refers to recent steps taken by CMS Administrator Mark McClellan under Part B of Medicare to speed access for beneficiaries to newly launched drugs by ensuring that lengthy coding delays will not be an impediment to access and payment for innovative therapies. This same objective under Part D should inform the USP's processes going forward. We recommend that USP adopt public notification on the web-site of requested modifications, establishment of a 30-day time-frame for submission of public comments, and a subsequent 30-day rule for subsequent disposition by the USP and systematic updating of the Model Guidelines. Finally, if a request for modification of the Model Guidelines is denied or deferred for any reason, USP should make public the basis for its determination and establish criteria and a process for reconsideration.

Thank you for this opportunity to comment on the Model Guidelines. If you have any questions about these comments, please feel free to contact me at 202-457-6328.

Sincerely,

Kathleen E. Means

CMS-4068-P-1305

Submitter : Ms. Michele Olyer **Date & Time:** 10/04/2004 09:10:57

Organization : Regional Center for Independent Living

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

To: Center for Medicaid and Medicare Services
From: Michele Olyer, Regional Center for Independent Living
Re: Comments on Proposed Rule for the Medicare Prescription Drug Program
Date: October 4, 2004

As an independent living center, our office works with many younger individuals with disabilities who are interested in returning to work. The Ticket to Work legislation opened up doors for many of these individuals who were prevented from working due to fear of losing their medical coverage. As a BPA&O specialist, I was thrilled to learn that New York State had opted to participate in a Medicaid Buy Program and have seen numerous individuals return to work using its coverage. This now makes these individuals dually eligible for Medicaid and Medicare. I have grave concerns about the continued success in getting people back to work if the Medicare Prescription Drug Program regulations are approved as they were recommended.

Specifically, individuals who return to work using the Ticket to Work incentives should be excluded from having to pay for prescription medication or should not be charged more than the $3.00 co-pay.

Respectfully submitted,

Michele Olyer
Regional Center for Independent Living
Manager of Special Programs

CMS-4068-P-1306

Submitter : Ms. J. David Odle **Date & Time:** 10/04/2004 09:10:52

Organization : Oklahoam HIV Treatment and Care Consortium

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file.

CMS-4068-P-1307

Submitter : Ed Saba **Date & Time:** 10/04/2004 09:10:25

Organization : Bashas' United Drugs

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

We are adamantly opposed to mandating mail order pharmacies by third party insurances. Patients must have personal interaction with THEIR pharmacist. The health care of the patient suffers if they are 'denied' direct access to their pharmacist.

We believe the government should model any Medicare Drug plan after the federal TRICARE plan. Customers should have a choice.

CMS-4068-P-1308

Submitter : Ms. Carmen Catizone **Date & Time:** 10/04/2004 09:10:15

Organization : NABP

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

See attachments

CMS-4068-P-1309

Submitter : Ms. Margaret O'Kane **Date & Time:** 10/04/2004 09:10:07

Organization : National Committee for Quality Assurance

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The National Committee for Quality Assurance (NCQA) appreciates this opportunity to comment on the proposed rule entitled ?Medicare Program: Medicare Prescription Drug Benefit,? (Proposed Rule) issued by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on August 3, 2004. NCQA is a private, not-for-profit organization dedicated to improving health care quality. NCQA is active in quality oversight and improvement initiatives at all levels of the health care system, from evaluating entire systems of care to recognizing individual providers who demonstrate excellence in key clinical areas. NCQA accredits and certifies a wide range of health care organizations covering 75 percent of the population enrolled in Health Maintenance Organizations (HMOs).

As a leader in quality measurement, NCQA manages the evolution of Health Plan Employer Data and Information Set (HEDIS?) and the Consumer Assessment of Health Plans Study (CAHPS? 3.0H) survey, the performance measurement tools used by more than 90 percent of the nation?s health plans. HEDIS is used by the majority of America's health plans, including both HMOs and Preferred Provider Organizations (PPOs), to measure performance on important dimensions of care and service. HEDIS is designed to provide purchasers and consumers with the information they need to reliably compare the performance of managed health care plans.

NCQA is pleased to work with CMS on the management of the Medicare Health Outcomes Survey (HOS) survey, a tool to monitor and evaluate the quality of care provided to Medicare beneficiaries. We are proud to be the first private accreditation organization to be recognized by CMS under its deeming authority in the Medicare Advantage program.

NCQA appreciates the opportunity to provide comments on the Proposed Rule.

Prescription drugs are a critical element of an evidence-based benefit package. When administered appropriately, a drug benefit can affect care across the spectrum ? from preventing infection or disease to managing or reversing the impact of chronic disease ? and control the cost of overall care. At the same time, a poorly managed drug benefit can worsen the health of beneficiaries, raise costs, and, potentially, negatively affect public health.

NCQA recognizes the difficulty of creating this new benefit and stands ready to assist CMS in its ongoing efforts. Based on our experience in the private sector, we believe administration of a drug benefit must simultaneously guard against the potential of underutilization of needed drugs and the overutilization of inappropriate pharmaceuticals. Each has the potential to negatively affect quality and costs for the individual and for society as a whole.

In the attached comments, we offer detailed recommendations on those sections of the proposed regulations that impact quality assurance. Thank you again for this opportunity to comment. We look forward to continuing to working with you. If you have any questions about these comments, please contact Richard Sorian, NCQA Vice President for Public Policy at 202-955-5102.

Sincerely,

Margaret O?Kane
President

CMS-4068-P-1309-Attach-1.doc

NCQA

Measuring the Quality of America's Health Care

October 4, 2004

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

Re: "Medicare Program; Medicare Prescription Drug Benefit"

Dear Dr. McClellan:

The National Committee for Quality Assurance (NCQA) appreciates this opportunity to comment on the proposed rule entitled "Medicare Program: Medicare Prescription Drug Benefit," (Proposed Rule) issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on August 3, 2004. NCQA is a private, not-for-profit organization dedicated to improving health care quality. NCQA is active in quality oversight and improvement initiatives at all levels of the health care system, from evaluating entire systems of care to recognizing individual providers who demonstrate excellence in key clinical areas. NCQA accredits and certifies a wide range of health care organizations covering 75 percent of the population enrolled in Health Maintenance Organizations (HMOs).

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In the attached comments, we offer detailed recommendations on those sections of the proposed regulations that impact quality assurance. Thank you again for this opportunity to comment. We look forward to continuing to working with you. If you have any questions about these comments, please contact Richard Sorian, NCQA Vice President for Public Policy at 202-955-5102.

Sincerely,

Margaret O'Kane
President

Enclosure

NCQA
Measuring the Quality of America's Health Care

NCQA Comments & Recommendations:
Establishment of the Medicare Prescription Drug Benefit

Cost Effective Drug Utilization Management. Section 423.153(b) would require each PDP sponsor or MA Organization offering a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to provide a cost-effective drug utilization management program.

Comments: Use of effective pharmaceuticals is becoming more and more important in the management of acute and chronic disease. With the availability of both generic and brand name pharmaceuticals it is important to carefully weigh not only the effectiveness but also the cost-effectiveness of these medications. While some branded drugs might offer incremental benefits compared to the generic "version" of the drug, given the often steep price differences a PDP sponsor or MA organizations offering qualified prescription drug coverage should ensure that pharmaceutical resources are wisely spent. Prior authorization, required step therapy, tiered cost-sharing and other tools all offer opportunities to influence the cost-effective use of pharmaceutical resources.

Best practices can be culled from existing pharmacy benefit management programs, balancing the results these programs achieve with transparency and consumer experience in using drug benefits managed using these practices. NCQA is currently exploring the identification and subsequent standardization of such processes and would be pleased to share its findings with CMS.

Quality Assurance. Section 423.153(c) would require each PDP sponsor or MA Organization offering a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to provide a quality assurance program.

Comments: Appropriate quality assurance mechanisms should not only be present in the physician offices and pharmacies of the network of a PDP sponsor or MA organizations offering a drug benefit, but also the sponsoring organization itself. For example, while the PDP sponsor should ascertain whether physician offices are prescribing electronically to prevent medication transcription errors, it should also be able to alert physicians, pharmacies, or patients when for example it uncovers a medication fill pattern suggestive of potential drug-drug interactions. Nationally standardized performance measures are currently being developed by NCQA to track a variety of safety and quality concerns with respect to medication management.

Consumer Satisfaction Surveys: Section 423.156 would conduct consumer satisfaction surveys among enrollees of PDPs and MA Organizations offering MA-PD plans in order to provide comparative information about qualified prescription drug coverage to enrollees.

Comments: NCQA strongly supports the use of a survey of consumers of the prescription drug benefit to help measure the experience of beneficiaries in this new benefit area. Beneficiaries can provide critical insight into the service quality as well as other performance domains of the organizations that service them. The Consumer Assessment of Health Plans study (CAHPS) has provided an important and critical source of information about the performance of health plans in the public and private sectors. Development of a CAHPS-like survey for PDP sponsors or the addition of relevant items to existing CAHPS surveys represent a unique opportunity to solicit such information in a cost effective fashion. AHRQ has provided critical leadership in that regard and will certainly be able to successfully fulfill the role of supplying a new or amending existing surveys working in close concert with other stakeholders and evaluators health care organizations such as NCQA. It will be important to ensure high quality implementation of the survey assuring consistency and oversight of the implementation process. NCQA has important experience with the implementation of surveys by multiple vendors and health care organizations that will lead to highly standardized processes and subsequently valid survey results. We would be pleased to work with CMS as it proceeds in this area.

Treatment of Accreditation: Sections 423.165, 423.168, and 423.171 extends existing deeming authority to will apply to PDP sponsors with respect to--(1) access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements; (2) quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse and waste; and (3) confidentiality and accuracy of enrollee records.

Comments: NCQA strongly supports the extension of deeming authority to PDP sponsors and believes the existing deeming program has created a powerful partnership between the public and private sectors. We are, however, concerned by the proposal in Section 423.165(f) that states: "We expect the accreditation organization to have a system in place for enforcing compliance with our standards." Accreditation organizations (AO), by their voluntary nature, do not have the ability or the authority to enforce federal standards. AOs can be a powerful fact-finding tool in the government's ongoing oversight and enforcement efforts but cannot and should not replace those functions. We recommend that CMS clarify this point.

Also, we are concerned by the proposal in Section 423.168(c) that "an accreditation organization notify us in writing within 3 days of identifying, with respect to an accredited PDP sponsor, a deficiency that poses immediate jeopardy to the PDP sponsor's enrollees or to the general public." While we view such instances with similar urgency we believe the current requirement of 5 days would provide the PDP and the AO with sufficient time to validate that the threat exists and to address and correct the problem.

Finally, it is important to note that an accreditation program for stand-alone prescription drug plans does not currently exist. While NCQA would be pleased to work with CMS and other organizations in developing such a program, such activity would require some work and time in order to assure the use of evidence-based standards and to utilize a consensus process that involves all stakeholders including, but not limited to, health plans, consumers, pharmacists, pharmaceutical manufacturers, academic experts, and others.

Submitter : Valerie Wilbur **Date & Time:** 10/04/2004 09:10:40

Organization : The Social HMO Consortium

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The Social HMO Consortium

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4068- P

Dear Sirs:

The Social HMO Consortium appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Prescription Drug Program.

The Social HMO Consortium represents the four Social HMO demonstration sites including Elderplan, Inc., SCAN Health Plan, Senior Advantage II of the Kaiser Permanente Northwest Division and Sierra Health Services/Health Plan of Nevada. The Comments herein are limited to the proposed rules for selected provisions of the Medicare Advantage Program and the new Part D Prescription Drug Benefit.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us or Valerie Wilbur, our senior policy advisor, at 202-624-1508.

Sincerely,

Eli Feldman
President & CEO
Elderplan

Ronnie Grower
Vice President for Quality Improvement
And Reporting
Sierra Health Services/
Health Plan of Nevada

Lucy Nonnenkamp
Project Director
Senior Advantage II

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Timothy Schwab, M.D.
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Comments to Medicare Advantage Program
Notice of Proposed Rule Making
Submitted by
The Social HMO Consortium
October 4, 2004

Subpart A: General Provisions

§Section 422.2 Definitions

§Section 422.2 Definition of "Institutional"

CMS defines institutional as residing in a Medicare or Medicaid long-term care facility for more than 90 days as determined by the presence of a 90-day assessment using the Minimum Data Set (MDS).

Social HMO Comments

The Social HMO Consortium supports the 90-day definition. We also recommend that plans be eligible to begin enrolling new beneficiaries in Specialized MA/special needs plans (SNPs) once they have resided in the facility 30 days or longer, if they have no active discharge plan. Verification of eligibility could be determined via confirmation of their admission date into the nursing home. Given the complex medical needs of the institutionalized population, we believe it is important to initiate specialized intervention and care management services as early as possible to prevent or delay further disability progression, maintain function and maximize health outcomes.

§Section 422.2 Definition of "Specialized MA Plans"

1. MA Plans that "Disproportionately" Serve Special Needs Individuals

The statute provides CMS the authority to designate as SNPs those that "disproportionately" serve special needs individuals. CMS invites comments on this definition, indicating that, at a minimum, disproportionate means a plan enrolls a greater proportion of special needs individuals than average in the service area.

Social HMO Comments

The Social HMO Consortium offers a 3-part definition for "disproportionate," including: (1) a general framework for establishing the criteria; (2) quantitative criteria for measuring "disproportionate;" and (3) capacity criteria that provide evidence of a plan's ability to meet the needs of high-risk beneficiaries.

a. General Framework for Definition: The definition for "disproportionate" should be:

- Quantitative
- Based on standard, industry-wide data
  - ✓ Number of diagnoses/ HCCs to provide evidence of condition severity
  - ✓ Risk score to provide alternative evidence of condition severity
  - ✓ ADL impairments to provide evidence of a disabling condition
  - ✓ Such other criteria as a plan may define and the Secretary may approve that demonstrates burden of illness or disability
- Established in relation to norms for all MA plans nationally

- Measured by plan contract for plans with more than one service area

The Consortium believes that the threshold should be set in relation to other MA plans, not the entire Medicare program, as special needs plans are defined in the law as a subset of the Medicare Advantage coordinated care plans. In addition, since only about 15 percent of all Medicare beneficiaries are enrolled in MA plans, setting a threshold in relation to all MA plans, not just MA plans in the plan's service area would assure uniformity in defining a threshold based on the overall MA plan experience.

b. Thresholds for disproportionate

A plan will be deemed to disproportionately serve special needs beneficiaries if they meet <u>one or more</u> of the following criteria:

- a plan level risk score in the upper quintile of all MA plans as measured by HCC scores; OR
- a frailty score in the upper quintile of all MA plans as measured by ADL scores from the Health Outcome Surveys; OR
- a combined HCC and frailty score in the upper quintile of all MA plans, as measured by HCCs and HOS data; OR
- A higher degree or burden of illness, frailty or disability as defined by the plan; burden of illness would be measured by such criteria as:

  - ✓ A higher concentration of members in advanced age
  - ✓ Greater proportion of members with geriatric syndromes such as Alzheimer's Disease
  - ✓ Higher prevalence of late stage conditions such as ESRD, CHF, COPD
  - ✓ Higher prevalence of members with multiple comorbidities, or specific comorbidity patterns, where comorbidity could be defined by a combination of diagnoses, functional impairments, geriatric syndromes, etc.
  - ✓ Higher concentration of nursing home members
  - ✓ Higher concentration of dually eligible members
  - ✓ Higher concentration of nursing home certifiable members

c. **Evidence of processes or clinical programs that are designed to address the unique needs of the special needs beneficiary group**. A plan would be required to provide evidence of the clinical capacity to serve the special needs of special needs individuals. Evidence could include, but would not be limited to, the following:

  - **Clinical Procedures or Programs**: Some of these criteria may be uniform across plans such as high-risk screening tools and care coordination procedures (although the specific tools may vary by type of special needs individual targeted), contracts with medical specialists such as geriatricians and nephrologists, etc. Other clinical programs may be unique to a particular type of special needs beneficiary, such as protocols for managing ESRD patients.
  - **Programs may provide evidence of the uniqueness of a program**, such as palliative care programs for SNPs that disproportionately enroll beneficiaries with one or more late stage illness, family support groups for SNPs that target the enrollment of Alzheimer's patients, etc.
  - **Marketing plans or materials** targeted toward special needs beneficiary categories.

- **Program components that reflect the presence of a critical mass** of the target population; e.g., the plan employs certain specialists such as gerontologists or has it's own home care agency instead of contracting for these services; a plan has a defined set of clinical protocols for specified combinations of chronic conditions like COPD, CHF and Diabetes (or other "disease clusters" common to special needs individuals).

d. Operationalizing Certification and Enrollment: Plans would be permitted to selectively enroll MA beneficiaries. The Social HMO Consortium recommends that plans define for approval by the Secretary enrollment procedures that allow plans to limit the enrollment of non-special needs beneficiaries. Enrollment procedures need to be flexible enough to accommodate different definitions of "disproportionate," different special needs beneficiary groups, and different strategies for targeting enrollment of these individuals. We also recommend that CMS establish a certification and compliance process. Plans should be certified annually. For newly designated plans, we recommend a three-year "start-up" period for new plans to meet the threshold. CMS provided a similar start-up period for Provider Sponsored Organizations when that category was first designated as a type of M+C plan under the Balanced Budget Act. In the event that a plan falls more than five percent below the specified threshold, the plan should be required to submit to CMS an acceptable plan of correction for regaining compliance. CMS will need to publish annually, or make available to plans upon request, risk score distributions to evaluate whether they meet thresholds in related to risk distribution.

2. MA Plans that Serve Dually Eligible Beneficiaries

The Interim Draft Guidance indicated CMS' intent to require plans to serve all dually eligible beneficiaries, but the proposed rule invites comments on whether plans should be permitted to serve subsets of the dual population.

Social HMO Comments

The Social HMO Consortium believes plans should be permitted to serve subsets of the dual population such as full benefit duals, frail elderly, nursing home certifiable duals, or adult disabled beneficiaries with physical disabilities or mental impairments. Demonstrations like the Wisconsin Partnership Program and Minnesota Senior Health Options Program provide a precedent for serving various subgroups of duals. The needs of different subgroups require different types or amounts of specific benefits and services. For example, the frail elderly require specialization in geriatric services and access to skilled nursing facility care; the developmentally disabled may require care in Intermediate Care Facilities for the Mentally Retarded; adult disabled females may require maternity services. In addition, full benefit dual eligibles require a different benefit design, care management services and financing structure than QMBs or SLMBs. An MA organization may be required to offer different plan options to meet the unique needs of multiple categories of duals. The experience of specialty plans and demonstrations for the dually eligible suggests that it takes significant investments of time and resources to develop targeted clinical programs for different subgroups of seniors and disabled individuals with different, complex chronic conditions. These programs should be protected and encouraged to thrive, and incentives should be provided for the expansion of such programs.

3. Provision of Part D Benefits by Specialized MA Plans

CMS proposes that SNPs be required to offer Part D drug coverage since special needs individuals need access to drugs to manage and control severe chronic conditions. Additionally, full benefit dual eligibles who are Part D eligible will be required to obtain their drug coverage from the MA in which they are enrolled and would not have access to drug coverage if not provided by the SNP.

Social HMO Comments
Social HMOs support this recommendation in principle, provided that (1) the pharmacy risk adjustment fully covers the risk associated with drug utilization and costs for special needs individuals and (2) the formula for determining the low-income subsidy covers plan premium costs without requiring beneficiary copayments for the standard benefit.

Subpart B: Eligibility, Election, and Enrollment

§422.52 Eligibility to Elect an MA Plan for Special Needs individuals

§422.52 Special Needs Plans for Beneficiaries with Severe or Disabling Chronic Conditions

CMS invites comments related to the development of special needs plans for subgroups of Medicare beneficiaries with severe or disabling chronic conditions. Specifically, they ask whether SNPs should be established to address the special needs of HIV/AIDS patients and whether ESRD beneficiaries should be considered to meet the requirements of special needs status.

Social HMO Comments
Social HMOs support the ability of plans to serve subsets of the Medicare population that meet the definition of "special needs individual." We believe the focus of SNPs, however, should be on serving high-risk beneficiaries such as frail elderly and adult disabled that have multiple chronic conditions requiring complex medical management. SNPs should serve as laboratories for developing population-based management protocols, not single-disease state management protocols for diagnoses that could be well served by a standard MA plan.

§422.52 Eligibility Requirements for Enrollment in Specialized Needs Plans

1. Deeming Continued Eligibility: PACE allows individuals to remain enrolled in its plan if, in the absence of continued enrollment and access to special care, the individual reasonably could be expected to regain eligibility within a six-month period. CMS proposes to provide the same "deemed eligibility" standard to SNPs.

Social HMO Comments
We support this provision as a strategy for promoting continuity of care, promoting quality and cost-effectiveness by preventing disruptions in coverage that could have result in adverse health events.

2. Exceptions:

Grandfathering: If an MA plan converts to a special needs plan, and some of the members do not meet the criteria for special needs individuals, CMS proposes that these beneficiaries should be allowed to stay enrolled in the plan. The Draft Interim Guidance for SNPs provided that such individuals would qualify for a Special Election Period (SEP) lasting for

the remainder of the calendar year or 90 days if redesignation occurs less than ninety days before the end of the contract year. The SEP would enable the member to move to another MA plan or to Original Medicare.

Social HMO Comments
The Consortium supports this provision.

Involuntary Disenrollment: If a *new* plan is established and an enrollee becomes ineligible after they have enrolled, or the plan is no longer able to provide the services needed due to a change in health status, CMS proposes that the plan involuntarily disenroll the individual. For example, if the resident of an exclusive institutional SNP is discharged to the community, the plan could require the person to disenroll.

Social HMO Comments
The Social HMOs support a requirement that individuals be voluntarily disenrolled if the beneficiary loses eligibility for special needs individual status for beneficiaries enrolled in plans exclusively serving special needs individuals. This policy should not apply to plans that disproportionately serve special needs individuals, however, since non-exclusive plans include a mix of special needs and non-special needs individuals. Accordingly, if an individual lost special needs status, they would still qualify for enrollment, unless by maintaining enrollment, a plan would be in jeopardy of falling below the threshold established for the proportion of special needs individuals a plan would need to maintain to qualify for this category. In such cases, the involuntarily disenrollment rule would apply.

We support the Draft Interim Guidance requirement that plans need to notify beneficiaries about the policy on continuous enrollment, apply it consistently and give the individual at least 30 days notice. In such cases, the rule should specify that CMS will provide continued funding for Part D and other benefits, whether or not the individual is eligible, for the period during which CMS requires continued enrollment (e.g. 30 days). The regulation also should specify that the individual would be eligible for a SEP so that they can move to another MA plan or back to original Medicare.

The Consortium also proposes that plans have the discretion to maintain enrollment of special needs beneficiaries who have a lapse in coverage if the lapse is expected to be temporary. In such cases, plans should have the discretion to maintain enrollment for up to six months. For example, dually eligible beneficiaries often move in and out of Medicaid eligibility due to administrative lapses such as failure to complete paperwork requirements to maintain eligibility. This provision would promote continuity of care and minimize adverse effects on health status resulting from a temporary disruption of coverage. This rule should also apply to non-exclusive special needs plans; that is, non-exclusive plans should have the same discretion, even if it temporarily resulted in the plan falling below the required threshold for enrollment of special needs individuals.

In cases where plans temporarily allow dually eligible beneficiaries to remain enrolled due to temporary lapses, the plan would be authorized to charge the individual for benefits no longer covered by the state or federal cost-sharing arrangements and to terminate coverage in the event of non-payment of premiums or cost-sharing.

3. Special Election Periods: CMS has the discretion to create new special election periods to allow beneficiaries to disenroll from one MA plan and enroll in another. CMS provides for SEPs for special needs individuals in certain circumstances, such as when beneficiaries choose to disenroll from a plan that is redesignated as an SNP.

Social HMO Comments

SEPs should be more broadly designated for special needs individuals. The Consortium recommends that CMS create a Special Election Period for special needs individuals that would be open for the duration of the individual's eligibility for a SNP. Special needs individuals must be permitted to enroll in SNPs when their health status changes and dictates the need for special services and interventions, not only at the time of standard open enrollment periods. Medicare beneficiaries cannot predict in advance when they may need permanent nursing home care or when they may become eligible for Medicaid benefits. Nor can they predict in advance when their health status may deteriorate to the point where access to special care interventions could mean the difference between maintaining and losing health reserves. This policy also is needed to ensure financial viability for SNPs. The lock-in requirement creates hardships for plans that serve high-risk beneficiaries, such as those requiring end of life care, and that, as a result, experience high annual attrition due to death. Further, if a beneficiary is forced to wait until the standard open enrollment period to enroll in an SNP, costs to Medicare (and Medicaid) are likely to increase by preventing special needs individuals from accessing more appropriate care in a timely fashion. Establishing a SEP that is open for the duration of an individual's eligibility would allow an enrollee who is eligible for an SNP to switch from a non-special needs plan or fee-for-service arrangement to an SNP at the time of need.

§Section 422.52 Other Waiver Provisions for Specialized MA Plans

The preamble states that, excepting the specific requirements that all Medicare-eligible individuals be permitted to enroll in MA plans and that ESRD beneficiaries be restricted from enrolling, all other MA provisions would apply to SNPs.

Social HMO Comments

The Social HMO Consortium recommends that CMS include a general provision in the rule that allows them to waive or modify MA requirements that conflict with the intent of the SNP provision. In its contracts with the Social HMOs, CMS has waived or modified some MA requirements that would not apply to the enrollment and marketing practices of the Social HMOs. We believe comparable waivers may be necessary for SNPs. Therefore, we believe it is important for CMS to incorporate the regulatory authority to waive requirements, as the need arises.

§Section 422.66 MA enrollees defaulting into an MA-PD plan on January 1, 2006

CMS is providing that individuals enrolled in an MA plan that, as of December 31, 2005, provides any prescription drug coverage, would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006.

Social HMO Comments
The Social HMO Consortium supports this position, including for dually eligible beneficiaries enrolled in plans with premiums at or below the low-income premium subsidy. To allow an existing beneficiary to remain enrolled in a plan when the premium exceeds the low-income subsidy, the Consortium suggests that plans be permitted to adjust their bid after the subsidy levels are announced so they can buy down the premium to the subsidy level with savings that may be available. Since some plans may not generate sufficient savings to fully fund all cost-sharing amounts for A/B, supplemental and Part D benefits, the Consortium urges CMS to work with programs serving the dually eligible to find an approach that minimizes the need for duals to pay out of pocket premiums they can ill afford.

The Consortium supports the proposal that states assume responsibility for determining eligibility for the low-income subsidy. For beneficiaries that are not already enrolled an MA plan, eligibility would need to trigger a special election period. Once a person enrolls in a plan, they should remain eligible for the entire year. The enrollee should be notified in writing of the need to be recertified for Medicaid eligibility prior to the next open enrollment period to have the option of remaining enrolled in the plan. If the person were found to be ineligible for Medicaid, they would be required to disenroll. A determination of ineligibility would require a special election period to allow the individual disenrolling from the plan to make another election.

Subpart D: Quality Improvement Program

§422.152 Quality Improvement Program

The MMA statute calls for a report to Congress no later than December 31, 2007, that assesses the impact of specialized MA plans on the cost and quality of services provided to enrollees. CMS invites comments on whether there are appropriate quality oversight mechanisms to improve quality for special needs individuals.

Social HMO Comments
The Social HMO Consortium recommends that CMS work with specialty MA plans and providers to develop alternative quality measures and performance evaluation systems that:

- are more appropriate to the special needs populations served;
- measure performance in relation to the unique health problems/risks faced by high risk populations and the special interventions employed to address these problems and risks;
- measure SNP performance in relation to comparable risk groups to ensure fair evaluation of outcomes in relation to risk; and
- measure performance across a time frame appropriate to programs that have an expected delay between a preventative intervention and effects on utilization and health status outcomes.

We recommend that CMS:

1. *Establish an expert panel of plans, providers, researchers and consumer representatives to devise alternative quality measures for high-risk beneficiaries, where appropriate, and a performance evaluation methodology that complies with the characteristics outlined above.*

2. *Evaluate the use of ACOVE (Assessing Care of Vulnerable Elders) measures developed by Rand as more appropriate measures for evaluating quality for frail elderly*. According to Rand, "the vulnerable elders are a particularly important group for quality-of-care evaluation because of their risk for serious declines in health and function and disproportionate use of health care resources. Objective measures to evaluate their care are not adequately represented in current quality-of-care measurement systems. The ACOVE project assembled a panel of geriatric experts to develop a method of identifying a community-based sample of vulnerable elders, selected clinical conditions for quality measurement and an evidence-based set of 236 ACOVE-1 quality-of-care process indicators to evaluate the care provided to vulnerable elders." These indicators focus on 22 medical conditions that are prevalent among older adults and likely to contribute to morbidity, mortality and functional decline. They include geriatric syndromes overlooked in our current risk adjustment system such as dementia, depression, osteoarthritis, and incontinence as well as treatment domains such as appropriate use of medication, continuity and coordination of care and end-of-life care – all criteria areas of focus for vulnerable elders. The indicators focus on four domains of care including prevention, diagnosis, treatment and follow-up (see Exhibit 1).

3. *Work with specialty plans and providers in pursuing research initiated by Rand, Johns Hopkins University School of Medicine and others regarding frailty as a distinct clinical entity that is treatable. The goal of the research effort would be to develop a model for predicting frailty and clinical protocols to prevent or delay frailty before it occurs and to treat it where it already exists to improve function and slow the rate of further progression.* There is a growing view in the field of medicine and geriatrics that frailty is not an inevitable part of the aging process, but a definable medical disorder that eventually could become an official ICD diagnosis. For example, according to Linda Fried and colleagues at Johns Hopkins[1], frailty, disability, and comorbidity are "distinct clinical entities that are causally related, occur frequently and have high import clinically." Fried defines frailty as a critical mass of 3 or more core "frail" elements including generalized weakness, poor endurance, weight loss, low physical activity, and slow gait speed. These findings have important implications for diagnosis and treatment of each clinical entity, including the potential to intervene in the causal relationships and prevent the onset of the related conditions.

   An article in the Annals of Internal Medicine which suggests that frailty is "a physiologic and biological syndrome separate from normal aging and disability that is treatable" validated these findings. [2] This article indicates that frail patients are increasing found to bear blood test abnormalities typical of systemic illness. These objective laboratory findings, together with well-validated survey tools of functional status, provide an opportunity to identify people at risk of frailty and initiate medical management measures to prevent or delay the onset of frailty. These and other studies suggest that ongoing research regarding frailty is critical as it affects diagnosis and treatment, costs and quality of care.

[1] Fried, Linda, et al. "Untangling the Concepts of Frailty, Disability and Comorbidity: Implications for Improved Targeting and Care. Journal of Gerontology, Series A: Biological Sciences and Medical Sciences, M255-M263 (2004).

[2] Wilson, Jennifer. "Frailty – and its Dangerous Effects – Might be Preventable. Annals of Internal Medicine. Volume 141, Number 6, 21 September 2004.

Subpart F: Submission of Bids, Premiums, and Related Information and Plan Approval

§422.254: Submission of Bids

§422.254: Appropriateness of Treating A/B Costs as Supplementary Costs for Bid Purposes

Plan bids are based on three cost-structures—Part A/B benefits, supplemental benefits and Part D benefits. If supplemental benefits increase utilization of Part A and B services by reducing the costs of accessing these benefits to consumers, CMS indicates that plans will need to include the costs of "induced demand" in the supplemental premium. For example, assume revenue requirements of $500 for the A/B benefit with no supplemental benefits, but revenue requirements of $550 when a supplemental benefit is added, precipitating higher use of home health or some other service. The extra $50 would need to be included in the supplemental premium.

Social HMO Comments

The Social HMO Consortium objects to this requirement. First, this policy is cannot be implemented in a fair and consistent way since it calls for a subjective evaluation on the part of the plan and CMS. While a plan can identify Medicare covered services, it cannot objectively determine which services or the proportion of such services used would be attributable to a supplemental benefit that reduced beneficiaries' out of pocket costs. For example, if the supplemental benefit is used to reduce cost sharing for home care services and an enrollee has seven home care visits following a hospital stay, how many of those visits should be attributed to the standard Part A benefit versus supplemental coverage? This would require a subjective determination on the part of the plan in calculating the distribution and on the part of CMS in evaluating whether the distribution was accurate.

Second, under the new bidding process, Congress has effectively capped payments for A/B services by establishing a benchmark against which plans must bid. This benchmark is based on A/B services provided in the fee-for-service sector where over two-thirds of beneficiaries carry Medigap or supplemental policies. Accordingly, since "induced demand" is already accounted for in the benchmark, requiring plans to shift these costs to the supplemental benefit package appears to set up a "double-dipping" phenomenon.

Third, assuming savings are produced, the rebate would not fully fund the increase in the supplemental premium since, under the new bidding rules, plans must return 25% of the savings to Medicare.

§422.254: Actuarial Equivalence for Mandatory Cost-Sharing

Beneficiaries are required to pay cost-sharing in an amount actuarially equivalent to Medicare FFS cost-sharing requirements for Part A and B benefits. The way actuarial equivalence is determined will significantly affect a plan's cost structure, and CMS invites comments on how actuarial equivalence should be determined.

Social HMO Comments

The Social HMO Consortium considered the different methods CMS proposes for determining actuarial equivalence for SNPs. While a plan-specific method may be the most accurate, upon further review and discussion with our actuaries, we believe that it would be burdensome to implement, due to data collection requirements, and it would not produce enough additional accuracy of the cost-sharing obligations to warrant this cost and effort. Accordingly, *we believe that AHIP's recommendation to use the proportional method developed at the local level may be in the best interest of our plans and members. We also support the recommendation that CMS explore the local establishment of proportions by service category, which would result in cost-sharing proportions more closely aligned with the mix of services used in each geographic area. SNPs experience may differ quite from local experience due to their unique membership characteristics and benefit design. Accordingly, we request that CMS carefully consider the impact of various methods for determining actuarial equivalence on SNPs before finalizing the approach for specialized MA plans to ensure that they are not inadvertently disadvantaged by the method chosen.*

§422.256 Negotiation and Approval of Bids: Adjustments for Rebate

CMS proposes to allow adjustments to rebate dollars related to the Part D bid and the MA regional plan bids because the beneficiary premium and the benchmark respectively are not known prior to bid submission.

Social HMO Comments

The Social HMO Consortium supports this proposal as well as AHIP's recommendation that CMS allow adjustments to rebate dollars to further reduce their Part D premiums to match the low-income premium subsidy. The creation of specialized MA plans is intended to afford special needs individuals enhanced, specialized services that meet their needs. The success of these programs would be seriously undermined if their Part D premiums exceed the applicable low income Part D subsidy because their dually eligible enrollment, which includes frail elderly individuals, would have an incentive to disenroll from these plans. The Consortium recommends that SNPs also be permitted to reallocate rebate dollars to ensure that dually eligible beneficiaries would not need to pay a premium for Part D if they enroll or remain enrolled in these MA plans.

§422.264: Calculation of Savings: Selection of Methodology to Adjust Savings

Any savings generated by plans that bid below the benchmark are risk adjusted, since the original bid is based on the national average risk profile of 1.0. The savings could be risk adjusted, based on the statewide average or individual plan level risk scores.

Social HMO Comments

The Social HMO Consortium requests that CMS use a plan-specific risk adjustment. Since the statewide average is likely to be lower than plan-level risk scores for SNPs, a plan-level adjustment would more accurately reflect the plans' actual costs. In addition, the rebate will be used to provide supplemental benefits or reduced cost-sharing requirements. Plans with higher-risk beneficiaries need additional revenue to provide the same level of supplemental benefits as a plan with enrollees with lower risk scores. This will be especially important for dually eligible SNPs to help reduce drug premium costs.

422.266 Beneficiary rebates: Use of rebate dollars to fund supplemental drug benefits

Social HMO Comments

The Social HMO Consortium recommends that CMS revise proposed §422.262(b)(2) to allow rebate dollars to be used both to pay for the Part D premium and to provide supplemental drug coverage at no cost to the beneficiary. This latter discretion is authorized by Section 1860D-21(a)(2)(B). This change is needed to clarify that MA plans have the right to use rebate dollars to fund supplemental prescription drug benefits at no cost to the beneficiary as part of the basic Part D prescription drug benefit offered by the MA plan. This provision is critical given the risks faced by dually eligible SNPs described in our comments at §422.264.

Subpart G: Payment for Medicare Advantage Organizations

§Section 422.308: Adjustments to Capitation Rates, Benchmarks, Bids, and Payments

§422.308(c): Risk Adjustment

The proposed rule states that SNPs will be paid the same as standard MA plans. Since SNPs serve a high-risk population with higher health care costs, the adequacy of the risk adjustment methodologies is critical to the financial viability of specialty plans. The Consortium urges CMS to carefully evaluate three key components of risk adjustment to ensure payment adequacy: the CMS-HCC diagnostic adjuster, the frailty adjuster and the pharmacy adjuster.

Social HMO Comments

CMS-HCC Risk Adjustment Methodology: *CMS should further evaluate the adequacy of this method for SNPs and determine if modifications to the HCCS are in order.* For example, while certain conditions like diabetes and cancer have several different HCC risk adjusters of varying intensity, COPD, CHF and other HCCs common among frail elderly have only one risk score. It may be more appropriate to have a mechanism for triggering a late stage or advanced stage of illness for certain conditions that triggers a higher risk score.

Frailty Adjustment: CMS has indicated that it does not have the legislative authority to pay SNP the frailty adjuster unless they are operating under demonstration authority. Without such authority they indicate they must pay all MA plans the same. Since CMS has not determined when and if it will make the frailty adjuster universal, it should work with Congress to obtain legislative authority to pay SNPs the frailty adjuster, as a special class of MA plan, whether or not it makes this risk adjustment universal across all plans. In addition, as we understand that CMS may be refining the risk adjustment methodology, we request that it conduct impact analysis on all specialty MA plans and demonstrations as early as possible to evaluate the effects of any changes in the methodology.

Pharmacy Risk Adjustment: Since SNP's average per member drug costs are higher than standard MA plans due to the enrollment of high-risk beneficiaries, the risk adjustment must be sensitive to costs of high-risk individuals and account for the types and costs of prescription drugs required by special needs individuals. To ensure that the pharmacy adjustment will be adequate, CMS should specifically test its pharmacy risk adjustment methodology on several and varied representative SNPs. It should also specifically evaluate whether there is a relationship between

functional impairment and higher drug costs that may not be accounted for by diagnosis alone and determine if the frailty adjuster needs to be further modified to account for higher pharmacy costs.

§422.308(e): Adjustment to Plan Premium

If the plan bid exceeds the benchmark, the difference becomes the plan premium. Since the bid is based on national average risk, however, plan premiums should be adjusted to reflect the plan's revenue needs in relation to actual beneficiary risk.

Social HMO Comments

We understand CMS agrees that it would be appropriate to adjust premiums in relation to the plan score since the bids on which the premiums are based assume a national average risk profile. *We recommend that CMS to include plan level risk adjustments of the premiums and appreciate consideration of this provision that was not required by law.*

Subpart J: Special Rules for MA Plans

§422.455 Special Rules for MA Plans

CMS indicated on their open door forum that SNPs would not be permitted to participate in regional plans.

Social HMO Comments

The statute does not appear to explicitly exclude SNPs from participating in regional plans. The Social HMO Consortium seeks clarification regarding why CMS believes SNPs cannot participate in regional plans and requests that this option be available to SNPs in the event that some wish to participate in such plans at some point in the future.

EXHIBIT 1

ACOVE TOPICS

Appropriate Use of Medication
Chronic Pain
Continuity and Coordination of Care
Dementia
Depression
Diabetes Mellitus
End-of-Life Care
Falls and Mobility Problems
Hearing Loss
Heart Failure
Hospital Care
Hypertension
Ischemic Heart Disease
Malnutrition
Osteoarthritis
Osteoporosis
Pneumonia
Pressure Ulcers
Preventive Care
Stroke and Atrial Fibrillation
Urinary Incontinence
Visual Impairment

Submitter : JoAnn Stubbings **Date & Time:** 10/04/2004 09:10:56

Organization : UIC College of Pharmacy Amb Care Pharm Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit.

The University of Illinois at Chicago College of Pharmacy (UIC-COP) operates five Ambulatory Care Pharmacies that serve University of Illinois Medical Center outpatients, UIC employees, and UIC students. A total of 800 prescriptions are dispensed daily. Since our pharmacies are located in a lower socioeconomic area of Chicago, approximately 41 percent of our prescriptions are dispensed to Medicaid recipients. In addition, 31 percent of our Medicaid patients are dual eligible for Medicare and Medicaid due to their age or disability. We recognize and understand the problems associated with access to pharmaceuticals, inability to pay for pharmaceuticals, and multiple medication usage. We have a staff of five pharmacists and one technician who offer Medication Therapy Management Services to patients with multiple chronic medications, multiple chronic diseases, and/or cognitive difficulties. The staff is currently not compensated for the medication management services they provide, however we believe they improve access and outcomes for this critical population.

We offer the following specific comments for consideration as CMS develops the final regulation.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

? We believe that the definition of covered drugs should be expanded to include nonprescription drugs. These drugs represent a cost effective strategy in medication management. If nonprescription drugs are not covered, there will be a disincentive for doctors to prescribe them under the new prescription drug benefit. We recently had an 89 year old patient who came to the pharmacy with widely distributed Medicare Drug Discount Card and seven new prescriptions. (see Table) Four of her prescriptions were for nonprescription drugs (acetaminophen, multi-vitamins, docusate, and sulfacetamide sodium ophthalmic drops), none of which were covered by her card. Three of the prescriptions were for prescription drugs (Fosamax, Tramadol, and nifedipine). Surprisingly, the two brand name drugs were covered but the generic drug (nifedipine) was not covered by the card. This patient left the pharmacy without any of her prescriptions because she could not afford the price of the five noncovered medications. She returned a few days later with a new Illinois Senior Care card (section 1115 Demonstration program). Due to Senior Care?s open formulary and coverage of most nonprescription drugs, the patient was able to have her prescriptions filled for $12.95 and she left the pharmacy with all seven prescriptions.

? We also believe that the definition of covered drugs should be expanded to include certain Part B drugs that can be self administered by patients. We have many patients in our outpatient clinics who are able to self administer their medications, however they visit the clinic and use clinic resources because it is the only way their medication is covered by Medicare. If beneficiaries are able to demonstrate that they are able to self administer their Part B medications, then the drug(s) should be covered as a Part D benefit. Oral immunosuppressants, oral chemotherapy, and self administered epoietin could be considered for the Part D benefit.

? We believe that negotiated drug prices reported to CMS by PDPs or MA-PDs should be reported for individual drugs, not in the aggregate. We are concerned that large discounts that may be secured for preferred brand name drugs may not be sufficiently passed on to beneficiaries. Beneficiaries may pay an unduly large portion of the cost of brand name preferred drugs. CMS can oversee that discounts are equitably passed on to beneficiaries by requiring the reporting of individual drug discounts, especially for preferred drugs.

? We are concerned that formulary decision making, such as which drugs to include on the formulary, tiered pricing, prior authorization, and others may be tied in part to the rebate offers made by pharmaceutical companies to PDPs or MA-PDPs. We are also concerned that rebates may not be sufficiently passed on to beneficiaries. We believe that two independent participants in the P&T Committee are not sufficient to steer the Committee to make decisions based largely on clinical factors rather than rebate factors. We suggest that at least half of the committee be independent of any financial relationship with the PDP or MA-PDP. We also suggest the implementation of a national formulary or minimal

formulary that all PDPs or MA-PDPs must adhere to. We would suggest the VA formulary as a model.

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

? We believe that the wording of Section 1860D-4?(2)(A)(i) of the Act should be changed from ?a pharmacist may furnish MTMP services? to ?a pharmacist must furnish MTMP services.? We believe that a pharmacist is the only health professional qualified to offer these specialized services, at any level, to beneficiaries. The pharmacist may work in different practice sites, such as community pharmacy or in nursing homes, but we believe it should always be a pharmacist who delivers these services to patients. If a pharmacist is not the health professional delivering the services, then there will be an incentive to PDPs or MA-PDPs to use lesser qualified people working largely from a script over the telephones to implement the services. Their incentive will be to reduce medication costs for the PDP or MA-PDP. By allowing non-pharmacists to implement MTMP services, especially workers who are directly employed by the PDP or MA-PDP, the ultimate goal of the MTMP services may be compromised.

? We believe that, for QI/QA purposes, the definition of MTMP services should be expanded to include assuring that beneficiaries are managed according to published standards, such as ADA guidelines for diabetes, ACCE guidelines for osteoporosis, etc.

? We believe that CMS should develop fee ranges and levels of care for the provision of MTMP services. Sponsors would compensate pharmacists for MTMP services within the construct provided by CMS. If general guidelines are not developed, there may be wide variability in the definition of MTMP among sponsors, along with the provision of services, measurement of the impact of MTMP services, and the providers of the service and payment for the services. In effect, MTMP services will be an unfunded mandate, since there will be no guidelines to sponsors for the funding of the services. Sponsors may want to pay little for the services. Again, the ultimate goal of the MTMP services may be compromised.

? We believe that CMS does in fact have the authority to set guidelines for fees paid to pharmacists for MTMP services. CMS does set payment levels for the payment of other providers, such as physicians, nurse practitioners, physician assistants, etc. Pharmacists are already recognized by CMS as providers in diabetes self education training and in immunizations. We believe that CMS should recognize pharmacists as providers of MTMP services. Even if these services are provided and paid for by a sponsor such as a PDP or MA-PDP, we believe that a guideline framework should be established by CMS to ensure consistency and fairness.

? We support the MTMS Definition and Program Criteria developed by 11 pharmacy organizations in July 2004. This can be found at http://www.aphanet.org/lead/MTMS_definition_FINAL.pdf.

? We recommend a demonstration project sponsored by CMS that would help define the provision of MTMP services, clarify the fee structure, and evaluate the impact on clinical and economic outcomes. It would be important to determine whether MTMP services represent an economic benefit to Part D, Part B, or both. We recommend that the various demonstration project sites implement MTMP using the same framework for services (defined in previous paragraph) and payment structure developed by CMS.

ELIGIBILITY, ELECTION, AND ENROLLMENT

? Since the introduction of the Medicare Drug Discount Cards in June 2004, we have gained experience working directly with Medicare beneficiaries. This has proven to be a major challenge. Seniors, especially those of low literacy, find the process very confusing. We have had success using pharmacy students who work in our pharmacies to meet with seniors one-on-one to explain the program to them, determine their eligibility, and sign up for the most appropriate card based on their prescription utilization. We believe that the best way to provide information on the new drug benefit to seniors is through independent sources who can work one-on-one with seniors to meet their individual needs. We propose that students in colleges of pharmacy would be very effective in this community outreach activity.

? We support your determination to publish the formularies, benefits, and cost-sharing so that seniors can compare various PDP or MA-PD plans. Our experience with the Medicare Prescription Drug Discount Cards is that no one plan offers the best option to a senior. We also found that prescription coverage may be less generous than the patient expects due to formulary revisions that occur after the patient signs up for the card. (see Table) We believe that allowing PDPs or MA-PDs to maintain restrictive formularies and allowing them to change the formularies frequently will undermine the benefit and will result in restricted access to necessary medications for beneficiaries.

? We believe that clinic pharmacies such as ours should be included in the PDP and MA-PDP networks and should count toward their pharmacy access requirements. Our pharmacies serve a large and important Medicare and dual eligible population and make a significant difference in

improving access to necessary medication for beneficiaries. We would expect that PDPs and MA-PDPs would have an incentive to include clinic pharmacies, especially those in underserved areas in their network and for our pharmacies to count toward the pharmacy access requirements.

? We believe that incentives for beneficiaries to use mail order pharmacies should be allowed; however, disincentives or penalties (such as higher copays) to beneficiaries for using community pharmacies should be prohibited.

CMS-4068-P-1311-Attach-1.doc

CMS-4068-P-1311-Attach-1.doc

CMS-4068-P-1311-Attach-1.doc

CMS-4068-P-1311-Attach-1.doc

October 4, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit.

The University of Illinois at Chicago College of Pharmacy (UIC-COP) operates five Ambulatory Care Pharmacies that serve University of Illinois Medical Center outpatients, UIC employees, and UIC students. A total of 800 prescriptions are dispensed daily. Since our pharmacies are located in a lower socioeconomic area of Chicago, approximately 41 percent of our prescriptions are dispensed to Medicaid recipients. In addition, 31 percent of our Medicaid patients are dual eligible for Medicare and Medicaid due to their age or disability. We recognize and understand the problems associated with access to pharmaceuticals, inability to pay for pharmaceuticals, and multiple medication usage. We have a staff of five pharmacists and one technician who offer Medication Therapy Management Services to patients with multiple chronic medications, multiple chronic diseases, and/or cognitive difficulties. The staff is currently not compensated for the medication management services they provide, however we believe they improve access and outcomes for this critical population.

We offer the following specific comments for consideration as CMS develops the final regulation.

Subpart B: Eligibility and Enrollment

- Since the introduction of the Medicare Drug Discount Cards in June 2004, we have gained experience working directly with Medicare beneficiaries. This has proven to be a major challenge. Seniors, especially those of low literacy, find the process very confusing. We have had success using pharmacy students who work in our pharmacies to meet with seniors one-on-one to explain the program to them, determine their eligibility, and sign up for the most appropriate card based on their prescription utilization. We believe that the best way to provide information on the new drug benefit to seniors is through independent sources who can work one-on-one with seniors to meet their individual needs. We propose that students in colleges of pharmacy would be very effective in this community outreach activity.

- We support your determination to publish the formularies, benefits, and cost-sharing so that seniors can compare various PDP or MA-PD plans. Our experience with the

Medicare Prescription Drug Discount Cards is that no one plan offers the best option to a senior. We also found that prescription coverage may be less generous than the patient expects due to formulary revisions that occur after the patient signs up for the card. (see Table) We believe that allowing PDPs or MA-PDs to maintain restrictive formularies and allowing them to change the formularies frequently will undermine the benefit and will result in restricted access to necessary medications for beneficiaries.

- We believe that clinic pharmacies such as ours should be included in the PDP and MA-PDP networks and should count toward their pharmacy access requirements. Our pharmacies serve a large and important Medicare and dual eligible population and make a significant difference in improving access to necessary medication for beneficiaries. We would expect that PDPs and MA-PDPs would have an incentive to include clinic pharmacies, especially those in underserved areas in their network and for our pharmacies to count toward the pharmacy access requirements.

- We believe that incentives for beneficiaries to use mail order pharmacies should be allowed; however, disincentives or penalties (such as higher copays) to beneficiaries for using community pharmacies should be prohibited.

Subpart C: Voluntary Prescription Drug Benefit and Beneficiary Protections

- We believe that the definition of covered drugs should be expanded to include nonprescription drugs. These drugs represent a cost effective strategy in medication management. If nonprescription drugs are not covered, there will be a disincentive for doctors to prescribe them under the new prescription drug benefit. We recently had an 89 year old patient who came to the pharmacy with widely distributed Medicare Drug Discount Card and seven new prescriptions. (see Table) Four of her prescriptions were for nonprescription drugs (acetaminophen, multi-vitamins, docusate, and sulfacetamide sodium ophthalmic drops), none of which were covered by her card. Three of the prescriptions were for prescription drugs (Fosamax, Tramadol, and nifedipine). Surprisingly, the two brand name drugs were covered but the generic drug (nifedipine) was not covered by the card. This patient left the pharmacy without any of her prescriptions because she could not afford the price of the five noncovered medications. She returned a few days later with a new Illinois Senior Care card (section 1115 Demonstration program). Due to Senior Care's open formulary and coverage of most nonprescription drugs, the patient was able to have her prescriptions filled for $12.95 and she left the pharmacy with all seven prescriptions.

- We also believe that the definition of covered drugs should be expanded to include certain Part B drugs that can be self administered by patients. We have many patients in our outpatient clinics who are able to self administer their medications, however they visit the clinic and use clinic resources because it is the only way their medication is covered by Medicare. If beneficiaries are able to demonstrate that they

are able to self administer their Part B medications, then the drug(s) should be covered as a Part D benefit. Oral immunosuppressants, oral chemotherapy, and self administered epoietin could be considered for the Part D benefit.

- We believe that negotiated drug prices reported to CMS by PDPs or MA-PDs should be reported for individual drugs, not in the aggregate. We are concerned that large discounts that may be secured for preferred brand name drugs may not be sufficiently passed on to beneficiaries. Beneficiaries may pay an unduly large portion of the cost of brand name preferred drugs. CMS can oversee that discounts are equitably passed on to beneficiaries by requiring the reporting of individual drug discounts, especially for preferred drugs.

- We are concerned that formulary decision making, such as which drugs to include on the formulary, tiered pricing, prior authorization, and others may be tied in part to the rebate offers made by pharmaceutical companies to PDPs or MA-PDPs. We are also concerned that rebates may not be sufficiently passed on to beneficiaries. We believe that two independent participants in the P&T Committee are not sufficient to steer the Committee to make decisions based largely on clinical factors rather than rebate factors. We suggest that at least half of the committee be independent of any financial relationship with the PDP or MA-PDP. We also suggest the implementation of a national formulary or minimal formulary that all PDPs or MA-PDPs must adhere to. We would suggest the VA formulary as a model.

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

- We believe that the wording of Section 1860D-4©(2)(A)(i) of the Act should be changed from "a pharmacist may furnish MTMP services" to "a pharmacist must furnish MTMP services." We believe that a pharmacist is the only health professional qualified to offer these specialized services, at any level, to beneficiaries. The pharmacist may work in different practice sites, such as community pharmacy or in nursing homes, but we believe it should always be a pharmacist who delivers these services to patients. If a pharmacist is not the health professional delivering the services, then there will be an incentive to PDPs or MA-PDPs to use lesser qualified people working largely from a script over the telephones to implement the services. Their incentive will be to reduce medication costs for the PDP or MA-PDP. By allowing non-pharmacists to implement MTMP services, especially workers who are directly employed by the PDP or MA-PDP, the ultimate goal of the MTMP services may be compromised.

- We believe that, for QI/QA purposes, the definition of MTMP services should be expanded to include assuring that beneficiaries are managed according to published standards, such as ADA guidelines for diabetes, ACCE guidelines for osteoporosis, etc.

- We believe that CMS should develop fee ranges and levels of care for the provision of MTMP services. Sponsors would compensate pharmacists for MTMP services within the construct provided by CMS. If general guidelines are not developed, there may be wide variability in the definition of MTMP among sponsors, along with the provision of services, measurement of the impact of MTMP services, and the providers of the service and payment for the services. In effect, MTMP services will be an unfunded mandate, since there will be no guidelines to sponsors for the funding of the services. Sponsors may want to pay little for the services. Again, the ultimate goal of the MTMP services may be compromised.

- We believe that CMS does in fact have the authority to set guidelines for fees paid to pharmacists for MTMP services. CMS does set payment levels for the payment of other providers, such as physicians, nurse practitioners, physician assistants, etc. Pharmacists are already recognized by CMS as providers in diabetes self education training and in immunizations. We believe that CMS should recognize pharmacists as providers of MTMP services. Even if these services are provided and paid for by a sponsor such as a PDP or MA-PDP, we believe that a guideline framework should be established by CMS to ensure consistency and fairness.

- We support the MTMS Definition and Program Criteria developed by 11 pharmacy organizations in July 2004. This can be found at http://www.aphanet.org/lead/MTMS_definition_FINAL.pdf.

- We recommend a demonstration project sponsored by CMS that would help define the provision of MTMP services, clarify the fee structure, and evaluate the impact on clinical and economic outcomes. It would be important to determine whether MTMP services represent an economic benefit to Part D, Part B, or both. We recommend that the various demonstration project sites implement MTMP using the same framework for services (defined in previous paragraph) and payment structure developed by CMS.

We thank you for giving us the opportunity to comment on this important legislation.

JoAnn Stubbings, R.Ph., MHCA
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Subpart C: Voluntary Prescription Drug Benefit and Beneficiary Protections

Table. Coverage of Medications with the Medicare Drug Discount Card Compared to Illinois Senior Care For an 89 Year Old Medicare Beneficiary at the UIC Ambulatory Care Pharmacy, August, 2004.

	Patient Payment	
	Medicare Drug Discount Card with $600 Transitional Assistance	Illinois Senior Care (section 1115 Demonstration program)
Fosamax (Rx)	$3.22	$4.00
Tramadol (Rx)	$0.59	$1.00
Nifedipine (Rx – generic)	Not covered ($70.16)	$1.00
Tylenol (non-Rx)	Not covered ($3.45)	$0
Multivitamins (non-Rx)	Not covered ($5.11)	$0
Docusate (non-Rx)	Not covered ($6.35)	$0
Sulfacetamide sodium ophthalmic drops (non-Rx)	Not covered ($6.95)	$6.95
TOTAL	$95.83	$12.95

CMS-4068-P-1312

Submitter : Mr. Jim Earley **Date & Time:** 10/04/2004 09:10:00

Organization : Smith's Drugs Vital Care

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document

CMS-4068-P-1312-Attach-1.doc

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

We are an independent home infusion company located in a rural area of North Carolina. Last year we provided infusion therapy and monitoring services for those therapies for over 360 patients in an eight county area surrounding our location in Forest City, NC. We specialize in chemotherapy, pain management with opiates, antibiotic therapy including recommending and monitoring aminoglycosides,and parenteral and enteral nutrition. We have provided many Medicare patients with enteral feedings, pain management and have serviced many HIV patients whose therapies were covered by Medicare. Our patient surveys indicate that the patients and caregivers have been very satisfied with our services and in fact, if it were not for our monitoring services with our pharmacists and dietitian the enteral patients we serve would have no contact with any healthcare provider were it not for our monitoring.

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

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

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

Recent experience clearly demonstrates the access issues that will arise when a Medicare adds new coverage of a home infusion drug without accompanying

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

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

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

- CMS should establish **specific requirements for prescription drug plans to contract with sufficient numbers of infusion pharmacies** to ensure adequate enrollee access to home infusion therapy under Part D.
  - CMS should require **specific standards for home infusion pharmacies** under Part D. The national accreditation organizations' standards for infusion therapy reflect the community standard of care for the provision of home infusion therapy, which far exceed the OBRA 1990 standards established for retail pharmacies.
- CMS should adopt the **X12N 837 P billing format** for home infusion claims under Part D so as to be consistent with the format that private sector health plans use for infusion claims.
- CMS should **mandate that prescription drug plans maintain open formularies for infusion drugs** to ensure that this population of vulnerable patients has appropriate access to necessary medications.

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

Sincerely,

Jim Earley, RPh
Director of Clinical Services
Smith's Drugs Vital Care

Submitter : Ms. Carolyn Ingram **Date & Time:** 10/04/2004 09:10:40

Organization : NM Human Services Dept., Medical Assistance Divisi

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

There are a number of unresolved issues that were not addressed in the proposed regulation. This is a very complex program, with significant impact on dual eligibles, the state?s, prescription drug plans and CMS. We strongly recommend CMS continue working with states on these issues. It is important to the public to provide additional input when these issues have been fully shaped.

CMS-4068-P-1314

Submitter : **Ms. cindy Boerger** **Date & Time:** **10/04/2004 09:10:08**

Organization : **Oklahoma State Dept. of Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Concerned with not allowing ADAP wraparound, comprehensive drug coverage and transitional coverage of dual coverage clients

CMS-4068-P-1314-Attach-1.doc

October 4, 2004

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

File Code: CMS-4068-P

On behalf of Oklahoma, 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. Oklahoma 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. We strongly urge CMS to publish a final rule that ensures that Medicare beneficiaries living with HIV/AIDS at all income levels have affordable access to all HIV-related medications.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

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

While Oklahoma appreciates 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.

The Oklahoma ADAP program has implemented a $12,000 yearly client benefit cap in efforts to hopefully delay having to implement a waitlist for acceptance into the program.

Regrettably, the availability of the Part D benefit will do little to reduce the pressure on ADAPs fiscal viability and Oklahoma's fiscal viability specifically because such funds cannot count toward the catastrophic limit and the benefit may be too limited to respond to the needs of Medicare beneficiaries with HIV/AIDS. In this environment, federal policy should not create a disincentive for states to wrap-around the Medicare Part D benefit.

When the Medicare prescription drug benefit 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 implications. Treatment interruptions and non-adherence to regiments leads to increased viral loads and an increased risk of developing resistance to currently available HIV-related antiretroviral medications and therefore an increased risk of transmission. 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. Not all ADAPs have the financial wherewithal to pay for these individuals' expenses indefinitely.

In several places in the proposed regulations, 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.

Oklahoma 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. The state of Oklahoma contributed $901,000 in FY 2003 to the state's ADAP. To deny Oklahoma from using the state funds that have been 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 to move toward the model of purchasing their drugs directly, under the 340B Program, instead of using a rebate model. Oklahoma 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.

There are several states that use a rebate option model available to ADAPs under 340B to purchase drugs instead of the direct purchase model. These states, including California and New York, the two largest ADAPs, have carefully analyzed the cost-benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study which demonstrated that after calculating 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.

Oklahoma's 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 the 340B pricing. We understand that several 340B entities have begun entering into partnerships with various state and local government programs to provide more individuals access to 340B pricing. However, there are 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)

Oklahoma strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with HIV/AIDS be defined as a special population. We feel this is critical to ensuring that Medicare beneficiaries with HIV/AIDS have continued and unhindered access to all of the drugs that are medically necessary for treating the disease. Furthermore, an "open formulary" will prove cost effective because it will prevent the use of more intensive and costly health care resources such as inpatient hospitalization that will occur if Medicare beneficiaries with HIV/AIDS are denied access to medically necessary prescription drugs. While the private drug plans are not at risk for this potential cost shifting, the federal government will incur these costs either through higher Medicaid expenditures or higher Medicare Part A and B expenditures.

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. 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.

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))

Oklahoma 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. We recommend that CMS require that a majority of P&T Committee members be independent and free of conflict with respect to the PDP sponsor and the prescription drug plan to ensure that recommendations by independent members are not ignored or outvoted.

We 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 THE PRESCRIBING OF DRUGS FOR OFF-LABEL PURPOSES WITHOUT PLACING UNDUE BURDEN ON CLINICIANS

Oklahoma 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 use that are standard practice in the medical community. For HIV disease, as with many complex conditions, clinical practice frequently progresses ahead of label indications as physicians learn what drug combinations best target their patient's symptoms and side effects. As an example, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV, although treatment for hepatitis B is not yet an indicated use of the drug.

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. [423.782(a)(iiii)]

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

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. 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 submit comment on the proposed rule to implement the Medicare Part D prescription drug benefit. Please contact me at 405-271-9444 #56616 or cindyb@health.state.ok.us if you need further information.

Sincerely,

Cindy Boerger, MSW
HDAP Program Manager
HIV/STD Service
Oklahoma State Department of Health

Submitter : Mrs. Betty Dod **Date & Time:** 10/04/2004 09:10:35

Organization : Mrs. Betty Dod

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Betty and Wilton
15018 Hollydale Dr.
Houston, TX 77062

Phone: 281-488-0974

Mark B. McClellan, M.D., Ph.D
Adminitrator
Centers for Medicare and Medicais Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Dr. McClellan:

We are writing to you regarding the proposed rule that was recently published by the Centers for Medicare and Medicaid Services for the new Medicare prescription drup benefit.

My husband, Wilton Dod, has served on the board for National Alliance for the Mentally Ill in Kansas City for a period of time and we try to be active advocates for those in our communities that suffer or at risk from mental illnesses. Psychiatric medications are critical to this group of people. We can certainly appreciate the enormity of the challenges you are facing in implementing this new benefit but we need to urge CMS to revise the proposed rule to insure adequate access to mental health medicatrions for the many Medicare beneficiaries requiring them.

Some of our major conerns are in regards to the final rules for the Madicare Part D drug benefit:

1. extending the deadline for switching their coverage from Medicaid to Medicare

2. grandfathering coverage of medications on which mental health consumers have been stablilized

Coverage of Dual Eligibles (423.34)

Of very serious 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. These very vulnerable beneficiaries must receive coverage for the medications they need. No one wants them harmed or made worse off when their drup coverage is switched from Medicaid to Medicare. How will dual eligibles maintain their medications when this is switched? Please allow adequate time to educate and enroll these vulnerable individuals and help to ensure that they will be able to receive the drug coverage to which they are entitled. Our communities will be safer as well as these consumers.

We have other major concerns about this that we would be happy to relay to you. I am fearful that this would not reach you in time if there was more elaboration at this time. Please call us or ask us about these concerns at your convenience.

Thank you for considering our comments,

Betty and Wilton Dod

CMS-4068-P-1316

Submitter : Ms. J. David Odle **Date & Time:** 10/04/2004 09:10:33

Organization : Oklahoam HIV Treatment and Care Consortium

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file.

CMS-4068-P-1316-Attach-1.doc

October 4, 2004

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

File Code: CMS-4068-P

On behalf of Oklahoma, 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. Oklahoma 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. We strongly urge CMS to publish a final rule that ensures that Medicare beneficiaries living with HIV/AIDS at all income levels have affordable access to all HIV-related medications.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

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

While Oklahoma appreciates 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. Since April 1, 2003, the Oklahoma ADAP program has had to implement a $12,000 per year

client benefit cap in hopes to delay having to implement a waiting list to be approved and access the program.

Regrettably, the availability of the Part D benefit will do little to reduce the pressure on ADAPs fiscal viability nationally and on Oklahoma's ADAP because such funds cannot count toward the catastrophic limit and the benefit may be too limited to respond to the needs of Medicare beneficiaries with HIV/AIDS. In this environment, federal policy should not create a disincentive for states to wrap-around the Medicare Part D benefit.

When the Medicare prescription drug benefit 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 implications. Treatment interruptions and non-adherence to regiments leads to increased viral loads and an increased risk of developing resistance to currently available HIV-related antiretroviral medications and therefore an increased risk of transmission. 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. Not all ADAPs have the financial wherewithal to pay for these individuals' expenses indefinitely.

In several places in the proposed regulations, 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.

Oklahoma 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. In FY2003 the state of Oklahoma contributed $901,000 to Oklahoma's ADAP. To deny Oklahoma from using the state funds that they have 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.

PEOPLE LIVING WITH HIV/AIDS ARE A SPECIAL POPULATION THAT REQUIRE SPECIAL TREATMENT AND ACCESS TO AN OPEN FORMULARY (§423.120)

Oklahoma strongly supports the CMS recommendation to implement "open formularies" for special populations and strongly recommends that people with HIV/AIDS be defined as a special population. We feel this is critical to ensuring that Medicare beneficiaries with HIV/AIDS have continued and unhindered access to all of the drugs that are medically necessary for treating the disease. Furthermore, an "open formulary" will prove cost effective because it will prevent the use of more intensive and costly health care resources such as inpatient hospitalization that will occur if Medicare beneficiaries with HIV/AIDS are denied access to medically necessary prescription drugs. While the private drug plans are not at risk for this potential cost shifting, the federal government will incur these costs either through higher Medicaid expenditures or higher Medicare Part A and B expenditures.

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. 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.

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))

Oklahoma 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. We recommend that CMS require that a majority of P&T Committee members be independent and free of conflict with respect to the PDP sponsor and the prescription drug plan to ensure that recommendations by independent members are not ignored or outvoted.

We 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 THE PRESCRIBING OF DRUGS FOR OFF-LABEL PURPOSES WITHOUT PLACING UNDUE BURDEN ON CLINICIANS

Oklahoma 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 use that are standard practice in the medical community. For HIV disease, as with many complex conditions, clinical practice frequently progresses ahead of label indications as physicians learn what drug combinations best target their patient's symptoms and side effects. As an example, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV, although treatment for hepatitis B is not yet an indicated use of the drug.

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. [423.782(a)(iiii)]

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

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. 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 submit comment on the proposed rule to implement the Medicare Part D prescription drug benefit. Please contact me at 405-271-5816 if you need further information.

Sincerely,

J. David Odle, Co-Chair
Oklahoma HIV Treatment and Care Consortium
Department of Human Services

Janice Nicklas, MSW, M.A., Co-Chair
Oklahoma Treatment and Care Consortium

Donna Delise, R.NE
Evaluation Committee Co-Chair

Sharon Thoele, MHR
Evlauation Committee Co-Chair
Executive Director, Tulsa CARES

Victor Cutnose
Policy Committee Co-Chair

Terry Smith, R.N.
Policy Committee Co-Chair

Mike Jackson, M.D.
Services Planning Committee Co-Chair
Oklahoma Department of Corrections

Michael Atchely
Services Planning Committee Co-Chair

Jean Ann Van Krevelen, MSW
Needs Assessment Committee Co-Chair
Executive Director, Regional AIDS Interfaith Network

Heidi Ruster, M.A.
Needs Assessment Committee Co-Chair
Executive Director, CarePoint, INC

Larry Hayes
Membership Committee Co-Chair

Submitter : Dr. Marianne Ivey **Date & Time:** 10/04/2004 09:10:36

Organization : The Health Alliance of Greater Cincinnati

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I appreciate the opportunity to offer input on the proposed rules developed for the implementation of Medicare Part D benefit. I am the Corporate Director of Pharmacy Services at the Health Alliance in Greater Cincinnati, a six-hospital system with a large number of outpatients in Ohio and Kentucky. While I believe that there is the potential for greatly improved medication management for Medicare patients through this legislation I am concerned that the proposed rules could have a negative impact on medication services provided to Medicare beneficiaries.

In order for this program to be successful, I urge CMS to incorporate rule language that will 1)ensure compensation for all pharmacy providers that perform medication therapy management (MTM)services, and 2)allow for all pharmacies to serve as a prescription product provider for Medicare beneficiaries. Below are specific recommendations.

MTM Services

1. CMS rules must allow for all pharmacists to be included, not precluded. Pharmacists at The Health Alliance are an integral part of the health care team, helping to daily manage the care of Medicare patients with chronic diseases. These services improve the quality of patient outcomes and dramatically lower medication and medical costs by decreasing hospitalization and ER visits Pharmacist-managed patients, with physician oversight include patients receiving anticoagulation therapy, patients with heart failure, blood sugar and medication management and education for diabetics, asthma patients who benefit from specific education about inhaler use, cholesterol monitoring and compliance management education for HIV patients with multiple medications and complex dosing schedules.
2. All pharmacists practicing with a region should be afforded the opportunity to provide and be paid for MTM services such that plan sponsore should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service. Furthermore all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.
3. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist paid at not a lesser rate than rate than to other providers of MTM services. Payment should not be descriminated to only certain providers.
4. Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services.
5. MTM services should be able to provided in conjunction with and outside of product dispensing.
6. An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims similar to electronic submission of prescription claims.
7. Plan sponsors should be required to establish a CMS-specified set of MTM services.
8. CMS should consider developing a program to accredit plans that agree to meet the above-stated conditions that add value and lower the cost of care.

Access to Pharmaceuticals within Part-D

1. Plans should be required to use standard contract language to pharmacies willing to participate in prgram with prescription and MTM services.
2. Co-payment reduction should not be provided to coerce beneficiaries into using preferred pharmacy providers olely on the basis of pricing or cost.
3. CMS must assure an adequate reimbursement formula that at a minimum covers the average cost of filling a prescription or providing MTM.
4. Plan sponsors could consider incentives for using "preferred" pharmacies over others based on well-defined quality principles related to a high level of pharmacy services that all pharmacies can be allowed to show proof of achieving.

Thank you.

Yours truly,

Marianne F. Ivey, Pharm. D., MPH
iveymf@healthall.com
513-585-6198

CMS-4068-P-1318

Submitter : Mr. Adolph Falcon **Date & Time:** 10/04/2004 09:10:29

Organization : National Alliance for Hispanic Health

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Section 423.34, Part D Enrollment Process

The Alliance supports the interpretation of automatic enrollment of dual eligible beneficiaries in prescription drug plans to include Medicare Advantage Prescription Drug Plans (MA-PDPs). The proposed CMS interpretation will allow automatic enrollment of a Medicare Advantage (MA) full benefit dual eligible into a MA-PDP offered by the same MA organization. This interpretation is consistent with the intent of the MMA that all dual eligibles continue to have prescription drug coverage and which allowed for the automatic enrollment process to ensure that those beneficiaries who have not enrolled on their own are not left without a prescription plan.

BACKGROUND

The Alliance supports CMS timeline for implementation of the MMA full prescription drug benefit and Medicare Advantage Program by January 1, 2006. Extension of the comment period beyond October 4, 2004 as announced in the Federal Register notice (August 3, 2004) would unnecessarily delay the program?s implementation and critical benefits for underserved communities, particularly low-income Medicare beneficiaries without prescription drug coverage. The Alliance encourages CMS to put in place a beneficiary satisfaction and monitoring program to ensure that program implementation is meeting the needs of Medicare beneficiaries and necessary program adjustments made based on results of beneficiary satisfaction and monitoring data.

BENEFITS AND BENEFICIARY PROTECTIONS

Section 423.566, Coverage Definitions

The Alliance supports the provision of appeal information on non-covered pharmaceuticals under a PDP at the point of pharmacy contact. When a pharmacist tells a beneficiary that a prescribed drug is not covered under their PDP, CMS rules should require that the beneficiary be given information on the appeals process at that point. This is the point when the beneficiary most needs the information. Furthermore, CMS should require that information include the phone number for an appropriate state or local ombudsman or counseling service and such information be made available in the language the beneficiary is most comfortable reading or other appropriate format for blind and low-literate beneficiaries.

Section 423.568; Standard timeframe, notice requirements for coverage determinations.

The Alliance supports reduction of the allowed period for an exception request to three days. Under the proposed rule, a PDP has 14 days in which to issue a decision about an exception request and send a denial notice to the patient and physician. The standard for many commercial plans is two to three days to issue such an exception and under Medicaid in many states is within one day. No more than three days and preferably one day should be the standard under the CMS rule.

Section 423.600, Reconsideration by an independent review entity (IRE)

The Alliance supports automatic referral to an IRE and allowing appeal on behalf of beneficiary by provider or pharmacist. A beneficiary must file a written request for a reconsideration of a drug denial by an IRE. This process should be automatic rather than requiring a written request. Furthermore, under the proposed rule a prescribing provider could only seek an exception or expedited re-determination on behalf of a beneficiary but not further appeal. The rule should allow all available appeals to be pursued by a prescribing provider and should also extend this role to the pharmacist. Furthermore, the rule should include a standard form to designate a person to act in an appeal on behalf of a beneficiary.

Section 423.772; Definitions, Resources

The Alliance supports increased specificity under the ?Resources? definitions to include those resources not included for purposes of eligibility determination. The CMS decision to include only liquid resources in eligibility determination is an important decision that will not penalize a beneficiary for owning their home or burial plot, as was clearly the intent of the law. In order to ensure success of outreach efforts for MMA implementation, it is important that CMS specifically state in this section that liquid resources for purposes of eligibility determination do not include:
(1) a beneficiary?s residence nor the land on which the primary residence is located,
(2) burial plot for self or family,
(3) burial funds or life insurance,
(4) wedding or anniversary jewelry such as a wedding or engagement ring, nor
(5) any officially designated retirement account such as an IRA or 401(k) plan.

Section 423.773, Requirements for eligibility

The Alliance supports the automatic enrollment in the full MMA subsidy of persons identified as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State?s plan. The current decision by CMS to conduct facilitated enrollment for this group of beneficiaries under MMA transitional assistance has showed that facilitated enrollment for QMB, SLMB, and QI beneficiaries is an important tool in ensuring full participation and will be critical to ensure that no eligible person is left without a PDP for any period under MMA implementation.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Section 423.48, Information about Part D

The Alliance supports the addition of specific language requiring outreach to underserved populations. It is important under this section that CMS add language requiring plans to have specific outreach for underserved populations, including lower income, rural, disabled, and LEP beneficiaries. Such outreach would be consistent with CMS requirements that plans cannot enroll only higher income populations within the service areas they cover.

The Alliance supports addition of language committing CMS to a national outreach effort to undeserved populations. Under this section, CMS should state, as it has in other venues, that CMS will launch a national education effort to reach underserved populations and that this effort will provide funding to community-based organizations that have a record of effectively serving underserved populations.

GENERAL PROVISIONS

The Alliance strongly encourages that the preamble to the final rule for implementation of the Medicare Prescription Drug Benefit and Medicare Advantage Program specifically state that all data collection under these programs must include collection and reporting of racial and ethnic data for beneficiaries in compliance with OMB directive 15 on racial and ethnic data classification.

The Alliance strongly encourages that the preamble to the final rule specifically state that all services delivered and outreach efforts must be in compliance with Executive Order 13166 and the U.S. Department of Health and Human Services Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons.

CMS-4068-P-1318-Attach-1.pdf

CMS-4068-P-1318-Attach-2.doc

CMS-4068-P-1318-Attach-1.pdf

CMS-4068-P-1318-Attach-2.doc

CMS-4068-P-1318-Attach-1.pdf

CMS-4068-P-1318-Attach-2.doc

CMS-4068-P-1318-Attach-1.pdf

CMS-4068-P-1318-Attach-2.doc

CMS-4068-P-1318-Attach-1.pdf

CMS-4068-P-1318-Attach-2.doc

National Alliance for Hispanic Health
1501 Sixteenth Street, N.W. • Washington, D.C. 20036-1401 • (202) 387-5000 • www.hispanichealth.org

October 4, 2004

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

RE: File Code CMS-4068/4069-P

Dear Dr. McClellan:

I am pleased to submit comments on CMS' proposed rule for implementation of the Medicare Modernization Act (MMA) Medicare Prescription Drug Benefit (42 CFR 403, 411, 417, and 423) and Medicare Advantage Program (42 CFR 417 and 422). These comments are submitted on behalf of the National Alliance for Hispanic Health (the Alliance).

The nation's action forum for Hispanic health, the Alliance is the oldest and largest network of Hispanic health professionals. Alliance members provide quality health services to over 12 million persons every year.

The enclosed comments are organized under the categories of "general" followed by comments organized by the appropriate rule section. Please feel free to contact me or Adolph P. Falcón, Vice President for Science and Policy, at (202) 797-4341 if we can provide any additional information or clarification. Thank you for your commitment and efforts to improve the Medicare program and our Nation's health.

Sincerely,

Jane L. Delgado, Ph.D., M.S.
President and CEO

Enclosure

COMMENTS
National Alliance for Hispanic Health

Centers for Medicare and Medicaid Services Request for Public Comment
Proposed Rule
Implementation of the Medicare Modernization Act (MMA) Medicare Prescription Drug Benefit
(42 CFR 403, 411, 417, and 423) and Medicare Advantage Program (42 CFR 417 and 422)

General

- The Alliance supports CMS' timeline for implementation of the MMA full prescription drug benefit and Medicare Advantage Program by January 1, 2006. Extension of the comment period beyond October 4, 2004 as announced in the Federal Register notice (August 3, 2004) would unnecessarily delay the program's implementation and critical benefits for underserved communities, particularly low-income Medicare beneficiaries without prescription drug coverage. The Alliance encourages CMS to put in place a beneficiary satisfaction and monitoring program to ensure that program implementation is meeting the needs of Medicare beneficiaries and necessary program adjustments made based on results of beneficiary satisfaction and monitoring data.

- The Alliance strongly encourages that the preamble to the final rule for implementation of the Medicare Prescription Drug Benefit and Medicare Advantage Program specifically state that all data collection under these programs must include collection and reporting of racial and ethnic data for beneficiaries in compliance with OMB directive 15 on racial and ethnic data classification.

- The Alliance strongly encourages that the preamble to the final rule specifically state that all services delivered and outreach efforts must be in compliance with Executive Order 13166 and the U.S. Department of Health and Human Services Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons.

Section 423.34 — Part D Enrollment Process

- **The Alliance supports the interpretation of automatic enrollment of dual eligible beneficiaries in prescription drug plans to include Medicare Advantage Prescription Drug Plans (MA-PDPs).** The proposed CMS interpretation will allow automatic enrollment of a Medicare Advantage (MA) full benefit dual eligible into a MA-PDP offered by the same MA organization. This interpretation is consistent with the intent of the MMA that all dual eligibles continue to have prescription drug coverage and which allowed for the automatic enrollment process to ensure that those beneficiaries who have not enrolled on their own are not left without a prescription plan.

Section 423.48 — Information about Part D

- **The Alliance supports the addition of specific language requiring outreach to underserved populations.** It is important under this section that CMS add language requiring plans to have specific outreach for underserved populations, including lower income, rural, disabled, and LEP beneficiaries. Such outreach would be consistent with CMS requirements that plans cannot enroll only higher income populations within the service areas they cover.

- **The Alliance supports addition of language committing CMS to a national outreach effort to undeserved populations.** Under this section, CMS should state, as it has in other venues, that CMS will launch a national education effort to reach underserved populations and that this effort will provide funding to community-based organizations that have a record of effectively serving underserved populations.

Section 423.566 — Coverage Definitions

- **The Alliance supports the provision of appeal information on non-covered pharmaceuticals under a PDP at the point of pharmacy contact.** When a pharmacist tells a beneficiary that a prescribed drug is not covered under their PDP, CMS rules should require that the beneficiary be given information on the appeals process at that point. This is the point when the beneficiary most needs the information. Furthermore, CMS should require that information include the phone number for an appropriate state or local ombudsman or counseling service and such information be made available in the language the beneficiary is most comfortable reading or other appropriate format for blind and low-literate beneficiaries.

Section 423.568 — Standard timeframe, notice requirements for coverage determinations.

- **The Alliance supports reduction of the allowed period for an exception request to three days.** Under the proposed rule, a PDP has 14 days in which to issue a decision about an exception request and send a denial notice to the patient and physician. The standard for many commercial plans is two to three days to issue such an exception and under Medicaid in many states is within one day. No more than three days and preferably one day should be the standard under the CMS rule.

Section 423.600 — Reconsideration by an independent review entity (IRE)

- **The Alliance supports automatic referral to an IRE and allowing appeal on behalf of beneficiary by provider or pharmacist.** A beneficiary must file a written request for a reconsideration of a drug denial by an IRE. This process should be automatic rather than requiring a written request. Furthermore, under the proposed rule a prescribing provider could only seek an exception or expedited re-determination on behalf of a beneficiary but not further appeal. The rule should allow all available appeals to be pursued by a prescribing provider and should also extend this role to the pharmacist. Furthermore, the rule should include a standard form to designate a person to act in an appeal on behalf of a beneficiary.

Section 423.772 — Definitions, Resources

- **The Alliance supports increased specificity under the "Resources" definitions to include those resources not included for purposes of eligibility determination.** The CMS decision to include only liquid resources in eligibility determination is an important decision that will not penalize a beneficiary for owning their home or burial plot, as was clearly the intent of the law. In order to ensure success of outreach efforts for MMA implementation, it is important that CMS specifically state in this section that liquid resources for purposes of eligibility determination do not include:
  (1) a beneficiary's residence nor the land on which the primary residence is located,
  (2) burial plot for self or family,
  (3) burial funds or life insurance,
  (4) wedding or anniversary jewelry such as a wedding or engagement ring, nor
  (5) any officially designated retirement account such as an IRA or 401(k) plan.

Section 423.773 — Requirements for eligibility

- **The Alliance supports the automatic enrollment in the full MMA subsidy of persons identified as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.** The current decision by CMS to conduct facilitated enrollment for this group of beneficiaries under MMA transitional assistance has showed that facilitated enrollment for QMB, SLMB, and QI beneficiaries is an important tool in ensuring full participation and will be critical to ensure that no eligible person is left without a PDP for any period under MMA implementation.

Further information contact:

Adolph P. Falcón, MPP
Vice President for Science and Policy
National Alliance for Hispanic Health
1501 Sixteenth Street, NW
Washington, DC 20036
afalcon@hispanichealth.org
(202) 797-4341

CMS-4068-P-1319

Submitter : Mr. David Schulke **Date & Time:** 10/04/2004 09:10:38

Organization : American Health Quality Association

Category : Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Document Attached

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

Document Attached

GENERAL PROVISIONS

Document Attached

CMS-4068-P-1319-Attach-1.doc

CMS-4068-P-1319-Attach-1.doc

CMS-4068-P-1319-Attach-1.doc

THE AMERICAN HEALTH QUALITY ASSOCIATION
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October 4, 2004

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Washington, DC 20201

File Code: CMS-4068-P

Dear Dr. McClellan:

The American Health Quality Association (AHQA), representing the national network of Medicare Quality Improvement Organizations (QIOs), is pleased to be able to provide these comments on the proposed rule to establish the Medicare outpatient prescription drug benefit. The size of the proposed regulation can't begin to adequately measure the enormous complexity of implementing the provisions of Medicare Modernization Act (MMA). The dedicated staff at the Centers for Medicare & Medicaid Services (CMS) is to be commended for their efforts to move forward expeditiously with implementation of the law. I hope that AHQA's comments will be useful in that endeavor.

Our comments and suggestions are grouped and labeled as requested in the Federal Register notice published on August 3, 2004.

General Provisions

Quality Assurance Requirements (§ 423.153(c))

Recommendation: The regulation should explicitly encourage Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug plans (MA-PD plans) to coordinate and work directly with QIOs as a way to meet requirements for educational interventions, Medication Therapy Management and other quality improvement efforts targeted at providers, practitioners and beneficiaries.

AHQA strongly supports language in the narrative encouraging PDPs and MA-PD plans to work with QIOs on these activities. This will reduce the level of burden on plans, providers and practitioners to engage in efforts to improve the quality of prescription drug therapy. A number of plans participating in coordinated activities could contribute to achieving more widespread success in improving care across a region.

Quality Improvement Organization (QIO) Activities (§ 423.162)

Recommendation: AHQA suggested in its September 20, 2004 comments on the Summary of the QIO 8th Scope of Work (SOW8) that CMS should embrace a of number principles as it develops the QIO work related to the new drug benefit:

- Most drug-related problems in the elderly probably involve medications that are not

on anybody's "bad drug" list.

- A focus on simply reducing the total number of drugs that an older patient receives may be a misguided approach to quality improvement.
- Quality-improvement efforts should focus on specific classes of drugs or specific medical conditions.
- Physicians, with the help of QIOs, need to figure out better ways to work together with clinical pharmacists.
- CMS and the QIOs should use methods such as academic detailing, proven effective and cost-effective repeatedly in randomized controlled studies --
    - Soumerai & Avorn (1986): $2 saving for each $1 spent on program
    - Silagy, May & Avorn (1997): Academic detailing based services in some therapeutic topics within ongoing service-based programs, direct cash savings can exceed costs by a ratio of 6 to 1
    - Mason, Freemantle et al (2001): Even with small overall effect sizes academic detailing can be cost effective.

Recommendation: CMS must ensure that QIOs have access to the necessary data to perform the quality improvement functions envisioned in Section 109 of the MMA. The provider and pharmacy identifiers described in the narrative will be absolutely critical to these activities. The agency should create a Technical Expert Panel, with representation from the QIO community and others, to examine what data elements will be necessary for prescription drug quality improvement.

Recommendation: Create an exception to the information disclosure regulation at 42CFR Part 480 to permit QIOs to notify a patient's physician when a threat to patient safety is identified by the QIO.

The value and credibility of the QIO's quality improvement assistance to the plans and prescribers will be greatly enhanced if the QIO is able to timely notify the patient's physician(s) of patient safety issues that are suggested by the QIO's quality studies. At present, the QIO can know the details of these problems but is prohibited from telling the patient's physician because other physicians' treatments or actions may be thereby disclosed. We believe that protecting the patient's health and safety is the ultimate priority in the quality measurement and improvement system, and that such notifications must be transmitted or telephoned to appropriate physician(s), with appropriate caveats indicating that the perceived problem may in fact be something of which the patient and physician are already aware.

CMS is right to be concerned that there may be occasional objections to the sharing of such information with a patient's physician, but the notification process has safeguards built into it. A patient's physician may be assumed to be a safe custodian of personal information and certainly may be assumed to have the patient's interests in the forefront of their thinking when they are informed of the patient possibly being at risk. If the Medicare program were to collect information on such threats to patient safety (e.g., patients on high risk medications without any sign of appropriate lab work to ensure safe use of the drug) and NOT tell the physician(s) involved in the care of the patient, CMS must anticipate severe criticism for not exercising its role as a responsible steward of the patient's interest.

Requirements for Disclosure of Information (§ 423.322)

Recommendation: CMS should ensure that prescription transaction data, including the name of the prescriber with as much accuracy as possible, is made available on a timely basis to the QIOs.

Without this information, it will be extremely difficult for QIOs to execute the direction of Congress in section 109 of the MMA, where the law directs QIOs to offer assistance to practitioners and plans for the purpose of improving the quality of pharmacotherapy received by older and disabled Americans enrolled in the Medicare outpatient drug benefit. Because of the sophistication of the pharmacy and drug benefits management industries, today virtually all prescription drug claims are adjudicated online, real-time. QIOs must have timely data, but need not have real-time data. Some element of burden on PDPs and MA plans can be relieved by CMS arranging to receive batches of transaction data biweekly or perhaps monthly.

Recommendation: CMS should ensure there are no barriers to QIOs being able to link Part D transaction data to Part A and Part B claims as part of quality improvement efforts.

AHQA strongly agrees with CMS that the prescription drug data should collected in such a way that it is linkable with other data. The QIOs should be able to link these claims back to beneficiaries and prescribers, as well as plans, to identify prescribing issues that threaten the health and safety of Medicare enrollees. Examples of uses for such linkages and analyses include:

- Identifying plans and prescribers which have patients receiving warfarin therapy who are not receiving timely concomitant INR testing.
- Identifying plans, prescribers and hospitals which have patients discharged for heart attack or congestive heart failure but who appear not to be receiving beta blocker and ACE inhibitor therapy.

Subpart M-Grievances, Coverage Determinations, Reconsiderations, and Appeals

Recommendation: CMS should consider using the QIOs to perform expedited independent external appeals related to the drug benefit.

The QIOs have proven ability, through their handling of beneficiary fast-track appeals of termination of service and discharge notices, to respond quickly in making complex medical necessity determinations. They have significant experience evaluating published evidence and relating it to physicians' clinical decision making. Utilizing the QIOs in a similar role with prescription drug appeals would provide a consistent appeal mechanism that is familiar to and trusted by physicians and beneficiaries.

Recommendation: There should be a national outreach effort to inform beneficiaries and physicians of these appeal rights.

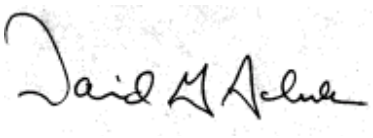
The QIOs already undertake educational efforts regarding beneficiary appeal rites, and CMS could take advantage of the existing QIO role with appeals to educate beneficiaries and physicians about the new appeal rites available under the drug benefit.

Recommendation: The beneficiary should be given at least a three day supply of the medication prescribed by his or her physician during the time an appeal is being evaluated.

We believe this is the standard under Medicaid law and will provide a necessary safeguard for beneficiaries during the appeal process.

I appreciate the opportunity to offer these recommendations for your consideration in developing the final rule for the prescription drug benefit. Please contact me if I can answer any questions or provide additional information.

Sincerely,



David G. Schulke
Executive Vice President

CMS-4068-P-1320

Submitter : Mr. Joel Hornberger **Date & Time:** 10/04/2004 09:10:53

Organization : National Mental Health Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

We urge CMS to address the following concerns in the final rules for the Medicare Part D drug benefit:
1. Coverage of Dual Eligibles. Please ensure continuity of care for dual eligibles by a. extending the deadline for switching their coverage from Medicaid to Medicare, and b. grandfathering coverage of medications on which mental health consumers have been stabilized. 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, ie, the dual eligibles. 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 (6) 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. Additionally, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. Therefore, 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 several states have done when implementing preferred drug lists.
2. Alternative, Flexible Formularies for Beneficiaries with Mental Illness. 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. Restrictive practices such as prior authorization, fail first and step therapy are inappropriate for people with mental illnesses. 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. 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 design.
3. Involuntary Disenrollment for Disruptive Behavior. Establish greater protections for beneficiaries threatened with and subjected to involuntary disenrollment by their drug plans for disruptive behavior. We are alarmed that CMS has proposed an expedited disenrollment process. This expedited process proposal must not be included in the final rule.
4. Appeals Procedures. Simplify the grievance and appeals procedures to prioritize ease of access and rapid results for beneficiaries and their providers and provide a truly expedited process for individuals with immediate needs, including individuals facing psychiatric crises. To accomodate the special needs of the mentally ill and others facing disabilities or low income, CMS needs to establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their providers, modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.
5. 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 illness. CMS must develop a specific plan for facilitating enrollment for the mentally ill that incorporates collaborative partnerships among agencies.

CMS-4068-P-1321

Submitter : Ms. trisha kurtz **Date & Time:** 10/04/2004 09:10:41

Organization : jcaho

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BACKGROUND

see attached

CMS-4068-P-1321-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: Comments on the proposed rule that would implement the new Medicare Prescription Drug Benefit.

File Code: CMS-4068-P

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) appreciates the opportunity to comment on the proposed rule that would implement the new Medicare Prescription Drug Benefit. The Joint Commission is the nation's oldest and largest standard setting and accrediting body in health care. Approximately 17,000 health care organizations are currently accredited by the Joint Commission, including a preponderance of the hospitals in this country. Our accreditation programs also evaluate the performance of home care agencies; ambulatory care settings whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; hospices; assisted living residencies; clinical laboratories; and managed care plans. Further, the Joint Commission is active internationally and has provided consultation and accreditation services in over 60 countries.

The new Prescription Drug Program (PDP)—known as Medicare Part D—represents the most significant change to the Medicare program since its inception in 1965. It is evident that in the course of drafting the proposed rule, CMS staff had to address a myriad of new and complex issues associated with providing prescription drug benefit and integrating it

into Medicare's structure. Thus, we recognize the tremendous amount of work that has gone into the preparation of this proposed rule and commend CMS on a job well done. This letter addresses provisions in the following subparts:

- Subpart B related to the Part D information that CMS provides to Beneficiaries (§ 423.48).
- Subpart C related to the dissemination of plan information (§ 423.128).
- Subpart D related to quality assurance (§ 423.153(c)), medication therapy management (§ 423.153(d)), consumer satisfaction surveys (§ 423.156), electronic prescription program (§ 423.159), and the treatment of accreditation (§ 423.165, § 423.168, and § 423.171).

SUBPART B

Part D Information that CMS Provides to Beneficiaries (§ 423.48)

Background. Section 1860D-1(c)(3) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) directs CMS to provide Medicare beneficiaries comparative information on benefits and prescription drug formularies; monthly beneficiary premium; quality and performance; beneficiary cost sharing; and the results of consumer satisfaction surveys. Section 423.48 would implement section 1860D-1(c)(3) of the MMA. In the preamble, CMS notes that information on quality and performance, as well as consumer satisfaction surveys will not be implemented during the first plan year; or the next plan year, if the information is not available or it would be impractical.

JCAHO Comment. Providing comparative information on quality, performance, and consumer satisfaction is an essential component of informed consumer choice. Because PDPs are new entities that must be formed to meet MMA requirements, the Joint Commission realizes that CMS will need time to develop measures of quality, performance, and consumer satisfaction. Nevertheless, we urge CMS to provide Medicare beneficiaries this information as soon as possible. The Joint Commission recommends that CMS establish an advisory task force to develop measures that assess

The task force should include individuals from both public and private entities that have experience with the development of quality and patient safety requirements and performance measures. The Joint Commission has been a leader in the development of quality and safety requirements, and performance measures, for a variety of health care providers, including hospitals, home health agencies, and assisted living facilities.

We also encourage CMS to the use an incremental approach in the development of quality and performance measures. Some measures of performance might be readily available after the first year of implementation, such as (1) the average time it takes customer service staff to answer the phone and (2) how long it takes beneficiaries to receive mail-order pharmaceuticals. Other measures will take longer to identify and develop. Because of the importance of providing Medicare beneficiaries with information on quality and performance, we recommend this incremental approach.

SUBPART C

The Dissemination of Plan Information (§423.128)

Background. Section 423.128 establishes the information PDP sponsors and MA-PD plans must provide to current and prospective Part D enrollees. The information specified in § 423.128(b) must be provided to each enrollee in a clear, accurate, and standardized form at the time of enrollment and annually, at a minimum, thereafter. The plan information must include a description of the plan's quality assurance program, including the medication therapy management program.

JCAHO Comment. CMS needs to provide greater specificity on the content to be included in the description of a plan's quality assurance program. CMS needs to clarify what they mean by "standardized form." We believe that CMS' use of the term "standardized form" should mean that all PDP sponsors and MA-PD plans provide a description of the plan's quality assurance program and medication therapy management using the same format, terms, definitions, and type of information. Providing information consistently will help Medicare beneficiaries make informed choices and will help

individuals that decide to switch among plans better understand the new plan's quality assurance program.

SUBPART D

Quality Assurance (§ 423.153(c))

Background. Section 423.153(c) requires PDP sponsors and MA-PD plans to provide a quality assurance program. The program must include measures and systems to reduce medication errors and adverse drug interactions, and improve medication use. CMS is proposing that quality improvement programs include requirements for drug utilization review, patient counseling, and patient information record-keeping. CMS invites comment on (1) the use of quality assurance regulations that were specifically developed for the Medicaid population, (2) information on industry standards related to quality assurance that are above and beyond those mentioned above, and (3) the cost and challenges of requiring network pharmacy providers to comply with the PDP sponsor or MA-PD plan's quality requirements. CMS provided a number of "elements" of a quality assurance system and invited comments on the use of such elements. CMS also asked for assistance in defining the term "medication error."

JCAHO Comment. It is evident in the proposed rule that CMS is struggling with the balance of ensuring that PDP sponsors and MA-PD plans have a rigorous quality assurance program and the minimizing any burden such a program may impose. As a leader in the health care quality arena, the Joint Commission supports a thoughtful deliberative process in the development of quality assurance program requirements. We recommend that CMS develop a regulatory framework that provides an opportunity to expand the quality assurance program requirements over time, as more information is obtained about the new Part D benefit, PDP sponsors and MA-PD plans. As noted above, to develop a robust set of quality and performance measures, which would be part of the quality assurance program, we recommend that CMS establish an advisory task force.

Many of the elements listed by CMS as desirable for a quality assurance system are addressed by Joint Commission accreditation standards, performance measures, and

National Patient Safety Goals. The elements that the Joint Commission views as essentials for the new Medicare Part D program are: electronic prescribing, clinical decision support, bar coding, adverse event reporting systems, and provider and patient education. As noted below, electronic prescribing will be an invaluable tool in helping to ensure that patients receive quality and safe care. Because PDP and MA-PD decisions should be made on sound therapeutic choices and not on financial incentives or disincentives, clinical decision support is an essential element of any quality assurance system. The quality assurance system should be able to assess all licensed, independent practitioners' clinical decisions, as well as pharmacists' performance in adhering to the recommended clinical decision protocols. The Joint Commission also supports the use of bar codes. We encourage facilities that we accredit to adopt bar coding technology as a mechanism to avoid adverse medical events.

The Joint Commission is a strong supporter of reporting adverse events to help others learn from mistakes and near misses. To facilitate the reporting of such events, we advocate a non-punitive environment. The Joint Commission maintains a Sentinel Event database on all our accredited and certified organizations. We define a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." The phrase "or the risk thereof" includes a process variation for which a recurrence would carry a significant chance of a serious adverse outcome. After a sentinel event has occurred, the Joint Commission works with the organizations to conduct a root cause analysis. The root cause analysis helps the organization to identify systems that were place that might have contributed to the sentinel event. The sentinel event database enables the Joint Commission to aggregate data in order to identify patterns and trends. When a pattern or trend is detected, the Joint Commission issues a *Sentinel Event Alert* that is transmitted in both hard copy and via the internet.

In response to the profound lack of agreement on definitions of things that go wrong in the health care environment, the Joint Commission developed a "Patient Safety Event Taxonomy." This taxonomy has been adopted by the World Health Organizations. Refinements to the taxonomy are being supported by a grant from the Agency for

Healthcare and Quality. To decrease confusion, improve patient safety and promote quality, the Joint Commission recommends that CMS adopt the patient safety event taxonomy.

Patient safety event definitions used by the Joint Commission and our accredited facilities include the following:

- *An adverse drug event* is "a patient injury resulting from a medication, either because of a pharmacological reaction to a normal dose or because of a preventable adverse reaction to a drug resulting from an error;" and
- *A medication error* is "any preventable event that may cause inappropriate medication use or jeopardize patient safety."

The Joint Commission also recommends that CMS require that PDP sponsors and MA-PD plans' quality assurance programs include an oversight component that ensures vendors and practitioners document the therapeutic interventions. Finally, CMS needs to ensure that PDP sponsors and MA-PD plans have systems in place to ensure that pharmacist are given an appropriate span of control over support personnel (e.g., pharmacy technicians).

Medication Therapy Management (§ 423.153(d))

Background. The MMA requires PDP sponsors and MA-PD plans to establish Medication Therapy Management Programs (MTMPs). In the proposed rule, CMS states that "neither we, norm many private insurers, have extensive experience requiring or reimbursing for MTMPs." CMS asked for comments on requirements for MTMPs, as well as on mechanism for targeting individuals that would benefit from MTMPs.

JCAHO Comment. The Joint Commission appreciates the challenges CMS faces with developing requirements for MTMPs. Providing Part D MTMP services and integrating them with other Medicare programs, such as the chronic care improvement program, will be difficult. Nevertheless, MTMP services are a vital component to ensure that Medicare beneficiaries receive the benefits of Part D in a safe and effective manner.

Once again, we recommend that CMS establish a task force that includes external stakeholders to flesh out requirements for MTMPs. The Joint Commission would welcome the opportunity to help CMS establish requirements for MTMPs. As the nation's oldest and largest standard setting body, we have many insights that CMS would find useful. CMS might also find our experience with accrediting different types of health care providers that both dispense and purchase pharmaceuticals useful. Again, we recommend that CMS establish a regulatory framework that provides the flexibility to evolve MTMP requirements over time.

Consumer Satisfaction Surveys (§ 423.156)

Background. Similar to the Medicare Advantage program, CMS will conduct consumer satisfaction surveys of enrollees in a PDP or MA-PD plan. CMS will work with AHRQ to develop the survey instrument.

JCAHO Comment. Assessing consumer satisfaction is an integral part of Joint Commission accreditation surveys. In fact, the President of the Joint Commission has frequently voiced strong support for the development of HCAHPs for Medicare certified hospitals. It is our understanding that hospitals may be required to conduct and pay for HCAHPs. In contrast, CMS conducts and pays for satisfaction surveys for entities participating in the new prescription drug and Medicare Advantage programs. In the proposed rule, CMS provides no rationale for these two different financing approaches. The Joint Commission recommends that CMS be consistent in their policy regarding how the assessment of consumer satisfaction is financed.

Electronic Prescription Program (§ 423.159)

Background. Section 1860D-4(e) of the MMA directs the Secretary to establish an electronic prescription program. In consultation with key stakeholders, including standard setting organizations, the National Committee on Vital and Health Statistics (NCVHS) is directed to provide recommendations on uniform standards for e-prescribing that promote patient safety, quality of care, as well as cost savings. Voluntary "initial" standards are to be published by September 1, 2005, and final standards must be ready by

April 1, 2008. The law also requires the implementation of a pilot project unless there is adequate industry experience with whatever standards the Secretary is planning to adopt.

Electronic prescribing programs will be used by physicians to send prescriptions to pharmacies and by PDP sponsors and MA-PD plans to transmit data. Section 423.159(a) would require PDP sponsors and Medicare Advantage Organizations offering MA-PD plans to support electronic prescribing programs including any standards that are established before the drug benefit begins in 2006.

Section 423.159(b) of this proposed rule allows MA-PD plans to provide a differential payment to participating physicians who prescribe covered Part D drugs in accordance with electronic prescription standards.

JCAHO Comment. To promote patient safety and quality care, the Joint Commission is a strong supporter of the development of a health care information technology infrastructure. The Joint Commission recognizes that electronic prescribing is an important stepping-stone for achieving an information technology infrastructure. The Joint Commission can provide invaluable assistance in developing and promoting the use of electronic prescribing. Our experience in accrediting various types of health care organizations, developing performance measurement metrics, and issuing National Patient Safety Goals provides valuable insights that can facilitate the development and adoption of electronic prescribing. Presently, the Joint Commission's Home Care Accreditation Program accredits internet-based pharmacies which dispense millions of prescriptions each year. Since 1987, the Joint Commission has used performance measurement data in our accreditation process through the implementation of the ORYX initiative. In addition, each year the Joint Commission issues new program specific patient safety goals. All Joint Commission accredited health care organizations are surveyed for implementation of the goals and requirements—or acceptable alternatives—as appropriate to the services the organization provides.

The Joint Commission's National Patient Safety Goals are closely aligned with the goals that support the establishment of an electronic prescription program. For example, in an effort to reduce communication errors, the Joint Commission issued a Patient Safety Goal that requires a person receiving a verbal or telephone orders to verify the accuracy of the information by "reading back" the complete order or test results. A 2005 National Patient Safety Goal requires health care providers to accurately and completely reconcile medication use across the continuum of care. To achieve this goal, providers must develop a process for obtaining and documenting a complete list of patients' current medications upon admission. The process must include a comparison of the medications the organization provides with those on the patient's list. A complete list of the patient's medications must also be communicated to the next provider of service when it refers or transfers a patient to another setting, service, practitioner or level of care within or outside the organization. This patient safety goal will significantly increase the interest in the electronic prescribing effort within health systems when it is implemented in 2005.

The Joint Commission would like to work collaboratively with CMS to eliminate paper based systems and promote electronic prescribing as an integral part of health care delivery. The Joint Commission recommends that CMS establish a program to develop standards and measures that can be used to assess the performance of vendors that provide electronic prescribing and electronic medical record services to PDP sponsors and MA-PD plans. Given the Joint Commission's expertise, we are well positioned to assist CMS in the development of such a program.

Treatment of Accreditation (§ 423.165, § 423.168, and § 423.171)

Background. MMA directs that deeming an organization in compliance with Medicare requirement though accreditation for (1) access to covered Part D drugs including the pharmacy access requirement, the use of standardized technology, and formulary requirements; (2) quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse, and waste, and (3) confidentiality and accuracy of enrollee records. Section 423.168(d)(2) states that "CMS or its agent may conduct a survey of an accredited organization, examine the results of the

accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process."

JCAHO Comment. The Joint Commission acknowledges the need for continuing Federal oversight of approved accreditation organizations. Unlike validation surveys currently in use in the hospital program, concurrent and observational surveys can be far more effective in assessing an accrediting organization's performance. During a concurrent or observational survey, CMS, or its agent, can evaluate surveyor skills, the process employed, and their ability to communicate about opportunities to improve quality and patient safety. In contrast, when CMS conducts a "look behind" survey, the review is likely to be inconsistent and the information obtained outdated.

If you have any question or require additional information regarding the issues presented in this letter, please contact Trisha Kurtz, Director of Federal Relations, at pkurtz@jcaho.org or 202.783.6655.

CMS-4068-P-1322

Submitter : John Dingell **Date & Time:** 10/04/2004 09:10:20

Organization : Committee on Energy and Commerce

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

These comments are from Reps. Dingell, Rangel, Waxman, Brown of Ohio, and Stark. The comments relate to both Title I and II.

CMS-4068-P-1322-Attach-1.doc

October 4, 2004

Comments on Proposed Regulations
File Code [CMS-4068-P]

Title I NPRM, Medicare Program; Medicare Prescription Drug Benefit
42 CFR Parts 403, 411, 417, and 423

As the Ranking Members of the Committee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Government Reform, we respectfully submit the following comments on the Medicare Prescription Drug Benefit Title I Notice of Proposed Rule Making (NPRM) issued August 3, 2004.

It is important to note that we continue to oppose the Medicare prescription drug benefit in its current form. The alternative we offered would have established a guaranteed, comprehensive benefit in Medicare and would have avoided many of the pitfalls and complexities in the Medicare Modernization Act (MMA) as well as this proposed rule. Although we oppose this ill-conceived law, in the absence of any current legislative opportunity to fix its flaws, we believe the regulations should address many of these flaws to protect Medicare beneficiaries as much as possible. It would be wrong to use regulatory fine print to essentially take away the promised drug benefit for many seniors.

We are particularly concerned that the Centers for Medicare and Medicaid Services (CMS) failed to take regulatory steps to strengthen the underlying law. Such action is necessary to ensure that the central focus of the Medicare program remains its beneficiaries, and not the profit motives of the health care industry. There are a number of policies in the proposed regulation that make matters worse for beneficiaries, with examples being the appeals process and oversight activities. Additionally, CMS's failure to use its authority to protect against "cost-management" tools, such as limiting the availability of certain drugs or the number of prescriptions, ensuring broad access to pharmacies, protecting beneficiaries against improper marketing, or ensuring simple enrollment of low-income individuals, should be corrected. We highly support the expanded definition of who qualifies for the low-income benefit and the more lenient assets test. Pro-beneficiary provisions, however, were only discussed in the preamble and should be included in the final regulations.

We are also concerned that much of the detail necessary to implement Title I is either too vague or missing from the NPRM. The MMA is the most complicated change to Medicare in the program's history. We strongly recommend that CMS either (1) conduct a second Notice of Proposed Rule Making using a new proposal that incorporates changes based on this first round of comments or (2) issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of input.

Due to the complexity and abundance of provisions in the Title I NPRM, we are focusing our comments on the most important provisions. The lack of comments from us on a specific

provision should not assume that we support the proposed regulations. In fact, we wish to affiliate ourselves with the comprehensive comments submitted by Families USA, the Center for Medicare Advocacy, the Medicare Rights Center and other organizations representing beneficiary interests. We urge your careful consideration of the issues and comments raised by these groups. Our detailed comments on the regulations are as follows:

Subpart B – Eligibility and Enrollment

We are very concerned that the proposed enrollment process will result in mass confusion for tens of millions of beneficiaries. We urge CMS to make significant changes to this portion of the rule. In particular, CMS must expand the assistance for low-income beneficiaries and beneficiaries with special needs. Given the confusion that will surround the initial years of implementing this benefit, we urge CMS to delay the instituting of the late enrollment penalty provisions for the first few years. Also, a simpler process as well as additional support for information and counseling are needed to ensure the maximum number of beneficiaries are reached. We urge CMS to use its resources, and to work through Congress, to secure additional resources for beneficiary and provider education on these matters.

The proposed rule falls woefully short on enrollment issues pertaining to dually-eligible beneficiaries, i.e., those enrolled in both Medicare and Medicaid. On January 1, 2006, 6.4 million dual eligible individuals will be transferred from their Medicaid coverage to the new Medicare drug benefit. The rule fails to adequately address the timing and the mechanics of this mammoth transition. Automatic enrollment in the Medicare benefit will not begin until May of 2006, even though Medicaid coverage of these beneficiaries ends in January of that year. Without substantial outreach and education efforts prior to 2006, many dual eligible individuals will in all likelihood have no drug coverage for several months. This is unacceptable and we urge CMS to begin right away working with states to identify and notify dual eligible individuals as quickly as possible. We urge the Administration to protect this population from any temporary loss of coverage by implementing any steps necessary such as delaying the transfer and extending Medicaid coverage for additional months. If legislation is needed to accomplish this, you should act quickly to provide Congress with the necessary legislative language.

In order to best implement automatic enrollment, we believe the states should administer the process. States have readily available data and are already required to perform the low-income subsidy enrollment. Along with this added responsibility the States should receive a transfer of sufficient administrative funds to ensure this implementation is done properly and thoroughly. We believe that states should receive 100 percent federal funding for this activity. In addition, the federal government should work with the states to ensure each has adequate systems and data to accomplish this task expeditiously.

It is our view that dual eligible individuals should have special enrollment periods and they should be exempt from the late enrollment penalty should this complex process result in a coverage gap of more than 63 days. Based upon the experiences of beneficiaries under the current plan participation, we expect these beneficiaries will have coverage gaps resulting in frequent changes from one plan to another. An ongoing commitment by CMS and the

Administration is essential to ensure no loss or disruption of coverage during the annual open enrollment cycle. All of these protections should extend as well to those eligible for full or partial low-income subsidies.

We have grave concerns as to the effect of the new Medicare benefit on continuity of care for dual eligible individuals. The proposed rule would require dual eligible individuals to enroll in the "benchmark" or average plan without regard to whether that beneficiary's drugs are covered or whether the plan's coverage is appropriate for that individual. In addition, because the Medicare subsidy will only pay enough to cover the average plan, a beneficiary may be unable to afford a different plan that meets their individual needs. Plan formularies are expected to be less comprehensive than current Medicaid coverage, and this could force beneficiaries to switch medications. Not only would such a change be disruptive, but also very difficult for those with complex or serious medical conditions such as mental illness. We believe that CMS should retain coverage of medications for dual eligible individuals and other especially vulnerable populations. Plans should offer special formulary protections for these beneficiaries as well.

Disenrollment

We oppose CMS making it easier for plans to involuntarily disenroll beneficiaries from their plan. We also oppose CMS's new policy on disruptive behavior, and fear the resulting negative consequences for those with mental illnesses. CMS should clearly outline the requirements for plans seeking to involuntarily disenroll a beneficiary. These requirements should include notice requirements, reasonable efforts to resolve the situation prior to disenrollment, and documentation of the process. Involuntary disenrollment should not be permitted simply because an enrollee chooses not to comply with a treatment regimen cannot afford the cost sharing or decides to seek treatment which the plan does not support , including the decision of receiving no treatment. Moreover, if there is no other plan in a geographical area, a plan that involuntarily disenrolls a beneficiary must be required to readmit that person. To fail to do so would be contrary to the entitlement nature of this benefit.

Plan Information

We recommend CMS strengthen the section pertaining to information that plans must provide to beneficiaries. Merely issuing guidance on this is insufficient; CMS needs to issue regulations that are binding and enforceable. In order for beneficiaries to make an informed choice about their drug plan, they must have all the necessary information to evaluate the plan. Written plan information should be provided annually, including premium information (including portion, if any, applicable for low-income individuals), benefits and formulary structure, coinsurance or copayments for each drug, negotiated prices (so that individuals know how much they will pay in the coverage gap), participating pharmacies, comparative value of the plan, out-of-service options (and charges), appeals and grievance procedures, and general information on plan performance (including quality measures, information on grievance and appeals rates, and so forth).

Marketing Protections

CMS must ensure final regulations are thoroughly protective of beneficiaries, who are frequently victimized by marketing abuses and scams. CMS must detail the specific information it will require plans to include in their marketing materials, including which drugs are on the formulary, pricing, and premium information. Plans should be expressly prohibited from telemarketing (either by phone or e-mail). There have already been numerous reports of telemarketing fraud under the Medicare discount card and we do not want this perpetuated under the Medicare drug benefit. To further protect beneficiaries, plans should not be allowed to market "other" services to beneficiaries. Having these plans offer additional non-Medicare services would be confusing for beneficiaries, who might believe that CMS had approved these services. This would also make the task of comparing plans more difficult for beneficiaries. CMS must also limit provider or pharmacy-based marketing, as this has the potential for those with a financial stake in a plan to inappropriately steer beneficiaries to that plan. Finally, any organization that has a primary purpose other than improving the health of beneficiaries should not be permitted to act as a drug plan. In particular, financial institutions, which are exempt from the HIPAA privacy rule, should not be permitted to participate in the program.

Privacy

CMS should include in the regulation plans are prohibited from using enrollee and applicant information obtained in the Medicare drug card program during the marketing of prescription drug benefit drug plans. In addition, CMS must specify in the final rule how it will disclose any personally-identifiable information to plans. The disclosure of a beneficiary's personal information should be limited to the minimal amount necessary. Certainly no health or financial information should be disclosed. Nor should telephone numbers or e-mail addresses be disclosed because plans do not need this information and telemarketing is objectionable. Beneficiaries should be given the choice of whether they want this information disclosed. CMS should also make clear that if beneficiaries opt-out of having this information disclosed, they can still enroll in a plan and will still receive information from CMS, rather than the plans, about the benefit.

Creditable Coverage

CMS must establish specific requirements for what it means to have "creditable coverage." Creditable coverage is a determination of the whether a beneficiary's current level of prescription drug coverage is comprehensive enough that the beneficiary may decide to stay with that coverage rather than switch to the Medicare Part D drug plan without incurring adverse consequences. If CMS decides a beneficiary's current prescription drug plan does not qualify as creditable coverage and the beneficiary still decides to retain current coverage instead of joining the Medicare Part D coverage, and then later changes their mind and decides to enroll in Medicare Part D, that beneficiary will be subject to a late enrollment penalty. Thus, failure to properly set out the creditable coverage requirements and notify beneficiaries will result in permanently higher premiums for beneficiaries. CMS must develop standard notices for beneficiaries so that they will know when they are losing coverage, and should provide notice

through as many avenues as possible, including retiree statements, medical billing correspondence, etc. Any changes in an individual's coverage status must trigger immediate beneficiary notification. Individuals who are not appropriately notified must be allowed special enrollment exceptions and must not be penalized financially.

Subpart C – Benefits and Beneficiary Protections

Definition of Person

Throughout the debate on this legislation we expressed concern over the inability of third parties to assist with a beneficiary's out-of-pocket drug costs without penalizing the beneficiary. We believe the regulation should re-define "person" so that family members can pay for covered Part D cost sharing.

Treatment of HSAs

Regardless of our opposition to Health Savings Accounts (HSAs) and similar plans, we believe the final rule should not give preferential treatment towards contributions from these plans in order to reach catastrophic coverage by counting them as incurred costs toward coverage during the coverage gap. This is particularly true when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Treatment of ADAP and SPAP Subsidies

We not only believe that employer sponsored group coverage should be counted as incurred costs, we also believe cost-sharing subsidies from AIDS Drug Assistance Programs (ADAP) should be counted as incurred costs. Not counting these costs will make it nearly impossible for many individuals with HIV/AIDS to attain catastrophic protection under the law. Forcing beneficiaries to forgo these subsidies could be a significant barrier to their obtaining needed medications and would pose a substantial financial burden on these individuals, many of whom are low-income. We support the provision in the rule allowing State Pharmaceutical Assistance Program (SPAP) expenditures to count as incurred costs. ADAP assistance should also be treated this way.

Tiered Cost Sharing Limits

The MMA permits tiered cost sharing to encourage the use of preferred drugs when it is clinically appropriate. We are concerned about the provision in the proposed rule that would allow Part D plans to apply tiered cost sharing without any limits. We strongly recommend CMS set a limit for the number of cost sharing tiers plans can use. Otherwise, plans could effectively eliminate coverage of a medicine by placing it in an extremely high cost sharing tier, undermining beneficiary access. Allowing plans to have unlimited flexibility in cost sharing would provide yet another opportunity to discriminate against beneficiaries who need costly or multiple medications. Unlimited tiers would also further complicate the ability of beneficiaries to compare plans.

Enhanced Alternative Coverage

Similarly, we are opposed to the provision in the proposed rule for "enhanced alternative coverage." The law already provides for standard prescription drug coverage and alternative coverage with at least actuarially-equivalent benefits and access to negotiated prices. Having yet another level of coverage would further complicate plan comparison and make it impossible for beneficiaries to make informed choices.

Negotiated Savings

We believe the final rule should require that plans pass along all of their negotiated savings to beneficiaries.

Access to Pharmacies

We believe that the regulations should require that pharmacy access standards must be met in each service area; plans should not be permitted to apply the standards across a multi-region or national service area thus limiting pharmacies to which a beneficiary can have access. Plans should not be allowed to count providers not physically located in the service area toward meeting these requirements.

In the interest of encouraging provider participation to improve beneficiary access, we recommend CMS develop a standard model contract and require plans to use it with pharmacies. The final rule also must ensure pharmacy access standards for Native American populations, those in long-term care facilities, and those that use federally qualified health centers and rural health centers. Plans should not be allowed to discriminate through cost sharing or otherwise against beneficiaries that use these pharmacies.

Therapeutic Classes, Formularies, Prior-Authorization, and Cost Sharing

We believe CMS must be as aggressive as possible in using its authority under section 1860D-11(e)(2)(D) to review plan designs as part of the negotiation process to ensure they do not discriminate. We have commented separately to U.S. Pharmacopia (USP) on the need for a therapeutic classification system that is solidly protective of beneficiaries to ensure broad access to needed medicines. The USP draft guidelines were deficient in that regard. We believe CMS should set the highest bar possible in analyzing plan formularies, cost sharing tiers and levels and how they are applied to assure beneficiaries who need multiple or costly prescriptions, or whose use of certain drugs predicts expensive health conditions, are not discriminated against. The current rule does not do that and CMS must develop and publish standards that are legally enforceable regulations, not merely guidelines.

CMS should also publish in the final rule guidelines for plans regarding prior-authorization and step therapies which require a patient to try lower costs or preferred medicines first. CMS should publish a list of conditions for which it is clinically inappropriate to require step therapies.

Many state Medicaid programs exempt certain conditions from such requirements, including mental illness and HIV/AIDS. In addition, we strongly support the provision in the proposed rule that requires plans to provide special treatment to certain populations due to their unique needs. These populations should be exempted as well from formulary restrictions and protected against tiered cost sharing and other barriers that could limit access to medically appropriate medications. At a minimum, these protections should extend to dual eligible individuals, persons with life-threatening conditions, pharmacologically complex conditions, individuals in institutions, and other vulnerable populations.

Pharmacy and Therapeutic Committees (P&T) are the first step in the process of obtaining access to needed medicines. As these committees determine which drugs are covered, they must be unbiased and independent and the final rule should have stronger protections to assure this. Those who serve on the committees should have appropriate expertise in the care and treatment of the elderly and individuals with disabilities. The committee process should be transparent and open to the public and must provide for consumer input and involvement.

Beneficiaries must be properly informed, in advance of any plan changes to covered medicine, including cost sharing changes. We believe CMS should limit the ability of plans to make mid-year formulary changes that would restrict coverage. Beneficiaries should be provided advance notice of any formulary changes and, at a minimum, those directly affected by the change must be notified in writing. Written notice should extend beyond changes in covered medication, and should also be sent when the plan changes procedures for accessing a particular medicine. Plans must be required to provide beneficiaries needed information in the explanation of benefits. The final rule must be strengthened to require a description of appeal rights and processes in the explanation of benefits. Plans must provide formulary information to all Part D eligible beneficiaries, not just plan enrollees. This information is necessary for potential enrollees to assess the ability of a plan to meet their needs and should be available. This formulary information should include not only covered drugs, but which tier and the amount of co-payment required.

Healthcare needs are not restricted to business hours. The final rule should require plans to offer 24-hour/7 days per week toll-free call centers for beneficiaries and providers may call for informationIn addition, the final rule should strengthen emergency access standards, including requiring plans to cover a temporary supply of medicine and allow medicines to be filled at non-network pharmacies in the event of an emergency or other urgent situation. As with other emergency care, beneficiaries should not be penalized in these instances.

Subpart D – Cost Control and Quality

Prescription Drug Plans (PDPs) should be prohibited from using restrictive cost-containment tools such as dispensing limits, requiring prior authorization, or offering therapeutic substitution without constraint. These types of management and cost containment tools will only create an access barrier for Medicare beneficiaries in reasonable need, and attempting to obtain a prescription medication that their physician prescribes. Overall, this will result in more costs for the entire Medicare system in the form of sicker beneficiaries and increased hospital visits.

Administrator McClellan testified before the Senate Committee on Finance that beneficiaries would not be subject to dispensing limits, prescription limits or limits on maximum daily dosages. He should be held to this commitment because such cost containment strategies could fully undermine a beneficiary's ability to stay healthy and independent. Similarly, as the Preamble indicates, therapeutic substitution should be prohibited unless there is physician approval. And, any process for prior authorization that does not minimize the burden on beneficiaries and physicians and does not provide emergency supplies of medications will result in denials of needed prescription medications and harm to Medicare beneficiaries. Prior authorization requirements are most harmful to individuals with conditions requiring complex pharmaceutical protocols such as mental illness, epilepsy, HIV/AIDs, and cancer. All such populations should be exempt from prior authorization.

We believe the draft regulations provide excessively broad authority for the private Prescription Drug Plans to employ strategies that could potentially impair clinical quality and harm beneficiaries. There should be specific language included in the regulations that prohibits or limits the use of such potentially harmful strategies, for example placing overly restrictive limits on dispensing quantities or number of refills, engaging in therapeutic substitution without the advance knowledge and written concurrence of the treating physician, or employing prior authorization procedures that impose excessive burdens on beneficiaries and physicians. The approval and oversight of these cost-containment strategies should be the responsibility of the Pharmacy and Therapeutics Committee of each plan to ensure the clinical needs of the beneficiaries are the primary consideration. It is unfortunate that cost-containment mechanisms in the MMA and the NPRM appear to rely solely on utilization controls that could negatively affect access to needed prescriptions, rather than on efforts to reduce prices.

We recommend that the requirements be strengthened in the regulation for the Quality Assurance programs provided by the PDP and Medicare Advantage (MA-PD) plans. Specifically, we request that all plans, at a minimum, be required to include in their quality assurance systems specific elements that are current or recommended standards of practice (e.g., electronic prescribing, clinical decision support systems, adverse event reports, and educational interventions). We urge the collection of quality evaluative data that includes plan error rates and the results of the standardized consumer satisfaction survey. These data should be comparable among all plans and be available in a form that the public can easily understand. Finally, we request that any regulation established to provide incentive payments to a plan be based primarily on measures of quality or improved overall health of beneficiaries rather than their ability to reduce costs through reduced utilization.

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

Given the instances of collusion between drug manufacturers and pharmaceutical benefits managers or other plans that have been documented in the press and recent lawsuits, we believe the final rule must clearly prevent such abuses in the Medicare program. Groups affiliated with drug manufacturers and manufacturers themselves should be prohibited from providing the Part D benefit. CMS must stringently regulate the financial relationships between entities offering the Medicare prescription drug benefit and drug manufacturers, and this must be spelled out in the rule.

As stated earlier, we have many concerns about formulary issues and have provided separate comments on the U.S. Pharmacopeia model guidelines. We hope those guidelines will be strengthened to better protect beneficiaries. For plans that do not use those guidelines, we urge CMS to make clear in the final rule that CMS will not approve plans which develop its own formulary using fewer classes than what we hope CMS will allow and that those will be better than the USP guidelines. In addition, the proposed rule states that CMS will not approve plans that are likely to "substantially discourage enrollment of certain Part D eligible individuals." The word "substantially" only adds confusion and potential for legal action. We urge CMS to drop the word "substantially" from the rule. Cherry picking is an abuse that should not be tolerated; it should not have to rise to the subjective level of "substantial" before CMS will act. The Preamble suggests that CMS will only consider discrimination based on health status, not on other factors. We urge CMS to include a broader list of factors that could potentially discriminate against beneficiaries and to clearly state these factors in the final rule, not only in the Preamble.

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

We support the view in the Preamble that the federal preemption language should be applied narrowly and should not preempt state law where CMS does not have specific authority to regulate.

Subpart K – Application Procedures and Contracts with PDP Sponsors

We strongly support the anti-fraud provisions in this Subpart. We urge CMS to be as aggressive as possible in protecting beneficiaries and program funds from unscrupulous activities. We request that CMS clarify that annual audits must be conducted (not "may") and urge CMS to allocate appropriate resources to do so. We urge CMS to submit any additional legislative authority or resource requests to Congress quickly. We have already requested that the Appropriators provide a $25 million increase in the budget of the HHS Inspector General, in part to ensure adequate funding for new responsibilities brought on by the MMA.

Also in this Subpart, we ask CMS to reconsider the minimum enrollment requirements for plans. Plans with a very small enrollment base cannot adequately leverage discounts on drugs for beneficiaries or efficiently operate to meet the other plan sponsor requirements.

Subpart M – Grievances, Coverage Determinations, and Appeals

We believe that the NPRM fails to provide sufficient due process protections for Part D beneficiaries. These rules should not be less protective of beneficiaries than Medicaid or Medicare, yet they are as drafted. CMS must strengthen these provisions in the final rule to ensure appropriate due process for beneficiaries. As currently proposed, the rules are overly complicated and will not provide timely redress for beneficiaries, many of whom will be forced to go without necessary medications during the appeals process. Congress, on a bipartisan basis, supported strong appeals protections in the versions of the Patients' Bill of Rights that passed the Senate and the House in 2001. Medicare beneficiaries should be afforded equally stringent protections for their prescription drug benefits. To the greatest extent possible, the process should mirror the existing Medicare appeals process. Furthermore, in the settlement of *Grijalva v. Shalala*, CMS established a fast-track, pre-termination review by an independent entity. The proposed rule fails to incorporate such a process. We believe it must.

The review processes in Subpart M must be substantially simplified with revised timeframes that ensure beneficiaries do not go without necessary drugs during the review process. The proposed rule sets an exceptionally high bar for receiving an "exception." Plans should not be allowed to require additional criteria beyond what CMS outlines for receiving an exception. The regulations leave plans too much discretion in this area. The burden placed on physicians to produce clinical evidence is excessive and the level of evidence required may not be available in all instances. The weight of clinical evidence or the physician's experience must be considered and should suffice particularly where clinical evidence is lacking or contradictory. The burden should fall on the plan to show why the doctor's decision is not definitive.

The timeframes for exceptions and redeterminations for appeals are too long. To this end we suggest all reviews be handled on an expedited basis, allowing 72 hours each for re-determinations and independent review entity (IRE) consideration, and access to an Administrative Law Judge within seven days after IRE review. Extensions must only be allowed at the request of a beneficiary, not a plan sponsor. Plans should be required to make determinations regarding exceptions and notify the beneficiary within 24 hours, as required under Medicaid for determinations regarding prior-authorization requests. At the initiation of the review process beneficiaries must be provided a 14-day supply of the requested prescription(s) and receive immediate notice of their review rights. Most medications are prescribed for immediate use and delay in obtaining the medicine could have disastrous health consequences.

CMS must clarify in the final rule that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. If the IRE does not review the evidence and make recommendations based on its own analysis, enrollees are denied independent review and thus due process. Denials should be automatically sent to the IRE for review as they are in Medicare Advantage. Beneficiaries should be allowed to aggregate prescriptions in order to meet the monetary threshold for higher level review.

Enrollees should be able to initiate review orally and should be able to have an authorized representative submit appeals on their behalf. CMS must improve upon the notice requirement and content of the notice. Beneficiaries must be presented notice immediately upon denial. This notice should explain why coverage was denied, rights to appeal (and any limitation on filing an

appeal), and rights to obtain an interim supply of medication. The notice should also include the clinical or scientific basis for denial.

Subpart O – Intermediate Sanctions

Under the MMA prescription drug plans are created to administer the Part D benefit to seniors and individual with disabilities. While Medicare provides guidance, the PDPs have the authority to set formularies, set their cost sharing, set their process and standards for appeals, set drug prices, and attest that they are complying with Medicare rules. We have commented more specifically on these deficiencies in other parts of the letter; however, it is imperative that Congress and HHS provide strict oversight to ensure that PDPs act in a manner consistent with the goals of Medicare and in accordance with the rules and regulations eventually finalized by CMS, particularly given the latitude that plans currently have under the regulations.

Although the proposed rules establish four types of sanctions and six bases for imposing the sanctions, they do not provide guidance on which sanctions should be applied when. In addition, the sanctions are all permissive. To protect Medicare beneficiaries and the taxpayers against fraud, waste, and abuse, sanctions should be administered through a clear process and methodology and should be mandatory.

Additionally, CMS needs to ensure that it has the ability and data necessary to determine when a specific PDP is not in compliance with stated rules and regulations. CMS should not farm out to accreditation organizations or any other entity the role of overseeing plans. It should not rely on outside entities to review the work of PDPs or information that a PDP may submit. CMS should have a direct survey process to review PDPs to ensure that Medicare beneficiaries' trust in their Medicare coverage is not undermined by a few rogue private PDPs and lack of oversight.

Subpart P – Premium and Cost Sharing Subsidies For Low Income Individuals and S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

Special attention needs to be given to ensure that Medicare's low-income population and Medicare individuals with disabilities will not be made worse off than they are today. This is a vulnerable population and all protections afforded them today should be guaranteed through the regulations. Moreover, it is very important that dual eligible individuals, those that were previously on Medicaid and are now going to be covered under Medicare's Part D program not be harmed by the transition from Medicaid to Medicare. We applaud CMS for choosing to define Medicare Savings Program (MSP) beneficiaries, those not fully qualified for Medicaid but low-income enough to receive some benefits under Medicaid, as full subsidy eligible individuals under the statute.

First, institutionalized individuals should be defined to include all those receiving home and community-based services under a Medicaid waiver and receive all the benefits of an institutionalized individual under the MMA. Individuals receiving services under a Medicaid home and community-based waiver have already met the criteria for being in a nursing home and were just lucky enough to live in state that affords them the option of living at home and receiving services there to maintain them. Their continuity of care should not be disrupted because these individuals took advantage of a program alternative that Congress, the Administration, and States support.

Second, information and outreach is imperative to ensure that the low-income population and individuals with disabilities that were receiving Medicaid or were Qualified Medicare Beneficiaries are enrolled in a Part D prescription drug plan before 2006 when Medicaid stops providing prescription drug services to them. The regulations needs to clarify explicitly that states are required to notify all deemed subsidy eligible individuals of their status by July 1, 2005. The notice should have next steps, sources for information, counseling and assistance information in choosing a Part D plan and what that will mean for them. Each individual should

also be told of their right to appeal the subsidy level to which they are entitled. CMS should have learned a valuable lesson about information and outreach from the Medicare Prescription Drug Cards. Information and program enrollment processes must be simple, timely, and clear or else beneficiaries will not enroll. Low participation will not only signal another failure for Medicare, but it will put 6.4 million low-income individuals and individuals with disabilities at risk as today each of these persons is cared for under Medicaid.

Third, we applaud the Administration's belated recognition of the benefits of automatic enrollment in the Medicare prescription drug program. MSP beneficiaries should be automatically eligible for the low-income subsidy as reflected in the proposed legislation.

Fourth, individuals applying for the low-income subsidy should be automatically screened for other important benefits by SSA or Medicaid, wherever the individual applies. For example, individuals should be screened for Medicaid, the Medicare Savings Program within Medicaid, food stamps, etc. It is important as we spend money on outreach and education that CMS be prepared to reap the benefits in other programs, specifically for programs we have been concerned about low participation, such as MSP. The joint applications should be straightforward and streamlined and as much as possible require no additional documentation or forms for screening of additional programs. CMS can act on our concerns by making enrollment straightforward and easy and working with the U.S. Department of Agriculture and the Social Security Administration to ensure they too are screening people for all programs for which they may be eligible.

Within this joint application process, however, CMS should ensure that, with regard to MSP screening, applicants will be given the choice of opting-out of the subsidies. Because of complex income calculations under different assistance programs such as food stamps or Section 8 Housing, the low-income Medicare benefits could endanger an individual's ability to enroll in the other assistance programs. Some Medicare beneficiaries signing up for drug discount cards early on were later disqualified from housing and food stamps qualification because of the drug card's discounts and subsidies.

Fifth, once screened for benefits, CMS should require states and SSA to notify individuals of determinations within 24 hours of making them.

Sixth, it is imperative that MSP eligibility requirements be applied in a standardized manner within each state regardless of who is screening the individuals for MSP and thus automatically for the low-income subsidy. Under the regulations, it is likely that the Social Security Administration would apply a more restrictive assets and income test than a state for MSP eligibility and thus fewer people would be deemed eligible for the low-income subsidy. Such confusion and unfairness will undermine the low-income subsidy.

Seventh, low-income beneficiaries must be protected from excessive co-payments and premiums during the time it takes for plans to be notified that an enrollee is a subsidy eligible individual. The regulations affirm that low-income Medicare beneficiaries should be protected from the excess co-payments and premiums, but as written a plan only protects the beneficiaries

once they have been notified to do so. The regulations should extend the protection to beneficiaries who present their notice of approval for the subsidy to their pharmacies.

Subpart Q – Guaranteeing Access to a Choice of Coverage (Fallback Plans)

We are opposed to the overall framework of the drug benefit in its reliance solely on private insurance plans. We believe that a fallback plan will be critical for many beneficiaries in Medicare. We continue to maintain that in the absence of a private Medicare drug plan, every area should have a continuously operating "fall back" plan that is available to all beneficiaries. The Administration's aggressive attempt to limit the fallback option is disconcerting. We believe that CMS should interpret the statute as liberally as possible to ensure continual operation of fallback plans and minimal disruption for beneficiaries. CMS should ensure there is a level playing field for fallback plans as well. The Preamble states that CMS is contemplating tying performance payments to fallback entities to average discounts they are able to negotiate. This is a higher requirement than for non-fallback plans. CMS also discusses examining bidders' pricing structure and the nature of their arrangements with manufacturers to ensure there is no conflict of interest leading to higher bids. This requirement should also be imposed on private plans, as they too could engage in collusion. The Medicare Advantage program could benefit from CMS's thorough review of plan costs and payments like CMS is proposing for the fallback plans. Finally, barring fallback organizations from acting as a risk plan for 4 years is unacceptable and will be a significant dampening factor on any entity's willingness to bid for such a contract.

Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans

We strongly believe the retiree provisions in MMA do not go far enough to retain current levels of retiree coverage. Currently, one in four Medicare beneficiaries receives prescription drug coverage from their former employers. CMS needs to draft regulations that mitigate, and not exacerbate, these provisions in the law.

We urge CMS to adopt and enforce an actuarial equivalence test that assess both design and practice and has strong retiree protections. The regulations did not propose an actuarial equivalence test, but offered a few options of how CMS could approach the definition. Although we agree that this is a complex issue and appreciate the opportunity to comment on three options that CMS proffered, it is precisely because this is an important and complex issue that we will need time to review any final formula which CMS adopts as well. However, we tend to believe that the "two-prong" test in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit is a good starting point to prevent cost shifting to beneficiaries. In implementing the test, the employer plans should be limited to the extent possible from making mid-year changes to their formularies or cost sharing unless they certify that the benefit value continues to meet the actuarial equivalence test in order to continue to get the subsidy. Retirees should receive notification when they are offered a drug benefit that is inferior to the Medicare Part D benefit. Any material changes should be noticed 90 days prior to the effective date of the change. Retirees who are misinformed or improperly informed about the employers level of coverage (or when the employer's attestation was not filed in a timely manner) should not incur penalty for late enrollment.

To ensure oversight in this area, subsidies given to employers should be transparent and reporting in disclosure should be made public. In addition, employees should be permitted to challenge an employer's attestation that its plan is actuarially equivalent.

Subpart T – Changes to Parts 403, 411, 417, 460, and 442

The disclosure notice concerning Medigap H, I, and J policies must be concise and easily readable. As proposed by CMS, the notice contains unnecessary information that may be confusing for beneficiaries, in particular the information about Medicare Part D and the value of Part D benefits. We object to the subjective editorializing on the overall drug benefit contained in the CMS proposal. We would note that the National Association of Insurance Commissioners (NAIC) provided CMS with a model notice as required under the law, which CMS apparently chose to ignore. Given NAIC's expertise in Medigap issues, and the fact that the NAIC notice was developed in an open public process, we believe CMS should work more closely with NAIC on this matter and build off the NAIC draft. Finally, CMS should develop a separate notice for those who have creditable coverage that counts towards their drug benefit; their options will be different than those who do not.

We also support the extension of the physician self-referral rules to Part D drugs.

Comments on Proposed Regulations
File Code [CMS-4069-P]

Title II NPRM, Establishment of the Medicare Advantage Program
42 CFR Parts 417 and 422

The Ranking Members of the Committee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Government Reform respectfully submit the following comments to the Establishment of the Medicare Advantage Program Title II Notice of Proposed Rule Making (NPRM) issued August 3, 2004.

We remain opposed to the underlying premise of the Medicare Advantage (MA) program – excessive spending to expand private health plans in Medicare in order to undermine traditional Medicare. While we have historically supported giving Medicare beneficiaries the *option* of enrolling in managed care plans – an option that has existed since the mid-1970s – we feel strongly, however, that the government should not pay these options more than traditional Medicare. Our experience with Medicare+Choice (M+C) and HMOs that preceded the M+C program has consistently shown that private plans cost significantly more relative to the traditional fee-for-service program. In addition, numerous studies and data show lower quality of care, or care that is comparable to the traditional Medicare program. The Medicare Advantage program essentially codifies this past waste and guarantees that private plans will always be paid higher rates than the traditional fee-for-service program. Data from the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary and Medicare Payment Advisory Commission (MedPAC) show that payments to Medicare Advantage plans will average 115 percent of fee-for-service expenditures – 107 percent for the formula and an additional eight percent to reflect the healthier, less expensive population enrolled in the private plans. This year plans will get an additional $552 per beneficiary per month, for a total of $2.75 billion in excess of fee-for-service in 2004 alone.

Indeed, we find it ironic that the NPRM's Executive Summary asserts that the MA program will "advance the goal of improving quality and increasing efficiency in the overall health system." Yet the MMA and the NPRM appear to point us in precisely the opposite direction. Paying the private plans more than traditional Medicare gives the HMOs and other plans a financial advantage to lure certain beneficiaries out of traditional Medicare, while funneling scarce taxpayer dollars into the pockets of managed care stockholders and industry executives. Such practice will ultimately decimate the traditional Medicare program and limit beneficiaries' choice of providers, while increasing costs to the government and undermining access to care. Indeed, given the recent experience of the PPO demonstration project, we remain very concerned about the willingness and ability of the CMS to oversee plan behavior and even to enforce the law.

The winners and losers associated with this harmful policy are clearly reflected in the data in the NPRM. The Medicare Advantage program will cost taxpayers an additional $50

billion over the next ten years relative to what would otherwise be spent in traditional Medicare. Table 4 on page 46930 of the *Federal Register* projects that the administrative costs will total nearly $2.5 billion over the next six years (the narrative description of Table 4 just above incorrectly states the administrative costs to be $1.2 billion, but this total appears to leave out the $1.3 billion administrative cost to local plans). Averaged across the 145 plans that currently participate in Medicare Advantage, this means that each plan will be paid about $3 million annually just to administer the Medicare benefit. These administrative costs are very high relative to the traditional fee-for-service program; other data have shown private plans operate on an overhead of about 5 to 25 percent compared to approximately 2 percent for Medicare fee-for-service.

Beneficiaries do not receive such a generous windfall. Despite claims that Medicare Advantage plans will result in generous extra benefits to enrollees, Table 2 on page 46928 of the Federal Register projects that only $1.4 billion will be spent on extra benefits. When divided among the 4.6 million people currently enrolled in Medicare Advantage plans, this amounts to a little more than $50 per enrollee per year. If enrollment in Medicare Advantage grows as anticipated, this paltry amount will be greatly reduced.

Our overall objection having been stated, we offer the following comments on the NPRM to guide implementation of the Medicare Advantage program. It should be the agency's role to act as necessary through the regulatory structure to ensure that taxpayer funds are wisely spent and that the central focus of the Medicare program remains its beneficiaries, and not the profit motives of the health insurance industry. We recognize the enormously difficult task of writing regulations to implement this hopelessly and unnecessarily complex law. However, we are particularly concerned that CMS has not taken regulatory steps where possible to strengthen the underlying law; for example, we were discouraged that the MMA eliminated the requirement that health plans make a special effort to reduce racial and ethnic disparities in treatment. The Secretary should use his authority to reinstate this requirement in the regulations, especially in light of the controversy surrounding the initial issuance of a "sanitized" National Health Care Disparities Report last December. Left unchecked, the quality chasm that exists for people of color in our health system will only grow wider. In other cases, it appears that the Administration has weakened current beneficiary protections beyond the damage done in the MMA.

Due to the complexity and abundance of provisions in the NPRM and the fact that many provisions of interest are absent, we have chosen to focus our comments on selected provisions. The absence of a specific provision from our comments should not automatically imply support. We would like to affiliate ourselves with the comprehensive comments submitted by the Medicare Consumers Working Group and urge your careful consideration of the specific issues raised by these groups.

We are very concerned that much of the detail necessary to implement Title II of the Medicare Modernization Act (MMA) is either too vague or missing from the NPRM.

For example, the lack of information on the regions that will be used for the MA regional plan make it difficult to envision precisely how the proposed regulations would be implemented. We also note with interest your decision to omit any detail on the "Comparative Cost Adjustment

program" – otherwise known as Premium Support. While we acknowledge that it is not slated to take effect for several years, we remain interested in the Administration's thoughts on implementation of this controversial section of the MMA to which we remain strongly opposed. Absent details, it is impossible for us to thoughtfully critique your proposals or offer constructive suggestions while adhering to the spirit of the Administrative Procedures Act. The MMA is the most complicated change to Medicare in the program's history. There are many interactions with the existing law that need to be taken into consideration. Therefore, we strongly recommend that CMS conduct a second Notice of Proposed Rule Making, incorporating changes from this first round of comments and allowing for public comment on the additional details that are currently under development or issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of input.

Subpart A

Definitions

We note that you have reminded the public of the requirement that the PPO "provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers." Given the recent findings in the Government Accountability Office's (GAO) evaluation of the PPO demonstration, we are concerned that the agency is not effectively enforcing current law. The lack of oversight in today's more limited private plan environment does not bode well for the future as envisioned by the Administration and other proponents of the MMA.

User Fees

We support your efforts to increase user fees upon the plans in order to support beneficiary education, and urge you to collect the entire $200,000 and work with the Congress to either index it or otherwise lift the cap if needed to adequately inform beneficiaries about the new complexities associated with private plans. However, we remain concerned that there is still neither adequate nor guaranteed funding for the State Health Insurance Programs (SHIPs), and urge you to consider dedicating a portion of the MA and PDP user fee revenues in support of SHIPs. We also think it is important to provide beneficiaries with comparative information on plan quality and access, in addition to cost-sharing and other benefit differences. Finally, in light of GAO's finding earlier this year that some of the Administration's materials constituted "propaganda" and others had serious problems (including "notable omissions"), we urge you to share future beneficiary education materials with the Committees of jurisdiction prior to finalizing them for release.

Subpart B

Disenrollment

We are very concerned about provisions under Section 422.74, which will make it easier for plans to disenroll individuals for disruptive behavior. These provisions should be removed. It is easy to imagine people with Alzheimer's, highly disturbed individuals (e.g., a patient undergoing a severe episode of psychiatric illness) and others who will be at risk of benefit termination. In addition, the NPRM asks for comment on whether plans should be able to involuntarily disenroll beneficiaries for non-payment of cost-sharing. While the NPRM asserts that care would be taken to protect "low-income" individuals and limit the authorization of this only to "significant" amounts, neither term is defined and the entire concept is problematic. This proposal should be rejected from additional consideration. Not doing so would place beneficiaries with high medical costs who may be temporarily unable to pay their cost-sharing at high risk of termination of plan benefits; unless the disenrollment occurred shortly after initial enrollment, most may be unable to find other supplemental coverage. Taken together, these new terminations would allow MA plans to dump the most expensive cases by transferring sicker, more costly patients into the traditional Medicare program. Of equal concern, these newly facilitated terminations would also cause unnecessary disruptions in beneficiaries' clinical care. We urge you to drop the provision in the NPRM that makes it easier for HMOs, PPOs and other private plans to stop serving people with mental illness or other complex conditions, and to stop pursuing additional opportunities to help private insurers at the expense of beneficiaries with high medical bills.

Marketing materials

We strongly oppose the decision by CMS in the NPRM to expand the "File and Use" program for MA plan marketing materials. Giving CMS just five days in which to "review" the materials abrogates important agency oversight and enforcement responsibilities, leaving the agency no choice but to rubber stamp all materials. This timeframe is wholly insufficient to ensure that prospective and current beneficiaries receive accurate, clear materials from MA plans. All MA plan marketing materials should be thoroughly reviewed by CMS to ensure plans are not using misleading tactics to cherry-pick or otherwise attract only the healthiest individuals. Marketing requirements should be strengthened, not weakened. Given both the track record of the private insurance industry with this population and the unique circumstances surrounding marketing to an older population, it is critically important that materials be straightforward and useful to prevent widespread abuses. We suggest MA plans present all marketing materials at least 30 days before proposed distribution, and that plans are in no circumstances allowed to distribute materials without the express written approval from CMS.

Subpart C

Basic Benefits

It is unfortunate that the NPRM fails to provide guidance regarding acceptable levels for the single deductible and catastrophic coverage levels required by the regional MA plans. Lack of guidance implies that the agency is willing to accept any level for these triggers. Relying on the ability of the agency to deny a plan only if it "substantially" discriminates in setting these

levels is an unrealistic response. We urge you to include additional detail or suggestions on these new requirements when the next regulation is published.

We are pleased that you intend to require that plans track the beneficiary cost-sharing in order to trigger the unspecified deductible and catastrophic coverage, and we hope that the notification requirements will be clear, promptly issued, and enforced. It is not clear how you intend to differentiate between "incurred" and "paid," but we urge you to choose a definition which ensures that all cost-sharing paid by or on behalf of a beneficiary is counted and tracked.

Disclosure Requirements

Beneficiaries must have ready access to current lists of contracting providers – both as prospective enrollees and once enrolled – with a clear distinction for which providers are preferred versus non-preferred, as applicable. Plans should provide information to current and prospective enrollees without any subjective judgment about those who are "reasonably expected" to enroll.

We do not object to requiring MA plans to establish Internet sites, but want to reiterate that such actions should supplement, not supplant, requirements to provide information in other forms and forums (e.g., written information via mailing, toll-free help lines, etc.). Data indicate that the vast majority of beneficiaries do not have access to or have working knowledge of the Internet.

Access to Services

We oppose the elimination of Section 422.112(b), "Rules to Ensure Continuity of Care." Among other things, these provisions guarantee that beneficiaries are receiving at least minimal levels of care from Medicare Advantage plans, such as providing enrollees with an ongoing source of primary care, ensuring that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health, and providing beneficiaries with an initial assessment of enrollees' health care needs. These are not "unnecessary" or "overly burdensome" provisions, as implied in the NPRM. In fact, continuity of care is what managed care plans allegedly *do*. And since Medicare pays the Medicare Advantage plans its fees each month regardless of whether a beneficiary receives care, maintaining these minimal requirements is imperative. While MA plans are required to cover all Medicare-covered services, even if provided out-of-network (OON), we are not sure what is meant by requiring all plans to offer beneficiaries "reasonable access to in-network cost-sharing" under certain circumstances. It appears that this is a nod in the right direction toward protecting beneficiaries from higher cost sharing, but we are not certain how that would be defined and what its practical effect would be. We urge you to elaborate on this proposal in the next publication on these regulations. In addition, we are concerned about the proposals to relax network adequacy and its potentially negative effect on beneficiaries in rural areas.

The proposal in the rule to tie allowable cost-sharing levels to the "robustness" of an HMO's provider network raises a number of issues. Beneficiaries need to be both protected in terms of access to *and* affordability of benefits. We are also concerned with how these trade-offs will be conveyed to beneficiaries in a manner to allow effective comparison among options. We

urge you to take a position that protects beneficiary access to care and minimizes cost-sharing. We are paying too much for these plans to allow beneficiary overcharges, too. Given the recent GAO report on PPO overpayments, we hope that CMS will strengthen beneficiary protections to ensure that beneficiaries are not overcharged by plans (relative to fee-for-service) for benefits, either in-network or out-of-network, and that access to covered benefits is not restricted by private insurance companies.

Subpart D

We strongly recommend that the requirements for MA plans to engage in quality improvement efforts be significantly improved. More specifically, we request that all plans be required, rather than encouraged, to participate in CMS and HHS quality improvement initiatives, that currently required (e.g. HEDIS) and any newly developed quality reporting data be collected in a manner that would allow comparisons among all programs, and that all quality data be available in easily understandable form to the public.

Quality Improvement

We object to efforts to undermine quality improvement activities by limiting the agency's ability to require data or otherwise weakening current activities. While the MMA appears to reduce the agency's ability to oversee these efforts, we support the agency's statement in the preamble that HEDIS and other tools can still be modified and improved as needed. We hope that this statement translates into the regulation itself.

You ask for comments on whether plan data should facilitate comparisons among all plans or just similar plans or plan types. We strongly urge you to require that data be compiled, analyzed and reported in a fashion to allow beneficiaries to compare across all plans. For those who have choices, it will be important for them to make an apples-to-apples comparison among their various options. Providing information by type of plan will make this task more difficult.

The NPRM's proposal to eliminate requirements relating to minimum performance levels and those that address clinical and non-clinical areas is deeply troubling; we urge you to reconsider.

Given the high level of payment provided to MA plans and claims that private plans provide superior care (relative to traditional Medicare), we believe it is important for the regulations to be as aggressive as possible in requiring the plans to prove their worth. Sadly, it appears that many provisions do the reverse. By allowing plans to pick their quality projects, manipulate samples for those projects, and rely on data from non-Medicare enrollees, it will be more difficult than ever to accurately and adequately assess plan quality.

We urge you to define what constitutes "measurable and sustained improvement" for quality, and to reject the NPRM's decision to gauge success by a "we know it when we see it" standard. If the MMA's efforts to dramatically increase enrollment in MA plans is successful, oversight and enforcement of quality measures could mean the difference between life and death for millions of beneficiaries.

Finally, we are very concerned about the possibility that the agency would further outsource its oversight to private accrediting bodies. We have seen problematic trends in other provider categories (e.g., JCAHO) and strongly believe that CMS should be doing more, not delegating more.

Preferred Provider Organizations (PPOs)

Generally speaking, all standards should apply to all plans – local, regional, HMO or PPO. With few exceptions, there is no supportable rationale for holding local and regional plans to different standards for performance, quality, data collection, reporting or other important activities. PPOs and HMOs are both serving beneficiaries, and as such, should be held to the same standards.

Subpart E

The MMA essentially eliminated requirements that limited the ability of plans to threaten or bribe physicians to provide less care (called "physician incentive plans" or PIPs). Last August, prior to the MMA's passage, CMS significantly weakened the regulations by eliminating routine reporting and replacing it with a requirement merely that the information be made available on request. Now, MA plans need only "assure" CMS that they aren't engaging in abusive behavior. Unfortunately, the NPRM fails to address the statutory requirement that plans provide sufficient assurance providers are not paid or otherwise financially rewarded to withhold needed care; we strongly suggest that the final rule explicitly require plans to attest their compliance with the physician incentive plan law. This will make the "assurances" meaningful, with virtually no additional regulatory burden, as false certifications will fall under the False Claims Act. CMS should monitor compliance during audits, and expressly state that non-compliant plans will be fined or dropped from the MA program.

Subpart F

This section needs much greater detail before interested parties can provide useful comment. That said, we are concerned about the lack of discussion around the certification process and whether this will hamper the government's ability to conduct proper oversight.

Beneficiary Premiums

On page 46898, there is discussion around premium payment options for beneficiaries. We think it is very important that plans and CMS make it clear that additional charges may apply if beneficiaries do not choose to have their premiums deducted from their Social Security checks. This need to be conveyed clearly and in writing before another option is exercised; plans should be required to state the precise charges that will apply for any other options.

Risk Adjustment

You ask for comment on whether risk adjustment should be done on a plan-specific basis or state-specific. We believe it is important to focus on the actual enrollment in the plan and employ a plan-specific approach. This is especially important given the issues resulting from service areas that cross state borders and the desire that a risk adjuster accurately reflect the health of actual enrollees (and adjust the plan's payments accordingly).

Subpart G

Risk Adjustment Data

We strongly object to the NPRM's proposal to move from the current practice of encounter-level data to targeted risk-adjustment data. It is imperative that sufficient and representational data be provided by the plans so that appropriate risk adjustment mechanisms can be designed and implemented. We are well aware of the historical risk adjustment problems and resulting overpayments that occurred with both Medicare+Choice and precursor plans. It is possible, if not likely, that the risk adjustment mechanism may change over time; without broad access to encounter-level data, however, such a change may be impossible, even if it may lead to a better approach. Among alternatives that should be considered are requirements to ensure that the submitted abbreviated samples are representational of the plan's population, or, even better, that the plans submit clinical severity data for the entire population.

Subpart J

This section deals with rules for regional managed care plans. We note again here that the lack of specificity in the proposed rule that makes it difficult to envision this new system regional plans. However, we would note that we are concerned in establishing regional plans with any waiver of state licensing requirements in the states that they are operating. We urge you to be as conservative as possible in deciding how long to waive state licensing requirements as described on page 46907. Knowing that health insurance industry is aggressively objecting to multi-state certification, even though they may be serving beneficiaries in multiple states, we are keenly interested in making sure that these plans are held accountable under the state laws in which they are operating.

Subpart M

We are very concerned that beneficiary grievance and appeals rights be protected and, if possible, improved in light of the expected increase in private plan enrollment. Unfortunately, this NPRM raises a number of issues with respect to obtaining and enforcing these rights. We write to specifically align ourselves with the detailed comments provided by the Center for Medicare Advocacy.

Advanced Beneficiary Notices

We appreciate your solicitation of comments with respect to whether providers (both network and non-network) should provide advanced beneficiary notices (ABNs) for non-Medicare services. We believe these notices should be provided, as they would be for beneficiaries in traditional Medicare. We also strongly support inclusion of a requirement that MA plans provide ABN-like notices to alert beneficiaries to the higher charges that may result by using non-network providers.

CMS-4068-P-1323

Submitter : Dr. Bohn Allen **Date & Time:** 10/04/2004 09:10:08

Organization : Texas Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Comments of Texas Medical Association on CMS-4068-P; Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule ? General Provisions (Electronic Prescribing)

CMS-4068-P-1323-Attach-1.doc

October 4, 2004

Honorable Mark B. McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–4068-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4068-P; Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule – General Provisions (Electronic Prescribing)

Dear Dr. McClellan:

On behalf of the more than 39,500 physician and medical student members of the Texas Medical Association (TMA), I am writing to comment on the aspects of the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Medicare Prescription Drug Benefit," see *69 Fed. Reg. 46,632* (Aug. 3, 2004) that pertain to electronic prescribing. TMA appreciates this opportunity to comment on these important aspects of the proposed rule. We look forward to working with CMS to ensure that these provisions are implemented in a manner that reflects our concerns.

TMA is the largest state medical society in the nation, representing more than 39,500 physician and medical student members. It is located in Austin and has 120 component county medical societies around the state. Founded in 1853, TMA's vision is to improve the health of all Texans. TMA aggressively supports Texas physicians by providing distinctive solutions to the challenges they encounter in the practice of medicine.

TMA generally supports the principles of electronic prescribing outlined in the Medicare Modernization Act of 2003 (MMA). We believe that electronic prescribing offers significant potential to improve the quality of health care by reducing medication errors, improving practice efficiency, and increasing patient therapeutic compliance. However, we are concerned that, in light of CMS's apparent interest in implementing at least some aspects of e-prescribing in conjunction with implementation of the Part D benefit in 2006, the agency will decide to move ahead with these provisions of the MMA without including appropriate safeguards to protect the interests of patients, the intended beneficiaries of this new technology.

Congress was obviously aware of the potential threat that this technology poses to patient and physician autonomy and specifically addressed this concern in the legislation. In particular, the MMA requires that electronic prescribing standards "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse drug interactions, and to improve medication use." *§ 1395w-104(e)(3)(D)*. Similarly, the accompanying Conference Report states that, under electronic prescribing, physicians should have access to "neutral and unbiased information on the full range of covered outpatient drugs," and that Congress did not intend for e-prescribing "to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians." *H.R. Conf. Rep. No. 108-391, at 455-56*.

We also note that physicians and other health care professionals have raised similar concerns during the public hearings conducted recently by the National Committee on Vital and Health Statistics (NCVHS). In its report to Health and Human Services Secretary Thompson, the NCVHS acknowledged these concerns, but made only general suggestions for their consideration. To wit (*pp 13-14*):

> **Observation 15 (Policies to Remove Barriers)**: Testimony identified widespread industry concerns relating to safe harbor, preservation of provider/patient choice, and freedom from commercial bias in messages received through e-prescribing applications.
> *Recommended Action 15.1*: HHS should ensure that regulations define the parameters of safe harbor, ensure preservation of provider/patient choice, and require that e-prescribing messages received through e-prescribing applications be free from commercial bias.

Again, we are concerned that the NCVHS recommendation do not provide sufficient detail to protect patients' interests adequately.

Consequently, we propose the following for your consideration:

1. Strictly prohibit inappropriate commercial messaging:

We urge CMS to establish regulations that will create a zone of autonomy that surrounds the physician-patient relationship and protects that relationship from commercial messaging. We recommend that CMS adopt a broad definition of commercial messaging that would extend beyond traditional advertising and include any non-clinical messaging from any third party that is aimed at influencing a physician in the act of prescribing (unless such messaging relates to information that was unknown and impractical to provide to the physician before the original prescribing decision was made) or a patient in the act of selecting a dispensing pharmacy. These policies would prohibit commercial messaging that:

- Tries to reverse a physician's intended selection at the point of prescription. We strongly believe that physicians and their patients should be advised of all clinical and financial issues related to the writing of a prescription *prior to* making a decision. But once a physician has made an informed selection, messaging should not be used to seek to change the physician's decision based on any party's financial interest. That does not add clinical value nor does it contribute to efficiency.
- Tries to influence a physician's prescribing decision simply because the electronic system has determined that the physician has indicated he or she is *about to* prescribe a drug from a certain category. This clearly would be inappropriate and would constitute unrelated messaging that is proscribed under the MMA.

2. Present formulary information in a neutral manner:

As noted earlier, the MMA requires that physician have access to "neutral and unbiased information on the full range of covered outpatient drugs." We believe that this means that, when physicians prescribe a drug, they should be presented with all pertinent information *at the beginning of the prescribing process*, including the complete list of drugs normally used to treat a particular condition. While accurate formulary information helps inform the physician's decision, formulary presentation should not be used to exert untoward influence on the prescribing process. Specifically,

- The list should indicate which drugs are on-formulary-preferred, on-formulary but not preferred, and entirely off-formulary.
- The e-prescribing interface should not attempt to unduly influence physicians' selections before they have been fully informed of the complete range of choices.
- The interface should not make it less likely that the physician will see the names of drugs that are on-formulary-not-preferred or off-formulary, but which may offer better efficacy and tolerability for the patient.
- The interface should not require the physician to take extra steps to prescribe drugs that are on-formulary-not-preferred or off-formulary, but which may offer better efficacy and tolerability for the patient.

3. Require plans to provide real-time prior authorization:
Obtaining accurate and timely prior authorization from health plans has been one of the worst headaches physicians and patients have experienced with managed health care plans. That is the case whether prior authorization involves medications, therapeutic or diagnostic procedures, or hospitalizations. It is vital that CMS take steps now to avoid those headaches when physicians begin to utilize electronic prescribing broadly. We believe that can be accomplished via real-time prior authorization of off-formulary medications.

The MMA clearly indicates a preference for the use of "real-time" information delivery with regard to this technology, specifically requiring that, "[t]o the extent feasible, the information exchanged [via e-prescribing] shall be on an interactive, real-time basis." *42 U.S.C. § 1395w-104(e)(2)(D)*. Additionally, the Conference Report states that "prescribing health care professionals [are] to have ready access" to prescribing information. See *H.R. Conf. Rep. No. 108-319, at 455*. Informing physicians electronically that prior authorization is required, but then forcing them to use non-electronic means to seek such authorization (e.g., telephones and faxes) would impose a significant burden on physicians and may influence their ultimate prescribing decisions. In contrast, real-time prior authorization would address the clinical bases for requiring prior authorization without unduly interfering with the patient's ability to receive the drug that the physician has deemed to be most appropriate.

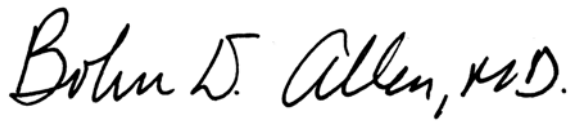
4. Move quickly in writing regulations for Section 108 grants:
In the proposed rule, CMS is seeking comment on ways to "spur adoption of electronic prescribing, [and] overcome implementation challenges." See *69 Fed. Reg. at 46671-72*. The literature clearly indicates that physician reluctance to invest in an unproven technology has been and is currently hindering adoption of electronic prescribing. For example, the eHealth Initiative's report, *Electronic Prescribing: Toward Maximum Value and Rapid Adoption (p. 10)*, states: "Key barriers to clinician adoption include startup cost, lack of specific reimbursement, and fear of reduced efficiency in the practice."

The MMA authorizes $50 million in 2007 for matching grants to physicians to implement electronic prescribing. *42 U.S.C. § 1395w-108.* Physicians may use these funds to procure relevant computer software and hardware, to upgrade existing computer systems, or for education and training.

We believe that making physicians aware of these funds, and how to apply for them, as soon as possible will help to overcome those barriers and spur adoption of electronic prescribing.

In conclusion, the physicians of TMA appreciate the opportunity to comment on these important issues. We urge you to address these concerns in a manner that protects the patient-physician relationship and otherwise furthers the underlying purposes of the MMA. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,



Bohn D. Allen, MD
President

BDA:sl

CMS-4068-P-1324

Submitter : Mr. Tim Gallagher **Date & Time:** 10/04/2004 09:10:09

Organization : Astrup Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to make some brief comments in regard to the proposed rule to provide for a prescription drug benefit under Medicare part D.

My first comment is that I applaud the effort to provide prescription drug coverage for Medicare beneficiaries. My main concern is that too much control over the benefit has been handed to the plan sponsors or PBM's, many of whom own their own mail order pharmacies. If these entities are allowed too much freedom in developing and implementing the program you will be dealing a death blow to community pharmacies as we know them today. The PBM's will do everything they can to push beneficiaries to their own mail order pharmacies which will have a devastating effect not only on local pharmacies but also on pharmacy services to seniors in this country, the outcome of which will be a tremendous increase in long-term healthcare costs. I strongly urge CMS to closely supervise the plan sponsors with assistance from national pharmacy organizations to ensure that the implementation of the benefit is achieved in a manner which is in the best interest of patients without harming local pharmacies.

Specifically, I have the following concerns:

Negotiated price concessions from drug manufacturers must be passed on to Medicare beneficiaries. Only a small portion should be allowed to be kept by the PBM's. All payments and discounts to PBM's should be disclosed to CMS. It is only through total transparency that we can keep these entities honest. Any objections that price transparency will lead to increased costs is utterly absurd. Price disclosure in any industry only leads to increased competition and lower costs.

The PBM's cannot be allowed to use the discounts and rebates they receive from pharmaceutical manufacturers to unfairly force patients away from their local pharmacies to their own mail order facilities. Patients must be allowed to go to the pharmacy of their choice where they have an established patient-pharmacist relationship.

PBM's must be required to pay pharmacies a resonable dispensing fee to cover the overhead costs of dispensing a prescription. The latest sudies show that the overhead costs of dispensing a prescription in Minnesota are approaching $8.00/prescription. Some of the current contracts being offered include dispensing fees as low as $1.00, which again is a tool used to drive pharmacies out of business and patients to mail order.

The proposed legislation has a provision for payment of medication therapy management services (MTM). We strongly support this aspect of the proposal. The development of the components of MTM programs however, must be done in conjunction with national pharmacy organizations. If left to plan sponsors, many patients who need these services will not receive them, plan sponsors will attempt to provide them over the telephone with their own employees and those pharmacies that are paid for these services will not receive adequate remuneration. These services need to be billed electronically using the standard ASC X12N 837 government billing format and be HIPAA compliant. In order to achieve this the MTM services should be assigned CPT codes and pharmacists need to be assigned national provider numbers.

Finally all plan sponsors/PBM's need to produce cards for beneficiaries that are in the standard NCPDP format to avoid confusion and excessive wait times for prescriptions.

Again, I srongly applaud the efforts behind the development of a Medicare prescription drug benefit, but caution you that if not implemented with prudence, it will amount to nothing more than a windfall for PBM's and a huge expense for the Government with very little benefit for patients.

Sincerely,

Tim J. Gallagher
VP Pharmacy Operations
Astrup Drug, Inc.
Austin, MN

Submitter : Mr. Jerrold Hercenberg **Date & Time:** 10/04/2004 09:10:51

Organization : BeneSolutions, LLC

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

BeneSolutions,LLC
607 14th Street, N.W. Suite 900
Washington, D.C. 20005
202-508-5835 Direct

October 4, 2004
VIA EMAIL
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 4068 (Part D Regulations)
CMS 4069 (Medicare Advantage Regulations)
Baltimore, MD 21244-8014

Dear Sirs/Madames:

This letter is to provide comments on both of the above referenced regulations. BeneSolutions is a benefits consulting firm that specializes in Medicare related solutions for large sized private and public companies and public entities that operate retiree health plans for state and local government. We appreciate the opportunity to submit comments on the regulations. These comments are divided into two parts: Part I addresses comments related to the Part D: Prescription Drug Regulation (CMS 4068) and Part II addresses comments related to the MedicareAdvantage Regulation (CMS 4069).

PART I: PART D REGULATIONS ? CMS 4068

A. Subsidy Program (Regulations Preamble Subpart R)

CMS is considering three alternative rules that would govern whether a subsidy is available to an Employer Group Health Plan (EGHP) that covers retirees with primary Medicare coverage. For some state and local governments, if their percentage contribution is not more than 50% of the cost of the prescription drug coverage, CMS contemplates excluding them from the subsidy program. This will eliminate many plans that are primarily financed by retirees but provide an economical means for such coverage. Following are the three rules under consideration:

? Single Prong (Gross Value) Test ? under this criteria, an Employer Group Health Plan (?EGHP?) would only have to demonstrate that the gross value of its covered prescription drug benefits would be actuarially equivalent to the standard Medicare benefit offered under Part D;
? Modified Single Prong Test ? under this criteria, it would use the same actuarial equivalence as the single prong test, but would limit the amount paid to an employer to its contribution. Under this test if a benefit plans gross value was $1,000 but the employer?s contribution was only $500, then CMS would limit the subsidy to $500, not the average $611. CMS has acknowledged that it may not have authority in the MMA to apply this test.
? Two Prong Test ? under this qualification criteria an EGHP would have to demonstrate a) that the total plan payout for the average Medicare beneficiary exceeds the value of the benefits
provided by Part D (benefits are actuarially equivalent) and, b) that the net value of the benefits provided to beneficiaries without beneficiary financing would exceed the subsidy or the average subsidy provided by Medicare ($611 per year).

Issues/ Comments ? Substantial numbers of employers no longer finance the full cost of retiree health benefits but still either finance a portion of the costs (through a defined contribution program) and enable savings to retirees through group purchasing arrangements or provide benefits through a defined contribution plan or capped contribution program. Often, EGHPs provide the financial cash flow for these plans and expect to be reimbursed for excess costs above its own contributions by the plan beneficiaries. If these arrangements are not economical to the beneficiary in comparison to arrangements available in the individual insurance marketplace, then retirees can drop out of the EGHP and have the option to enroll in Part D with a PDP or a MAPlan regardless of whether the group retiree health plan contracts with such alternative or offers alternatives that are less attractive and beneficial to its members.

CMS should not use the subsidy regulations to interfere with how contributions and financing of EGHPs are determined and should not dictate or interfere in the way that a subsidy payment received by an employer is allocated to the plan contributors. For example, in a Taft-Hartley type of p

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BENESOLUTIONS, LLC

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October 4, 2004

VIA EMAIL
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 4068 (Part D Regulations)
CMS 4069 (Medicare Advantage Regulations)
Baltimore, MD 21244-8014

Dear Sirs/Madames:

This letter is to provide comments on both of the above referenced regulations. BeneSolutions is a benefits consulting firm that specializes in Medicare related solutions for large sized private and public companies and public entities that operate retiree health plans for state and local government. We appreciate the opportunity to submit comments on the regulations. These comments are divided into two parts: Part I addresses comments related to the Part D: Prescription Drug Regulation (CMS 4068) and Part II addresses comments related to the MedicareAdvantage Regulation (CMS 4069).

PART I: PART D REGULATIONS – CMS 4068

A. Subsidy Program (Regulations Preamble Subpart R)

CMS is considering three alternative rules that would govern whether a subsidy is available to an Employer Group Health Plan (EGHP) that covers retirees with primary Medicare coverage. For some state and local governments, if their percentage contribution is not more than 50% of the cost of the prescription drug coverage, CMS contemplates excluding them from the subsidy program. This will eliminate many plans that are primarily financed by retirees but provide an economical means for such coverage. Following are the three rules under consideration:

- **Single Prong (Gross Value) Test** – under this criteria, an Employer Group Health Plan ("EGHP") would only have to demonstrate that the gross value of its covered prescription drug benefits would be actuarially equivalent to the standard Medicare benefit offered under Part D;
- **Modified Single Prong Test** – under this criteria, it would use the same actuarial equivalence as the single prong test, but would limit the amount paid to an employer to its contribution. Under this test if a benefit plans gross value was $1,000 but the employer's contribution was only $500, then CMS would limit the subsidy to $500, not the average $611. CMS has acknowledged that it may not have authority in the MMA to apply this test.
- **Two Prong Test** – under this qualification criteria an EGHP would have to demonstrate a) that the total plan payout for the average Medicare beneficiary exceeds the value of the benefits provided by Part D (benefits are actuarially equivalent) and, b) that the net value of the benefits provided to beneficiaries without beneficiary financing would exceed the subsidy or the average subsidy provided by Medicare ($611 per year).

Issues/ Comments – Substantial numbers of employers no longer finance the full cost of retiree health benefits but still either finance a portion of the costs (through a defined contribution program) and enable savings to retirees through group purchasing arrangements or provide benefits through a defined contribution plan or capped contribution program. Often, EGHPs provide the financial cash flow for these plans and expect to be reimbursed for excess costs above its own contributions by the plan beneficiaries. If these arrangements are not economical to the beneficiary in comparison to arrangements available in the individual insurance marketplace, then retirees can drop out of the EGHP and have the option to enroll in Part D with a PDP or a MAPlan regardless of whether the group retiree health plan contracts with such alternative or offers alternatives that are less attractive and beneficial to its members.

CMS should not use the subsidy regulations to interfere with how contributions and financing of EGHPs are determined and should not dictate or interfere in the way that a subsidy payment received by an employer is allocated to the plan contributors. For example, in a Taft-Hartley type of plan, CMS should not dictate whether its subsidy is returned to the employers who contribute to the trust or to the beneficiaries who also might contribute.

Likewise, for many governmental plans, CMS should not dictate how the subsidy should be allocated between plan members, plan contributors and employers (which sometimes operate similarly to a Taft Hartley Trust (e.g. multiple school districts) or might be funded by a single government entity.

CMS' duty is not to create new legislative rules on what entities might qualify for or be excluded from the subsidy. Rather, it should be making sure that whatever entity is paid a subsidy will remain viable throughout the year. This may require that the subsidy be paid to a trust if the benefit operates a trust and not be mingled with general revenues of the entity, or that the entity be bonded where it is financially shaky (e.g. a company in bankruptcy).

By restricting the subsidy to only those employers who are funding the majority of retiree benefits, CMS is indirectly regulating the arrangements between employers and retirees. Inadvertently, this could exclude many plans that CMS intends to include and preserve retiree benefits for. Its exclusion of plans that rely on heavy retiree contributions could actually reduce the purchasing power of such retirees and reduce their benefits below levels they already receive from the EGHP.

ERISA places fiduciary obligations on employers not to misrepresent or misstate benefits from their plans to beneficiaries. CMS is concerned that free market forces are not sufficient to prevent fraud against beneficiaries, but disclosure obligations that require employers to identify what percentage of the premium will be paid for by employer contributions versus the rebate might avoid unnecessary and counter productive regulations that will undermine existing retiree health benefits in plans that are struggling to maintain such benefits for retirees. Leaving the situation ambiguous is the worst scenario for employers and beneficiaries. We don't believe that CMS needs to exercise paternalist judgment whether retirees of the EGHP are capable of choosing among plans**.** If an EGHP is not passing on a subsidy to its members, it is very likely that its members will elect to enroll in a MAPlan or a PDP instead which offers a better deal. Government interferences in the private terms of benefits and coverage offered by an EGHP to a Medicare Beneficiary is only going to limit choices, eliminate efficient methods of purchasing now in use, and undermine efforts by public and private employers to maintain benefits for their retirees.

B. Windfalls

CMS' Administrator Mark McClelland has stated that the agency has a adopted a policy opposed to any employers obtaining windfalls from the Subsidy Program. Windfalls are generally described as "circumstances where the net value of the EGHP coverage after subtracting the retiree premium is less than the average plan payout (subsidy)". CMS is considering several options to either: exclude certain EGHPs that fail to contribute sufficient funds to the prescription drug plan from participating in the subsidy or to prevent EGHPs from obtaining windfalls. CMS believes it has discretion based upon the language in the MMA concerning "actuarial equivalence" to adopt new rules on windfalls.

Issues/ Comments – We have three sets of comments about this section of the proposed regulations.

- **CMS authority to regulate windfalls –** No explicit authority exists in the MMA legislation to allow CMS to regulate windfalls. Section 1860DD-22 of the MMA sets forth the detailed terms and conditions of the subsidy payment authority. It explicitly follows the approach that an EGHP make an actuarial attestation that the value of its coverage is actuarially equivalent to "standard Part D coverage". Nowhere does the statute even contemplate the issue of how benefits are financed within the EGHP. Nor does the statute identify or address prevention of windfalls from an EGHP. By contrast, Congress did give CMS authority with the prescription drug benefits offered by a Prescription Drug Plan or Medicare Advantage Plan under Part D, to regulate the "unsubsidized value" to the beneficiary that is equal to or greater than the "unsubsidized value offered in an alternative plan". Based upon a review of the Medicare Modernization Act statute and legislative history, it does not appear that there is sufficient basis for CMS to undertake legislative regulations of windfalls. It appears that the only policy assumed by Congress was the Single Prong Test. There is no provision under 1860DD-22 that references the obligation of the EGHP to provide an unsubsidized value to the beneficiary as there is under Part D of Medicare. Without any Congressional legislative history authorizing CMS to regulate windfalls, and without a solid basis for determining what circumstances produce windfalls, the current discussion on windfalls should be dropped. Instead, CMS should address the financial solvency and obligations of employers who receive subsidy payments to apply them to the cost of benefits (regardless of how such benefits are financed).

- **Financing of Retiree Group Health Plans and Beneficiary Choices –**
So far the proposed regulations have not adequately defined what a "windfall" is. What criteria should be used to decide what constitutes a windfall to an EGHP? CCWhen financing of benefits is shared between the retiree/beneficiary and his or her employer, shouldn't the contract or terms of contributions by the plan determine who receives the subsidy from Medicare? Moreover, many EGHPs provide for financing of benefits in a way that if an employer recovers costs, obtains savings, or obtains payment of a subsidy from a third party, the employer and EGHP retroactively pass along the savings in the form of subsequent year premium reductions to the retiree/beneficiary. Technically, under these circumstances, during a fixed time period (e.g. a calendar year), the employer may receive a subsidy before it was shared pro-rata with the retiree/beneficiary but the employer did not receive a windfall that did not eventually benefit the beneficiary. Finally, what is the concern of CMS in preventing windfalls if the beneficiary is assured of free choice between participating in the employer's EGHP or joining a PDP or MAPlan under Medicare, even without employer participation.

  COMMENT: CMS regulations guarantee that notwithstanding anything that permits an employer to obtain a subsidy, each beneficiary has the freedom to choose between enrolling in the employer's retiree health plan that covers outpatient prescriptions or enrolling in a

Part D plan either a PDP or an MAPlan. If an employer does not deal fairly with its retirees, the retirees will elect a different plan where they get a better deal. So long as the employer is not engaged in fraudulent conduct or other misconduct in misrepresenting to retirees what they receive from the plan, it seems that the issue of a windfall is a red herring. Attachment A sets forth some examples of circumstances where plans may appear to have "received windfalls". In many of these cases no windfalls actually occurred. These demonstrate why the issue of regulating windfalls is extremely complex.

- **Collective Bargaining and other Labor and ERISA Issues** -- Infringement by employers on the rights and benefits of retirees has long been the subject of debate and controversy; however, the Labor Management Relations Act and ERISA are the locus for such disputes. Retirees covered under collectively bargained plans do not need CMS to protect their rights to benefits and if an employer receives a subsidy that was using funds contributed by a retiree, it will be careful not to violate any collective bargaining agreements regarding such contributions, subsidies, or benefits. Likewise, for non-collectively bargained plans, ERISA places fiduciary obligations on employers on the use of contributed funds from beneficiaries. Misrepresentation or misstatements about benefits by employers to beneficiaries place employers in jeopardy for enforcement actions under ERISA fiduciary authorities and from Labor Department authorities. CMS is concerned that free market forces are not sufficient to prevent fraud against beneficiaries where EGHP's have underfunded benefits and thus potentially make retirees vulnerable to schemes to obtain windfalls from Medicare subsidies at the expense of Medicare beneficiaries. As long as members of an EGHP that is a Medicare beneficiary eligible for Part D has the right to opt out of an EGHP and join instead a PDP or MAPlan, this concern is misplaced. If an EGHP is not passing on the Medicare Part D subsidy to its members, it is very likely that its members will elect to enroll in a MAPlan or a PDP instead of remaining in the EGHP.
  COMMENT: CMS' regulatory concerns should focus on whether EGHPs that are "under-funded" will be able to meet their commitment to retirees to fund benefits, if they receive a subsidy, not how to allocate financing of the subsidy. This could mean that CMS could adopt a test which checks for the financial solvency of the funding and obtains a commitment that the entity receiving the subsidy not use the subsidy for any purpose other than paying benefits unless adequate funds are set aside to pay for benefits throughout the benefit year. Government interferences in the private terms of benefits and coverage offered by an EGHP to a Medicare Beneficiary is only going to limit choices, eliminate efficient methods of purchasing now in use, and undermine efforts by public employers to maintain benefits for their retirees.

C. Payment Terms to EGHPs

Background – For EGHPs that receive subsidies from Medicare for prescription drug benefits, CMS is considering four approaches to paying subsidies.

- The first approach would combine monthly drug subsidies with monthly adjustments (e.g. rebates, etc). By the 15th of each month, CMS would require each EGHP to submit an invoice to CMS indicating the gross amount of claims for covered drugs that are paid for qualified retirees under the program that exceed the $250 deductible. Then, the employer would also report what if any rebates or offsets to expenses they received that month. CMS would then determine what net amount would receive the 28% subsidy. The following month, CMS would make payment taking into account applicable adjustments.
- The second approach, CMS would make an annual retroactive Medicare retiree drug subsidy payment to each employer after **the end of the year**. By the beginning of the fourth month after

the end of the year, each employer would submit information to CMS on the number of months of coverage for each qualifying covered retiree and their **gross and allowable costs**. These costs would be based on data derived directly from claims payments and retiree cost-sharing for prescriptions dispensed during the year and discounts, chargebacks and rebates for that year. CMS would review this submission and make a payment for the year by the end of the following month. This alternative would be the simplest to administer and would obviate the need for interaction between CMS and employers other than during the review process. From the perspective of employers, however, this alternative may be problematic since payment would not be received until after the end of the year.

- The third approach, CMS would make interim payments throughout the year with a settlement after the end of the year. **Employers that sponsor qualified retiree plans would estimate the per capita Medicare retiree drug subsidy payments they would expect to receive, based on historical data on prescription drug claims for their qualifying covered retirees, along with rebates or discounts that the employer has received from drug manufacturers**. Employers would submit their estimated per capita retiree drug subsidy payment and any supporting documentation to CMS at the same time that they submit their attestation of their qualified retiree prescription drug plan's actuarial equivalence to standard Medicare Part D coverage. **CMS would review each employer's estimate and related documentation, and would determine an interim monthly per capita amount**. In order to minimize the possibility of having to recoup large amounts of money at the time of settlement, CMS **would pay each plan sponsor a percentage of this interim monthly per capita amount on a periodic basis for each of their qualifying covered retirees**. We are proposing under this alternative to pay 70 percent of the interim monthly per capita amount in 2006 and 2007, given the significant uncertainty that will exist in estimating Medicare retiree drug subsidy payments. This alternative is more administratively complex than the second alternative because it entails calculating an interim payment amount for each employer; making periodic payments during the year; and conducting a settlement with each employer after the end of the year with actual claims data. It would, however, provide Medicare retiree drug subsidy payments to employers during the year, which could be beneficial to employers from a cash flow perspective. ***Note: This approach most closely approximates what CMS is proposing for other entities receiving subsidies. Both MAPlans and PDPs will receive capitation payments based upon bid amounts that are compared with benchmarks prepared by CMS. CMS already pays some union and employer plans using this methodology when they administer Part B benefits. This system works well, but normally CMS pays the estimated costs based upon 100% of the estimated costs. After the first year, CMS can reduce its monthly capitation based upon actual experience. CMS's proposed 70% is stingy and unrealistic and deliberately intends to discourage this method, even though this method is likely to be the most accurate in accounting for rebates and reflects reasonable negotiations between employers and CMS over estimated costs.***
- The last approach is that CMS would make lagged Medicare retiree drug subsidy payments to employers based on actual claims experience, on a periodic basis throughout the year, with a settlement after the end of the year that would be limited to reconciling estimated versus actual discounts, charge-backs, and rebates. By the 15th day of the month after the end of the payment period, each qualified employer would submit information to CMS on **gross and allowable costs** for the previous payment period for each of their qualifying covered retirees whose gross costs to date exceeded the cost threshold, but did not exceed the cost limit. Employers would base the cost data that they submit to CMS on their actual claims experience, adjusted on a percentage basis for estimated discounts, charge-backs and rebates (each employer would also submit a justification for the percentage used). **By the 15th of the following month, CMS would review the submission and make a Medicare retiree drug subsidy payment to the employer**. (note: very

labor intensive by CMS and likely to result in huge bureaucracy and unnecessary delays in payment). By the beginning of the fourth month after the close of the year, the employer would submit documentation on actual discounts, chargebacks and rebates that were received for the plan, with a comparison to the estimated discounts, chargebacks and rebates that were used in calculating the payments. We would correct any underpayment or overpayment by adjusting the employer's subsequent periodic payments. Similar to the first, this fourth alternative is more administratively complex than the second and third alternatives considered here, but as with the first alternative it would provide employers with a payment stream that comes closer to subsidizing their actual plan expenditures as they occur. However in contrast to the first alternative, it **relies on projected amounts related to retrospective discounts, chargebacks, and rebates, with a reconciliation process, and thus does not come as close as the first alternative to ensuring that sponsors receive expeditious payment of the full retiree drug subsidy amounts to which they are entitled.** {It also doesn't artificially exaggerate the applicable rebate for the wrong fiscal year and mixes up cash accounting with accrual accounting.} CMS claims that compared with the first and third alternatives, this fourth alternative would reduce somewhat the risk to the government and employers that substantial overpayments or underpayments would need to be redeemed.

Issues and Comments – There are two key issues with CMS' proposals.

- First, only the third proposal actually accounts for drug costs of the EGHP on an accrual basis. The other methods appear to follow the cash flow of the plan but fail to recognize accrual accounting required for such plans. This means that the Government could offset the claim costs for rebates from rebates that accrued in a prior year, before the inception of the subsidy program and which might not even relate to Medicare beneficiaries (see discussion on rebates elsewhere).
- Second, CMS neglects to consider more user-friendly methods that are proposed for other cost based entities. For example, for Fallback prescription drug plans, CMS proposed (see page 46736) to pay such plans through a debit account system. Each Fallback plan would charge CMS the claim costs on a pay as you go basis, and be subject to cost reporting and settlement to address actual collected rebates that accrued. At least for small and medium sized employer plans this method would seem less onerous, fairer, and less burdensome.

In addition we have the following comments:

- The first approach does not seem to achieve any cost basis reconciliation which appears contrary to the statutory framework of the employer subsidy.
- The second approach would shift the entire burden of financing (cash flow) for outpatient prescription drugs to employers.
- The third approach is acceptable in that it sets prospective payments and provides for reconciliation but arbitrarily pays less than what the parties agree as the prospective rate. Contrary to CMS conclusions, drug costs for this population may be far more predictable than medical and other health care costs. By analogy, CMS pays for medical costs on a prospective basis to some union and employer plans and settles payment annually through a retrospective cost report, without withholding 30% of the projected payment (see MAPPO option).
- The fourth method appears more cumbersome and burdensome than others because it requires the EGHP to submit <u>monthly financials</u> on claim costs with estimates of adjustments. This is entirely too much paperwork.

D. UUPayments Terms: RX Rebates and Other Market Issues

The proposed regulations provides two diverse and potentially contradictory discussions of the rebates issue. When addressing rebates affecting PDPs and MAPlans, CMS' position under Subpart G does not take rebates directly into effect in determining the rates charged by these entities. Instead, rebates are used in two ways: a) to determine what premium will be charged to beneficiaries by the PDP or the MAPlan (based upon their determination) and b) to determine the allowable costs when determining reinsurance subsidies for catastrophic prescription drug cots. CMS has proposed a rebate accounting system in which the plans will report costs through a "step-down" structure. The step down structure would enable plans to more accurately reflect rebates, which are based upon the actual volume of drugs purchased. For example, if 90% of a particular group of drugs were attributed to Medicare beneficiaries then 90% of the rebates for those drugs would be attributed to Medicare beneficiary allowable costs. While this method is more complex, it is more accurate and more likely to yield fair results.

- Under the Subpart R proposed regulations - For EGHPs, CMS uses rebates to determine the net "allowable retiree costs" of the EGHP's prescription drug plan. (see p. 46738). CMS requires each EGHP to make a full accounting of rebates.

- CMS is considering one of two methods for determining what portion of the rebates received from PBMs for EGHPs should be used to offset the net "allowable retiree costs" that receive the 28% subsidy. First, CMS is considering an approach to apportion rebates based upon total dollars spent. Its second method is to apportion rebates based on the number of covered lives. CMS wants to follow an apportionment method that will be quickly linked to the subsidy payments (even for interim payments). CMS' discussion focused only on linking the rebates to the timing of subsidy payments, but did not address in detail any rationale for an apportionment methodology.

- In addition, CMS is concerned that EGHPs will negotiate lower rebates with PBMs and receive lowered administrative fees in exchange, which will lead to higher Medicare subsidies under the Program. CMS intends to monitor and audit rebate arrangements between employers and their PBMs.

Comments/Issues – We agree with CMS concerns that rebates be fairly reported. However, neither of the two apportionment methodologies mentioned appear to be very accurate or sound. Instead, CMS needs to consider apportionment methods using volumes of drug costs relative to the particular rebates received. Rebates wholly unrelated to the Medicare beneficiary population should be excluded from offsetting an EGHP's allowable costs. In addition, CMS should consider methods to estimate rebates on an interim payment basis while paying subsidies and then reconcile the rebates and the subsidy payments at the end of each year

E. Payment Terms: Medicaid "Best Price" Requirement

Background - For the past decade, Medicare and Medicaid law and regulations created an artificial barrier to discounts available to employers and others who sought discounts from drug manufacturers. The MMA at §1860D-2(d)(1)(C) eliminates this barrier. No longer will discounts offered by a manufacturer to an employer receiving a subsidy or a PDP or MAPlan participating in the Medicare Part D program be counted when determining discounts for purposes of Medicaid. Previously, any discount below those given to a Medicaid program was considered a violation of the "best discounted price" policy of Medicaid and was required to be passed along to Medicaid as well. However, it is not clear from the proposed regulations exactly how this policy will apply with respect to employers.

Comments/Issues -- Because employers purchase outpatient prescription drugs for both Medicare and non-Medicare beneficiaries it is not clear whether CMS' policy will exempt all or only a portion of the negotiated price prescription drugs that are related to the MMA program. Moreover, if CMS applies the policy only to outpatient prescription drugs that are exclusively for Medicare beneficiaries, it could undermine the purchasing practices of negotiated pricing through PBMs. Unless CMS interprets this policy broadly, it will fail to achieve the legislative relief intended by Congress.

F. Plan Year versus Calendar Year Enrollment and Dis-enrollment

Background -- (See Part D of the Preamble -- Enrollment Periods p. 46639) The MMA legislation created authority for coordinated open enrollment and a system very different than the current system of enrollment in Medicare. Under current law, a person who joins a Medicare health plan (MA Plan) may elect to dis-enroll and join another health plan or join a Medigap insurance plan or return to an EGHP on a month-to-month basis. Under the new MMA, Congress mandated that beginning in CY 2006, all Medicare beneficiaries will have to select a MAPlan, a PDP, or an EGHP, and remain enrolled for an entire calendar year. Although, MMA provided some exceptions to the calendar year enrollment requirements, and allow for dis-enrollment for cause to enable switching plans, nothing in the legislation or regulations address how an employer that operates on a fiscal year that is different than a calendar year should participate in the Medicare. For example, many state and local government employers operate with either a July 1 or October 1 fiscal year and plan year

Issues and Comments - CMS provides for initial year leeway of 6 months for persons who become eligible for Medicare for the first time during the period from June 2005 through June 2006. **Yet, there is no provision for leeway of an entire EGHP's membership which operates open enrollment at times that are different than the initial open enrollment period**. Nor are such variations among plans included among **the circumstances in the regulations that are considered special exceptional circumstances that warrant a "Special Enrollment Period" (SEP)".** CMS has invited comments and suggestions on what circumstances warrant a SEP. States and local governments that operate a different enrollment period cycle may need an SEP in order to coordinate with Medicare. (See MMA Part D Regulations Part D Enrollment Periods §423.36) (NPRM pp. 46639-46640).

In addition, CMS is inviting comments on the logistics for conducting enrollment. More EGHPs and their outsourcing administrators are able to handle such enrollment over the internet. CMS MUST MAINTAIN A FLEXIBLE PROCESS FOR SUCH ENROLLMENT PROCESSES. Traditionally, CMS has required a paper form process for enrollment. However, with so many beneficiaries enrolling in a concentrated time period, an electronic process IS ESSENTIAL

Enrollment and dis-enrollment from a PDP potentially should be based upon entirely different criteria than dis-enrollment from an MAPlan (HMO, PPO, etc.). CMS has proposed to require all beneficiaries who move outside a designated service area of a PDP or of a MAPlan to disenroll automatically. The consequences of such dis-enrollment may be loss of benefits and loss of creditable service. We believe that EGHPs that have retirees who relocate for part of the year in the winter and part of the year in the summer, need more flexible arrangements.

G. Enrollment in and Out of the Part D Program – The Enrollment Regulations Appear to Lack of Any Feature or Option to Return to An EGHP Program After a Beneficiary Enrolls in Part D – Clarification Is Needed

Background - In order to assure that all Medicare beneficiaries are accounted for and either elect to participate in Part D or elect to remain with an EGHP, CMS proposes to establish a comprehensive system to track the creditable service of each Medicare beneficiary. Through this system, each employer will be obligated to report on whether a Medicare beneficiary was enrolled in a prescription drug plan that provides coverage at least equal to the actuarial value of the Medicare standard drug coverage. Medicare beneficiaries who fail to elect to either participate in Part D or fail to elect to obtain coverage from a qualified EGHP, will be charged a late enrollment fee for joining Part D of Medicare after they are initially eligible. It appears that there could have been an oversight, however, in the system that CMS is engineering. If a Medicare beneficiary elects to join a PDP or an MAPlan (for both Medicare and outpatient drug coverage) and later elects to return to his or her EGHP, there is no provision in the regulations that permit a right of return to opt out of Medicare Part D. (see discussion below regarding MAPlans). Indeed, at several points in these regulations, CMS prohibits returning to anything but another Part D plan. (see page 24 below of this Review). CMS does not consider returning a EGHP participant or beneficiary to his or her employer's plan if the person terminates coverage with a Part D plan. This seems to be an oversight but could cause major problems if Medicare beneficiaries are penalized for returning to an EGHP's subsidized prescription drug plan after they try out either an MAPlan or a PDP. [See also Preamble of the Medicare Advantage regulations at page 46875]

Comments/Issue – CMS should clarify its regulations to allow any Medicare beneficiary who is entitled to coverage by an EGHP and who enrolls in an MAPlan or PDP and elects to return to an EGHP that is receiving a subsidy, not to penalize such election return if in subsequent years the beneficiary wants to return to Part D participation. The regulations should be amended to clarify this issue.

H. Record Keeping Disclosure, Reporting, and Data Exchanges

Actuarial Attestation and Reporting To CMS

To qualify for the Medicare subsidy, the MMA requires that each employer must provide CMS with an actuarial attestation that its prescription drug coverage is actually equivalent to (if not better than) the basic Part D coverage. Actuarial attestation will be a significant new obligation for employers because both the independent actuary and the plan are obligated to be accurate with the data and information forwarded to CMS. False data or false assumptions or misrepresentation of data could expose the EGHP and the actuary to significant risks and problems with CMS. CMS has been working with the American Academy of Actuaries to develop a standard data set, which they recently released on 9/9/04. If the circumstances associated with coverage changes in the middle of the year, the EGHP is obligated to furnish an updated attestation. (see §423.884).

Comments/Issues – The data set and documentation are too tentative to comment upon at this time. CMS needs to be more forthcoming about how much data and what types of data will be required and how they will be used.

Disclosure and Annual Certificate of Creditable Coverage to Retirees and Beneficiaries and Coordination of Benefits System

A key new feature of the proposed Part D regulations is the new rules to require coordination between Medicare and EGHP plans. CMS is considering an extensive coordination of benefits system that will require all payers to exchange a variety of information including:

- Enrollment file sharing
- Claims processing data
- Premium payment data on basic and supplemental coverage

- Third party reimbursement data on out-of-pocket costs, and
- Other administrative processes

CMS is also proposing major obligations for employers and payers to establish a new system for tracking which Medicare beneficiaries have been covered by plans that at minimum meet the criteria for coverage of Part D or substitute for Part D coverage. Each employer that elects to opt out of Part D and receive the subsidy payment will be obligated to issue a certificate of coverage that indicates that its covered beneficiaries received not less than the same actuarially equivalent coverage as the basic Part D benefits. MMA requires employers to give notices to beneficiaries whether their program provides creditable coverage at least equal to the Medicare Part D program. CMS is soliciting comments regarding how to give notice to beneficiaries. They are considering the following features:

- Standard disclosure materials prepared by CMS and distributed by each EGHP to its retirees;
- individual notices that must be mailed to each Medicare beneficiary of the EGHP (similar to COBRA or HIPPA notices) but would be sent out to all beneficiaries prior to the open season period (November of each year);
- individual notices to beneficiaries of their creditable coverage whenever they request; and
- Notice from each EGHP to CMS in order to administer Part D

Comments/Issues - These various notices will be expensive and labor intensive to administer. CMS needs to consider various ways to reduce the burden and cost to EGHPs. One way might be to allow all beneficiaries who have internet access to obtain the certificates by logging on to an EGHP web site. That way, the employer can reduce the costs of notice requirements. Also, EGHPs need to make it easier to communicate with retirees and such arrangements might better achieve coordination with retiree information needs.

Tracking True Out Of Pocket Costs ("TROOP")

Background –("TROOP") means "true out of pocket expenditures" paid solely by a) the beneficiary; b) a person related to the beneficiary; c) a charity, or an entity other than insurance company, employer, or group health plan that has an obligation to pay for benefits. Congress created a donut hole benefit structure in the Part D benefits that prohibits coverage by Medicare when a third party subsidizes the out of pocket costs of plan $$. Whenever coverage reduces cost sharing by beneficiaries beyond basic coverage, TROOP delays catastrophic coverage from Medicare to the plan. TROOP only applies to benefits furnished under Part D. Benefits furnished by an EGHP that is not participating in Part D are not affected by TROOP. TROOP must be calculated in order for CMS to determine whether to pay reinsurance subsidies for catastrophic costs of Part D benefits. In order to administer TROOP CMS is considering imposing a major obligation on all third party payers to coordinate benefits and to provide data to CMS so that eligibility, benefits, and spend down of payment obligations can be determined at the point of service for each pharmacy provider that a beneficiary uses to obtain covered prescription drugs. CMS is interpreting the MMA to require CMS and its agents to coordinate claims for Part D with other payers. See Regs at p. 46700-46704. Ultimately CMS's goal is to "design and implement a Part D coordination of benefits system" to enable pharmacies to obtain information about secondary insurers as well s the correct billing order. In the short term, CMS is considering three ways to deal with the burden of information exchanges involving tracking of TROOP costs:

- Method 1 – Obligate the PDPs and MA-PD plans to be solely responsible for tracking TROOP costs.
- Method 2: - Engage a TROOP administrator to voluntarily collect data from all payers and the administrator would exchange the data so that proper determinations of coverage and TROOP costs are determined on a point of service basis.
- Method 3 – Form a mandatory Query System for the Part D program similar to the current Medicare query system but with mandatory participation and data feeds by all payers, including employers.

Comments/Issues – Only method 1 is viable in time for CY 2006. Moreover, until data and other features of this system is worked out, it is not feasible to exchange information in a meaningful or helpful manner. We do not see how Methods 2 and 3 above will be helpful to employers and others under Part D. Substantial analysis and further work needs to be done before these options can be considered.

Data Exchange

CMS seeks to require coordination of benefits information and data exchanges by and between Medicare, the various payers, MA plans, PDPs, and various EGHPs. CMS is considering the following :

Requiring all employers to furnish to CMS a standardized data set on retirees that will include the following:
Employer Tax ID
Sponsor name
Sponsor Address
Contact Name, title & email
Actuarial Attestation
Full names of each "qualifying covered retiree" with their:

- HIC number
- Date of birth
- Sex
- Social security number
- Relation to retiree (former employee)

Collecting data for TrOOp calculations and for subsidy calculations

Aggregate vs. Individual Level Cost Data – "Qualified Retiree Prescription Drug Plan Sponsors (or EGHPs) will need to submit cost data relating to their qualifying covered retirees so that CMS will be able to accurately calculate each sponsor's Medicare retiree drug subsidy payment. CMS is considering three alternatives relating to the level of detail of this cost data: (1) Submission of aggregate allowable costs data, (2) submission of beneficiary-level total allowable costs data, and (3) submission of actual claims data.

- **Alternative 1: Submission of Aggregate Level Cost Data** --Under this alternative, CMS would require the plan sponsor (or the plan administrator designated by the sponsor) to submit the aggregate total of all allowable drug costs for all of the qualifying covered retirees that were enrolled in the plan during the time period in question. These costs would represent the allowable costs incurred between the cost threshold and cost limit for each qualifying covered retiree, with a reduction for the anticipated rebates and discounts (which would be calculated based upon historical data). Under this alternative, the plan sponsors would not submit separate cost data for each qualifying covered retiree. However, each plan sponsor (or their administrator) would have to maintain the individual-level claims data that support its submission for audit purposes. This alternative will probably be easier for the sponsors and would be the most protective of the individual's privacy,

- **Alternative 2: Submission of Beneficiary Level Cost Data** --Under this alternative, the plan sponsor (or its plan Administrator) would submit the total allowable costs for each individual qualifying covered retiree during the time period in question. This alternative would be more complex, labor intensive, expensive to administer, and time consuming for the

sponsor and would raise some privacy questions. CMS believes that it would be more reliable in terms of calculating the Medicare retiree drug subsidy payments.

- **Alternative 3: Submission of Actual Claims Data** -- Under this third alternative, each plan sponsor (or its plan Administrator) would submit the actual claims data for each qualifying covered retiree during the time period in question. However, this alternative would be the most complex in terms of calculating the Medicare retiree drug subsidy payments and would be the most problematic in terms of privacy concerns. Accordingly, CMS has ruled out this alternative. ***Comment: Even though CMS has ruled out submission of this data, each employer will need to maintain a permanent record of this data in easy to locate formats. This will mean that adoption of compliance plans will be necessary in which employers will maintain quarterly or monthly claims records on CD disks to enable easy audit and review of records. Employers experienced with Medicare cost reimbursement will be equipped to maintain this additional administrative function and expense without much additional effort.***

Comments/Issues – Clearly, Alternative 1 above is the best of the three options for EGHPs offered by CMS.

Annual Application Requirements

Background – Each year, each EGHP that wishes to receive a subsidy must apply to CMS and fill out the CMS application forms to qualify for an employer subsidy and must furnish an actuarial attestation of plan benefit value of its retiree health plan coverage of outpatient prescription benefits. The timing of this application, the calculation of rebates to determine the net allowable costs of its outpatient prescription drug benefits, and the dynamic and uncertain market that may evolve from the new MMA pose significant challenges to employers, unions and others who sponsor EGHPs. Documentation and other information that will need to be exchanges, along with disclosure requirements will place many employers in a challenging new arena to manage and provide coverage, even while they are struggling to keep their existing retiree health benefit programs.

Comments/Issues – CMS needs to form a task force of employer organizations to investigate less burdensome and more efficient ways to carry out the MMA. Unless more user friendly means can be devised, many employers will become discouraged with the proposed issues and obligations of funding a retiree health benefit plan. This will undermine the goals of CMS and the MMA legislation

I. EGHP Participation in Part D: Issues with Prescription Drug Plans (PDPs)

There are two issues with this part of the regulations:

- Negotiation of pricing discounts by PDPs to EGHPs
- Access requirements

Negotiation of Pricing, Discounts, and Benefits from PDPs

Background: Under Subpart G -CMS requires that all beneficiaries covered by a PDP must receive uniform benefits for prescription drugs, (See p., 46675 discussion of bidding by PDPs) through a system that sets a specific coverage, pricing, and timetable for each PDP's proposal, negotiation, and adoption of bids. CMS states that "under the Part D Prescription Drug Program . . .both the negotiated prices and the benefit structure will be the same for all enrollees in a given PDP or MA-PD." CMS defends its right to

unilaterally set all pricing and benefit packaging by PDPs without regard to any separate pricing and benefits negotiated by an EGHP. CMS justifies this as consistent with the methods used by the Office of Personnel Management with the FEHBP Program (see p. 46679). Set forth are the details behind CMS' policy.

- Part D Regulations Preamble at p. 46698 acknowledges that Section 1860D-21(b) of Act [the MMA] authorizes prescription drug plans to use waiver authority to establish "*separate premium amounts"* for Part D enrollees who are participants or beneficiaries of employment-based retiree group health coverage sponsored by employers or labor organizations (i.e., EGHPs). CMS states that it will consider waivers of its rules for pricing by PDPs but its interpretation of "separate premiums" means just the amount that the participant or beneficiary pays, not the total amount paid by the beneficiary and the EGHP combined. CMS claims that the MMA statute does not allow the premium charged by a PDP to be different for an EGHP or its beneficiaries than for individuals that enroll in the same plan.

- CMS also acknowledges that with respect to the waiver authority, it will not allow waivers of EGHP wrap around plans that change the TrOOp costs of a beneficiary enrolled in either PDP or MA Plan that results in increased costs to Medicare. For example, if an EGHP pays to fill in the costs of the Part D deductible ($250) or reduces the coinsurance to a fixed amount of $10 for generics, these costs do not increase the Medicare costs/reimbursement to the PDP. But if the EGHP fills in the "donut hole" the gap between initial coverage and catastrophic coverage, then CMS will not provide a waiver for this purpose. Ironically, CMS will consider waivers that allow the PDP to create a separate plan (p. 46699) and exclude all other PDP enrollees from joining such plan. Such plan could provide additional benefits not offered by the PDP to individual Medicare beneficiaries. However, CMS takes the position that where the EGHP subsidizes a PDP's coverage in excess of standard coverage, "the plan sponsor or the beneficiary must bear some of the costs that would have been covered by the Part D reinsurance subsidy" (i.e., catastrophic costs) (see discussion on impact on beneficiaries at p. 46699).

Comments/Issues – CMS policy seems to overlook that the Medicare beneficiary market traditionally has included two payors, the Medicare program and the secondary insurer. While CMS is attempting to balance between its goals in preserving the self-pay features of the "donut hole", it has largely ignored its objective to enable employers to keep existing retiree health plans to supplement Medicare coverage through this rule. **There are several good reasons why CMS should change this position:**

- CMS review of rates and bids is for its regulatory proposes not for the purpose of market intervention. When an employer seeks expanded benefits or less expensive benefits, or different coinsurance terms for its retirees (such as for those covered by collective bargaining), it must be able to address areas where CMS does not become involved in negotiations with the PDP.
- CMS policy on uniform rates and benefits makes it impossible for an employer that does not qualify for the subsidy or can not administer the subsidy program to forego arrangements with its beneficiaries to coordinate between the employer plan and PDPs (including fall back plans) that are available through Medicare. This policy prohibiting private arrangements between an employer and a PDP could materially interfere with the employer's existing plan which is more generous than the PDP in their area and may also interfere with contractual rights that are covered by collectively bargained plan or any other retiree health plan.
- CMS policy to limit the freedom of an EGHP to negotiate or make private arrangements with a PDP is contrary to the plain meaning of the MMA statute at 1860D-22(b). Each PDP is allowed to offer multiple prescription drug plans (see 1860D-12(b)). It is obstructive, unduly inflexible, ill-considered, and potentially harmful interference in the pre-existing relationship between employers

and their retirees to prohibit a PDP to structure a unique plan with unique pricing and discounts for its employer clients.

- At minimum, CMS should acknowledge that any EGHP that wants to have a PDP offer a plan that matches its existing prescription drug coverage without taking away benefits from retirees should be allowed to do so on an exclusive basis by the waiver process set forth on p. 46699.
- Finally, the timetable for submitting bids for PDPs full, partial, or "fall back" plans are fixed by CMS. Significant issues exist with whether the CMS timetable will they be timely to the bidding process for employers considering direct subsidy programs and programs that supplement the CMS process. This could be especially problematic for plans that operate on a non-calendar year basis. CMS should allow waivers for these plans for the initial years of the Part D program.

Access and Issues with PDP Service Areas (p. 46655)

Background - CMS has proposed that each PDP's pharmacy network must meet minimum access and other standards in order to participate under subpart D and each PDP will be limited by the geographic reach of its pharmacy network. For employers wishing to contract with a single PDP under the Part D option, the access requirements could pose some problems. First, not every PDP will be able to contract with participating pharmacies throughout the US. Second, no access standards will apply to EGHP's electing the direct subsidy under Subpart R of the regulations. While access and other performance standards are desirable to protect beneficiary rights and to maintain qualify of performance, some of these standards are not common to today's pharmacy practice and may be too onerous. Some flexibility in dealing with EGHPs may be appropriate.

Comments/Issues -- CMS has proposed that it will waive the access requirements that apply to PDPs for any MA Plan (HMO, PPO, or other plan) participating in the Medicare Advantage Program. (see p. 46697) A category of automatic waivers should be granted to PDP arrangements with national, multi-state, or large employers who have beneficiaries located in multiple areas and who contract on a group basis with such PDPs.

J. EGHP Participation in Part D Options with Medicare Advantage Plans (MAPlans) Negotiation of Pricing and Discounts from MAPlans

On page 466882 of the Part D Regulations – CMS states that,

> "Under the previous M+C program, we permitted M+C organizations to waive premiums or to offer mid-year benefit enhancements to their benefit packages. However, in order to maintain the integrity of the bidding process, we believe that it is no longer appropriate to allow either MA organizations or PDP sponsors to waive premiums or offer mid-year enhancements as would be de facto adjustments to benefits packages for which bids were submitted earlier in the year. These adjustments would be *defacto* acknowledgement that the revenue requirements submitted by the plan were overstated. Allowing premium waivers or mid-year benefit enhancements would render the bid meaningless. Excessive amounts included in the bid will be subject to recovery by the government in the risk corridor calculations following the coverage year."

Comments/Issues – See comments to Part II of these comments regarding Medicare Advantage Plans. We strongly disagree with the rationale of CMS. First, some EGHPs operate on different cycles than a calendar year and as circumstances change, they should be able to negotiate different and more favorable arrangements after the annual bid process. Second, CMS has mis-characterized the bid process as an absolute measure of a health plan's financial requirements, when health plan financial requirements are constantly changing. Indeed, the proposed process differs significantly from the FEHBP process which

has both a reconciliation process and a settlement process. MedicareAdvantage full risk based plans have neither and if a plan wishes to offer a more competitive option after the open season in order to compete for additional new business from large groups or from mid year new enrollment, it should be allowed to do so. Further, nothing in the statute appears to support CMS' conclusion regarding this inflexible requirement.

K. Waivers to support or improve flexibility for EGHP contracting with PDPs or MAPlans

Background – Section 1860D-22(b) of the MMA provides CMS with broad waiver authority to grant waivers to employers, prescription drug plans, MAPlans, and others in order to accommodate the needs of employers who offer supplemental coverage to Medicare's benefits. CMS has acknowledged that one of its primary goals is to "maximize the number of retirees retaining employer based drug coverage". CMS also at various points in the regulations identify some of the waivers that it will not grant and asks for comments on a few waivers it will grant. However, nowhere is there a full list of the waivers available to employers, an inventory of the issues that CMS will consider for waivers and identification of issues that are not the subject of waivers. .

Comments/Issues – CMS needs to provide comprehensive information on the waiver options available to EGHPs in order for EGHPs to make informed choices and not rule out plans designs or options that would preserve benefits for retirees

L. Treatment of Administrative Costs

Background - The cumulative effect of the various changes proposed by CMS are overwhelming and expensive for retiree health plans to administer. While retiree plans will be better off either because of the subsidy or because of the improved outpatient prescription drug coverage to their beneficiaries, the new MMA poses significant new challenges to the cost of administration. Moreover, it does nothing to improve the costs of administration under traditional Medicare where many employers have significant administrative costs and a morass of administrative problems with Medicare. Strict limits on payment of Administrative costs by the MMA statute also limit the ability of employers to recover these costs, even when beneficiaries are contributing for their full share of costs through premiums because of rules under ERISA.

Comments/Issues – Even while the MMA relieves employers of some of the costs of retiree health care, it shifts new costs to employers for administration and management of their retiree plans. These are not costs that can commonly be transferred to retirees and must be absorbed by the sponsors (employers, unions, and others). There is not sufficient time in the comment period to assess how much of a true burden this will be on employers, but it appears that the estimates made by CMS in the impact analysis section of the regulation are too low. CMS needs to assemble a team of employers to better assess the process requirements if it hopes to be able to administer this program by CY 2006. It also should consider funding demonstration projects to enable employers to establish more efficient processes for this program.

PART II: COMMENTS ON PROPOSED MEDICAREADVANTAGE REGULATIONS (CMS 4069)

A. Protection of benefits for MA Plan enrollees from large EGHPs

Background — These regulations implement the MMA which replace the original Medicare pricing regulations with a combination of bidding and negotiated pricing system. Originally, Medicare set a price for HMOs, PPOs, and other privatized plans that participated on a risk basis by setting Medicare's price using the Average Adjusted Per Capita Costs (incurred by Medicare), known as the "AAPCC". If a MA-Plan (previously it was referred to as M+C Plan) submitted a rate proposal (known as "ACR"), 100% of the difference was available at the election of the plan to give reduced costs of benefits to enrolled members. CMS referred to this old system as "Administered Pricing". CMS now has a competitive bidding system, where each MA-Plan submits a competitive bid. Each bid is then compared against the benchmarked CMS price for the same service area. If the bid is below the benchmarked price then the balance of the bid is shared 25% back to CMS and 75% in the form of supplemental benefits. Each MA-Plan may develop multiple supplemental and basic plans and apply the "savings" to the Medicare deductible, coinsurance or other benefits for those plans. CMS authority for this new rate setting process is based upon Section 1854 of the Medicare law. Yet, it appears that neither the regulations or the statute really contemplate a true competitive bidding marketplace.

Comment/Issues – The new system was mandated by the MMA act. However, the Secretary of HHS has some discretion on how to risk adjust the benchmark and and bid on a plan specific basis. This will be material to whether MA-Plans will produce bargains to employers and beneficiaries or will be disappointments. CMS has not yet proposed a methodology on how risk adjustment will be applied.

COMMENTS: 1) CMS MUST ENSURE THAT any risk adjustment system will take into account the traditionally higher cost and utilization of large group EGHPs.
2) CMS SHOULD CONSIDER MODIFICATION OF ITS BIDDING SYSTEM to better accomplish the objectives of a competitive bidding market place. Instead of taking back 25% of the difference between each bidder and the benchmarked CMS price, CMS should consider a system that rewards the lowest bidder by taking back a lower percentage of the difference between the low bid and the benchmarked price. Accordingly the low bidder should have 100% or nearly 100% of the difference between its bid and the benchmarked price to offer to beneficiaries, while the highest bidder might have 25% or more of its price returned to CMS.

Restrictions on returning to Traditional Medicare and EGHP Coverage

Background – Under current law, a Medicare beneficiary that joins a privatized health plan under the M+C program was allowed to enroll or dis-enroll on a monthly basis. The new MMA law requires enrollment to be conducted on an annualized basis and only during a fixed open enrollment period, except when CMS determines that a Special Enrollment Period is needed. CMS has retained its discretion to use SEP's but has not identified any circumstances where an SEP will apply to the unique circumstances associated with Large EGHPs. Moreover, in the Preamble to the MA regulations, CMS has stated [page 46875] that under the MMA law [Section 1851(e)(2)(C)

> ". . . a change of election made to during an open enrollment period and later years to the same type of plan the individual making the election is already enrolled in. Specifically an individual in an MA Plan that dones not provide drug coverage may onloy be changed to another similar MA plan, or to original Medicare but may not enroll in an MA plan that provides Part D coverage or enroll in a Part D plan. An individual enrolled in an MA Plan that includes Part D coverage similary may enroll in another MA Plan with Part D coverage or change to original Medicare coverage with an election of a Part D Plan."

CMS has solicited for comments on this inflexible policy.

Comments/Issues -- This policy restricts a beneficiary from switching between Part D and outside of Part D during the middle of a calendar year, even when that person's circumstances have changed (e.g. they moved, are dependent on a person for care or support, or have had bona fide problems with their health plan. Because CMS is already pursuing exchanges of data and various point of service information exchanges, it should be more adaptable to transfers of patients between and among the various plan options where warranted. We believe that it is appropriate to preserve patient and EGHP flexibility to transfer between plans to whatever extent the MMA allows. This may include allowing plans that have non-calendar year plan years to offer two opportunities for transferring between plans (during the CMS open enrollment and during the EGHP open enrollment). Likewise, transfers involving changes from Part D and non-Part D status should be accommodated, especially as here where Medicare is allowing such transfers in limited exceptions.

C. Auto Enrollment from EGHPs to MAPlans

Background – Section 1851(c) (3) of the MMA authorizes CMS to implement a default enrollment system to carry out the new Part D regulations (see p. 46876). If applied, these rules provide that a beneficiary who is already enrolled in an M+C plan that has a prescription drug benefits will be deemed to make an election into the same MAPlan that offers a prescription drug benefit under Part D. This will apply to the initial enrollment period in the Fall of 2005. Normally, while an M+C plan must accept any individual who applies, there is a required process for enrollment that includes an application and signature by the beneficiary. In addition, if a large EGHP wishes to benefit from the new subsidy program, they could insist that the MAPlan limit coverage to their members for non-prescription drugs. If no default option applies then the MA Plans and EGHPs will be required to undertake a whole reenrollment of members in the Fall of 2005. CMS is leaning away from implementing a default option, even though it is considering a default option for Medicaid beneficiaries who have dual eligible coverage with Medicare.

Comments/Issues -- Because these arrangements depend largely upon the decisions of the EGHP, the default option should be linked to agreements between CMS and the EGHP to operate an automated and default enrollment system. This is just one aspect of a significantly modified enrollment process that CMS should consider in working with large EGHPs.

D. <u>Coordination of Benefits with EGHPs</u>

Background – The MMA revised Section 1857j to allow CMS to waive or modify requirements that hinder the design of, offering of, or the enrollment in an MA plan offered by an employer, a labor organization, or an EGHP. MMA also allows MA Plans to restrict enrollment to beneficiaries of EGHPs for individual plans or for all of its offerings.
Comment- Because this broad authority opens up creative opportunities for EGHPs to improve coordination with MAPlans, now is a good time for CMS to propose specific areas for such waivers.

E. <u>Negotiated Bidding for Large EGHPs</u>

Background -- A. Bid Structure -- Under the pre-MMA law, HMOs and others that participated as M+C plans had flexibility to structure various benefit plans when working with employers. Under the new MMA, CMS regulations require each MA Plan to offer 2 choices of plan packages, a basic bid or a mandatory supplemental benefits bid. CMS has proposed extensive regulations governing the bidding

and negotiation process (see 46889 – 46899). **B. Uniform Premium -** Because CMS requires very specific bid processes and calculates savings available to beneficiaries on a per-capita basis, it requires each plan to charge each beneficiary the same amount for the same coverage regardless of whether the beneficiary is part of a large EGHP. (See preamble pp. 46898). A key feature of the differences between the M+C system and the new MMA system is that in the past CMS allowed MAPlans to finance the cost of extra benefits from the savings between Medicare rates and the MAPlan's rate proposal (formerly ACR). Now, CMS applies the savings as a rebate to whatever premium is charged to the beneficiary for the coverage of Medicare basic benefits (Medicare deductible and coinsurance) and mandatory supplemental benefits (non-Medicare coverage that supplements Medicare). **C. Mid-Year Changes and Enhanced Benefits –** See page 46899. In the M+C program, CMS allowed MAPlans to offer new plans, benefit enhancements, and other changes during the middle of a year including rebates, coverage improvements, and even reductions in premiums to beneficiaries. CMS claims that such practices are not allowed based upon section 1854(a)(1)(A). CMS claims that any changes in mid-year constitutes a defacto adjustment to the bid, which is not allowed.

Comments/Issues –A. Bid Structure -- The choice of only two bids – a basic bid or mandatory supplemental bid appears to conflict with other parts of the MMA that allows plans to offer multiple plans. If CMS will only approve two types of bids in setting prices for services, how will it be feasible for plans to offer multiple plans and customize plans to individual EGHPs? CMS needs to clarify its bidding process to make clear that it does not intend to limit the choices of supplemental benefit plans offered to EGHPs by its competitive bidding system. It should explain how this will work when an EGHP requests a different benefit design than either the basic or mandatory supplemental bid. **B. Uniform Premium --** CMS needs to clarify its regulations to allow separate pricing of optional supplemental benefits to EGHPs and to waive pricing from the bid process when negotiating supplemental benefits and coverage packages generally. This flexibility is essential to customizing coverage for large EGHPs. Failure to do so will undermine CMS efforts to attract more retirees and beneficiaries from EGHPs into MAPlans. **C. Mid-Year Changes and Enhanced Benefits –** This appears to be a logical place for CMS to allow waivers for Large EGHPs. First, because some EGHPs have plan years out of cycle with the calendar year, MAPlans may wish to respond to changes in the market that were not known at the time of their bid. Second, CMS seems to cite a faulty authority for its position on this issue. Section 1854(a)(1)(A) does not relate to MMA changes that affect MA Plans after CY 2006. Instead it governs the transition ACR process for CY 2004-2005. Unless CMS can cite specific authority that prohibits this arrangement by plans, or has a reasonable reason to prohibit adjustments for mid-year open enrollment by States, local governments, or other EGHPs, then it should allow either waivers or modify its policy on this issue.

*** * ***

We appreciate the opportunity to submit these comments and are available to answer any questions you may have regarding these materials.

Sincerely yours,

Jerrold J. Hercenberg
President

Attachment A

Cc: Steven Sacher, Esq.
Kevin Brown, President, Amisys-Synerterch, Inc.

CMS-4068-P-1326

Submitter : Mr. Michael Montgomery **Date & Time:** 10/04/2004 09:10:34

Organization : California DHS, Office of AIDS

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

1) "Cost-sharing subsidies from ADAPs do not count as incurred costs"(Subpart C)
2) ADAPs and 340B Pricing (Subpart C)
3) Enrollment of Dual Eligibles Into Part D (Section 422.50)

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

1)Formulary Policies Must Respond to the Clinical Needs of Medicare Beneficiaries. (Section 423.120 (B)(1))
2) People Living with HIV/AIDS are a Special Population that Require Special Treatment and Access to an Open Formulary (Section 423.120)

ELIGIBILITY, ELECTION, AND ENROLLMENT

1) Consumer Information and Outreach Issues (Section 423.48)

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

1) Need for Expidited Appeals for Persons with HIV/AIDS (Section 423.560)

CMS-4068-P-1326-Attach-1.pdf

CMS-4068-P-1326-Attach-1.pdf

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CMS-4068-P-1326-Attach-1.pdf

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

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

Dear Sir or Madam:

FILE CODE: CMS-4068-P

These comments are being submitted by the Department of Health Services, Office of AIDS (DHS/OA) in response to the proposed regulations, "42 CFR Parts 403, 411, 417, and 423 Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule."

DHS/OA has lead responsibility for the State's response to the HIV/AIDS epidemic. This includes directing a variety of HIV/AIDS programs and services addressing the prevention, education, epidemiology and care needs for an estimated 150,000 Californians living with HIV or AIDS. Of particular interest to OA are the implications of the Medicare Prescription Drug Benefit bill on the California AIDS Drug Assistance Program (ADAP).

Without an available cure for HIV/AIDS at this time, access to lifesaving prescription medications are of the highest priority for persons living with HIV/AIDS. OA urges the Centers for Medicare and Medicaid Services (CMS) to publish a final rule that insures that all Medicare beneficiaries living with HIV/AIDS have equal and affordable access to HIV medications.

Subpart C: Benefits and Beneficiary Protections

Cost-sharing subsidies from ADAPs do not count as incurred costs." (46651)

We strongly recommend that the final regulations be changed to allow ADAP's contribution to a beneficiary's out-of-pocket thresholds be counted towards a client's out-of-pocket drug costs. Without recognition of ADAP's contribution, the cost-sharing requirement could prevent clients from being able to fill necessary prescriptions, especially if those medications are not available through their state ADAP. Additionally,

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beneficiaries who cannot meet their out-of-pocket thresholds will never be able to access full, meaningful benefit under part D.

Over the past ten years, new medications for the treatment of HIV/AIDS have led to a significant decline in the number of HIV-related deaths. The success of the newer HIV medications means that an increasing number of persons with HIV are now relying on ADAPs to obtain these life-sustaining medications. Unfortunately, ADAP funding has not kept pace with this growing need.

For the past two years, budget constraints have forced California to consider the possibility of limiting access to the State's ADAP. Unfortunately, the availability of the proposed Part D benefit will only increase the fiscal pressure on ADAPs. Currently California's ADAP budget includes $66.54 million in state general funds. OA would request that ADAPs be allowed to subsidize Part D cost-sharing requirements, including considering ADAP's drug cost contributions toward the beneficiaries' out-of-pocket expenses with state funds. OA would also encourage CMS to grant ADAPs the same status as the State Pharmaceutical Assistance Programs, allowing ADAPs to wrap-around the Part D benefit.

ADAPs and 340B Pricing (46651)

The regulations encourage state ADAPs to move toward the model of purchasing their drugs directly, under the 340B Program, instead of using a rebate model. OA feels it is inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview and recommends that such comments not be included in the Part D regulations. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by the Health Resources and Services Administration, the federal agency that oversees the Ryan White CARE Act and the 340B Program.

There are several states that use a rebate option model available to ADAPs under 340B to purchase drugs instead of the direct purchase model. These states, including California and New York, the two largest ADAPs, have carefully analyzed the cost-benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study that demonstrated 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.

Enrollment of Dual Eligibles into Part D (Section 422.50)

OA encourages CMS to reconsider its timeline for auto enrollment of dual eligibles into the Part D program. Given the medical frailty and higher medication needs of persons with HIV, it would be devastating for this vulnerable population to be left without drug coverage because of the complications of transitioning from a public drug benefit to a private benefit. We would recommend that CMS either consider delaying enrollment of dual eligibles until six months after implementation of the Part D benefit, or consider automatic enrollment of dual eligibles by January 1, 2006.

Formulary Policies Must Respond to the Clinical Needs of Medicare Beneficiaries [Section 423.120(B)(1)]

OA recommends strengthening the CMS reference to Pharmaceutical and Therapeutic (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 Public Health Service 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.

People Living with HIV/AIDS are a Special Population that Require Special Treatment and Access to an Open Formulary (Section 423.120)

OA strongly recommends that CMS designate people with HIV/AIDS 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.

Subpart M: Appeals and Grievance

Need for expedited appeals for persons with HIV/AIDS (Section 423.560) [Section 423.5789(c)(2)]

Interruptions in treatment can have severe consequences for persons with HIV/AIDS. For this reason, we recommend that this population be granted expedited appeal rights under Part D. We would also recommend that beneficiaries receive a medication supply pending appeal. Also, due to the possibility of physical or cognitive difficulties

that could limit a person's ability to advocate for their own health needs, we recommend that physicians, advocates, and family members be allowed to submit appeals on behalf of beneficiaries.

Subpart B: Eligibility, Election, and Enrollment

Consumer Information and Outreach Issues (Section 423.48)

Although not included in the proposed regulations, we wish to take this opportunity to recommend CMS substantially increase their consumer education and outreach activities associated with implementation of the Part D benefit.

Experience with the discount drug card has shown us that a majority of CMS's education and outreach efforts were specifically focused on the needs of seniors and did not address the specific needs of younger disabled beneficiaries. CMS should develop specific outreach and education strategies for disabled Medicare beneficiaries and should consider partnering with disability groups such as HIV/AIDS service providers in an attempt to successfully assist persons with HIV/AIDS to access benefits that will best meet their needs.

And in conclusion, we would recommend that CMS clarify and strengthen their rules regarding the individual drug plan's obligation to clearly disclose their drug formulary at the time a beneficiary is considering enrollment in a plan. CMS should consider requiring a standardized explanation of benefits, which would allow consumers the opportunity to make comparisons between plans. Additionally, drug plans should be required to provide direct notification to beneficiaries whenever the plan makes changes to their formulary. This type of required information sharing will not only empower beneficiaries to be able to make the best plan selection on their behalf, but will also assist the beneficiary who relies on multiple prescription drug programs, including ADAP, to coordinate all of their anticipated medication needs.

Thank you for your consideration of these recommendations. Should you have questions or need additional information, please contact me at (916) 449-5905.

Sincerely,

Michael Montgomery, Chief
Office of AIDS

Submitter : Ms. SHEILA NUDELL-JOHNSON **Date & Time:** 10/04/2004 09:10:22

Organization : MEDICAL PHARMACY MOORHEAD

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AS AN INDEPENDENT PHARMACY PROVIDER I FEEL IT IMPERATIVE THAT THE MEDICARE PROGRAMS ARE NOT RESTRICTIVE ON WHICH PHARMACIES PATIENTS CAN USE. WE HAVE MANY MEDICARE ELIGIBLE PATIENTS AND THEY RELY ON THE MEDICATION INFORMATION WE GIVE THEM, SINCE THEY KNOW US PERSONALLY THEY FEEL COMFORTABLE ASKING QUESTIONS, ETC.

CMS-4068-P-1328

Submitter : Ms. Carmen Catizone **Date & Time:** 10/04/2004 09:10:01

Organization : National Association of Boards of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

See attachment - Appendix A

CMS-4068-P-1328-Attach-1.doc

Appendix A

NAPLEX Blueprint

(Revised 7/03)

The NAPLEX Competency Statements

The NAPLEX Competency Statements provide a blueprint of the topics covered on the examination. They offer important information about the knowledge, judgment, and skills you are expected to demonstrate as an entry-level pharmacist. A strong understanding of the Competency Statements will aid in your preparation to take the examination.

Area 1 Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes (Approximately 54% of Test)

1.1.0 Obtain, interpret and evaluate patient information to determine the presence of a disease or medical condition, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management.

- 1.1.1 Identify and assess patient information including medication, laboratory and disease state histories.
- 1.1.2 Identify and/or use instruments and techniques related to patient assessment and diagnosis.
- 1.1.3 Identify and define the terminology, signs, and symptoms associated with diseases and medical conditions.
- 1.1.4 Identify and evaluate patient factors, genetic factors, biosocial factors, and concurrent drug therapy that are relevant to the maintenance of wellness and the prevention or treatment of a disease or medical condition.

1.2.0 Identify, evaluate, and communicate to the patient or health-care provider, the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems.

- 1.2.1 Identify specific uses and indications for drug products.
- 1.2.2 Identify the known or postulated sites and mechanisms of action of pharmacotherapeutic agents.
- 1.2.3 Evaluate drug therapy for the presence of pharmacotherapeutic duplications and interactions with other drugs, food, diagnostic tests, and monitoring procedures.
- 1.2.4 Identify contraindications, warnings and precautions associated with a drug product's active and inactive ingredients.
- 1.2.5 Identify physicochemical properties of drug substances that affect their solubility, pharmacodynamic and pharmacokinetic properties, pharmacologic actions, and stability.
- 1.2.6 Interpret and apply pharmacodynamic and pharmacokinetic principles to calculate and determine appropriate drug dosing regimens.
- 1.2.7 Interpret and apply biopharmaceutic principles and the pharmaceutical characteristics of drug dosage forms and delivery systems, to assure bioavailability and enhance patient compliance.

1.3.0 Manage the drug regimen by monitoring and assessing the patient and/or patient information, collaborating with other health care professionals, and providing patient education.

- 1.3.1 Identify pharmacotherapeutic outcomes and endpoints.
- 1.3.2 Evaluate patient signs and symptoms, and the results of monitoring tests and procedures to determine the safety and effectiveness of pharmacotherapy.
- 1.3.3 Identify, describe the mechanism of, and remedy adverse reactions, allergies, side effects and iatrogenic or drug-induced illness.
- 1.3.4 Prevent, recognize, and remedy medication non-adherence, misuse or abuse.
- 1.3.5 Recommend pharmacotherapeutic alternatives.

Appendix A

Area 2 Assure Safe and Accurate Preparation and Dispensing of Medications (Approximately 35% of Test)

2.1.0 Perform calculations required to compound, dispense, and administer medication.

2.1.1 Calculate the quantity of medication to be compounded or dispensed; reduce and enlarge formulation quantities and calculate the quantity of ingredients needed to compound the proper amount of the preparation.

2.1.2 Calculate nutritional needs and the caloric content of nutrient sources.

2.1.3 Calculate the rate of drug administration.

2.1.4 Calculate or convert drug concentrations, ratio strengths, and/or extent of ionization.

2.2.0 Select and dispense medications in a manner that promotes safe and effective use.

2.2.1 Identify drug products by their generic, brand, and/or common names.

2.2.2 Determine whether a particular drug dosage strength or dosage form is commercially available, and whether it is available on a nonprescription basis.

2.2.3 Identify commercially available drug products by their characteristic physical attributes.

2.2.4 Interpret and apply pharmacokinetic parameters and quality assurance data to determine equivalence among manufactured drug products, and identify products for which documented evidence of inequivalence exists.

2.2.5 Identify and communicate appropriate information regarding packaging, storage, handling, administration, and disposal of medications.

2.2.6 Identify and describe the use of equipment and apparatus required to administer medications.

2.3.0 Prepare and compound extemporaneous preparations and sterile products.

2.3.1 Identify and describe techniques and procedures related to drug preparation, compounding, and quality assurance.

2.3.2 Identify and use equipment necessary to prepare and extemporaneously compound medications.

2.3.3 Identify the important physicochemical properties of a preparation's active and inactive ingredients; describe the mechanism of, and the characteristic evidence of incompatibility or degradation; and identify methods for achieving stabilization of the preparation.

Area 3 Provide Health Care Information and Promote Public Health (Approximately 11% of Test)

3.1.0 Access, evaluate, and apply information to promote optimal health care.

3.1.1 Identify the typical content and organization of specific sources of drug and health information for both health-care providers and consumers.

3.1.2 Evaluate the suitability, accuracy, and reliability of information from reference sources by explaining and evaluating the adequacy of experimental design and by applying and evaluating statistical tests and parameters.

3.2.0 Educate the public and health-care professionals regarding medical conditions, wellness, dietary supplements, and medical devices.

3.2.1 Provide health care information regarding the prevention and treatment of diseases and medical conditions, including emergency patient care.

3.2.2 Provide health care information regarding nutrition, lifestyle, and other non-drug measures that are effective in promoting health or preventing or minimizing the progression of a disease or medical condition.

3.2.3 Provide information regarding the documented uses, adverse effects and toxicities of dietary supplements.

3.2.4 Provide information regarding the selection, use and care of medical/surgical appliances and devices, self-care products, and durable medical equipment, as well as products and techniques for self-monitoring of health status and medical conditions.

CMS-4068-P-1329

Submitter : Mr. Kyle Ardoin **Date & Time:** 10/04/2004 09:10:12

Organization : Louisiana Independent Pharmacies Association

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

File Code CMS - 4068-P
On behalf of the Louisiana Independent Pharmacies Association, Inc. and its members, we offer these comments to CMS on the Proposed Rule for the Medicare Prescription Drug Benefit. Our comments address on 42 C.F.R. Section 423.120 Access to Covered Part D Drugs.

42 C.F.R. Section 423.120(a)(4)
The comments to 42 C.F.R. Section 423.120(a)(4) suggest that it is "unreasonable to assume that a PDP sponsor or MA organization could establish a network using a uniform set of terms and conditions throughout a service area." To the contrary, the Louisiana Medicaid program has a uniform set of terms and conditins, with the only distinction being at two-tiered reimbursement rate: the reimbursement rate for independent pharmacies has been maintained slightly above that of chain pharmacies. We agree with the suggestions in the comments that rural pharmacies should be subject to special consideration to assure access as required by the Act. Most rural pharmacies in Louisiana are aindependent pharmacies; therefore, a higher reimbursement rate for independents is justified. We recommend that 42 C.F.R. Section 423.120(a)(4)(i) be revised add the following:

(iii) May provide for a higher reimbursement rate for independent pharmacies:

We believe that the provisions of 42 C.F. R. Section 423.120(a)(5) permitting "preferred pharmacies" are in conflict with section 1860D-4(b)(1)(A) of the Act requiring PDP sponsors and MA organizations offering as MA-PD plan to permit the participation in their plan networks of any pharmacy willing to accept the terms and conditions of the plan. Proposed rule 42 C.F. R. Section 423.120(a)(5) would permit a PDP sponsor or MA organization effectively to coerce patients to use a sub-network of pharmacies by offering reduced co-payments or coinsurance for the use of a preferred pharmacy. Such an arrangement is likely to result in reduced access for rural plan beneficiaries. The proposed rule has already reduced access for Medicare beneficiaries under Section 423.120(a)(1)(iii). They should not be further exposed to the potential for lost access. We propose that 42 C.F.R. Section 423.129(a)(5) be deleted.

We belileve that the substance of 42 C.F.R. Section 423.120(a)(6) is contrary to Section 1860D-4(b)(1)(D) of the Act requiring PDP sponsors and MA organizations to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. In fact, the substance of 42 C.F.R. Section 423.120(a)(6) is contrary to the language of its heading "level playing field between mail-order and network pharmacies." By requiring an enrollee to pay the difference in price for a drug at the network retail pharmacy versus the network mail-order pharmacy, the filed is anything but level. If an enrollee must pay a higher price to get a 90 day supply of drugs from a retail pharmacy, the plan is encouraging the use of mail-order. By statute, Louisiana prohibits a health plan from imposing upon an employee or retiree who does not utilize a designated mail order pharmacy a copayment fee or other condition not imposed upon employees or retirees who utilize the designated mail order pharmacy. See La. R.S. 22:226(A)(2). An employer-provided health plan is also barred from requiring the employee or retiree to obtain prescription drugs from a mail order pharmacy as a condition of obtaining payment for such drugs. See LA. R.S. 22:266(A)(1). We propose that 42 C.F.R. Section 423.120(a)(6) be revised to provide:
A PDP sponsor or MA organization is prohibited from imposing upon an enrollee who elects to use a network retail pharmacy a copyament fee or otehr condition not imposed upon an enrolle who utilizes a network mail-order pharmacy.
This language exemplifies the itnent of the Act to allow enrollees to choose to receive prescriptions at a network retail pharmascy instead of a network mail-order pharmacy without penalty.

CMS-4068-P-1329-Attach-1.doc

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8014

Re: File Code CMS -4068- P

On behalf of the Louisiana Independent Pharmacies Association, Inc. and its members, we offer these comments to CMS on the Proposed Rule for the Medicare Prescription Drug Benefit. Our comments address on 42 C.F.R. ' 423.120 Access to Covered Part D Drugs.

42 C.F.R. ' 423.120(a)(4)

The comments to 42 C.F.R. ' 423.120(a)(4) suggest that it is Aunreasonable to assume that a PDP sponsor or MA organization could establish a network using a uniform set of terms and conditions throughout a service area.@ To the contrary, the Louisiana Medicaid program has a uniform set of terms and conditions, with the only distinction being at two-tiered reimbursement rate: the reimbursement rate for independent pharmacies has been maintained slightly above that of chain pharmacies. We agree with the suggestions in the comments that rural pharmacies should be subject to special consideration to assure access as required by the Act. Most rural pharmacies in Louisiana are independent pharmacies; therefore, a higher reimbursement rate for independents is justified. We recommend that 42 C.F.R. ' 423.120(a)(4)(i) be revised add the following:

(iii) May provide for a higher reimbursement rate for independent pharmacies;

42 C.F.R. ' 423.120(a)(5)

We believe that the provisions of 42 C.F.R. ' 423.120(a)(5) permitting Apreferred pharmacies@ are in conflict with section 1860D-4(b)(1)(A) of the Act requiring PDP sponsors and MA organizations offering a MA-PD plan to permit the participation in their plan networks of any pharmacy willing to accept the terms and conditions of the plan. Proposed rule 42 C.F.R. ' 423.120(a)(5) would permit a PDP sponsor or MA organization effectively to coerce patients to use a sub-network of pharmacies by offering reduced co-payments or coinsurance for the use of a preferred pharmacy. Such an arrangement is likely to result in reduced access for rural plan beneficiaries. The proposed rule has already reduced access for Medicare beneficiaries under ' 423.120(a)(1)(iii). They should not be further exposed to the potential for lost access. We propose that 42 C.F.R. ' 423.120(a)(5) be deleted.

42 C.F.R. ' 423.120(a)(6)

We believe that the substance of 42 C.F.R. ' 423.120(a)(6) is contrary Section 1860D-4(b)(1)(D) of the Act requiring PDP sponsors and MA organizations to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. In fact, the substance of 42 C.F.R. ' 423.120(a)(6) is contrary to the language of its heading Alevel playing field between mail-order and network pharmacies.@ By requiring an enrollee to pay the difference in price for a drug at the network retail pharmacy versus the network mail-order pharmacy, the field is anything but level. If an enrollee must pay a higher price to get a 90 day supply of drugs from a retail pharmacy, the plan is encouraging the use of mail-order. By statute, Louisiana prohibits a health plan from imposing upon an employee or retiree who does not utilize a designated mail order pharmacy a copayment fee or other condition not imposed upon employees or retirees who utilize the designated mail order pharmacy. *See* La. R.S. 22:226(A)(2). An employer-provided health plan is also barred from requiring the employee or retiree to obtain prescription drugs from a mail order pharmacy as a condition of obtaining payment for such drugs. *See* La. R.S. 22:266(A)(1). We propose that 42 C.F.R. ' 423.120(a)(6) be revised to provide:

> A PDP sponsor or MA organization is prohibited from imposing upon an enrollee who elects to use a network retail pharmacy a copayment fee or other condition not imposed upon an enrollee who utilizes a network mail-order pharmacy.

This language exemplifies the intent of the Act to allow enrollees to choose to receive prescriptions at a network retail pharmacy instead of a network mail-order pharmacy without penalty.

CMS-4068-P-1330

Submitter : Valerie Wilbur **Date & Time:** 10/04/2004 09:10:33

Organization : Medicare Policy Coalition High Risk Beneficiaries

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Improving Payment and Performance for High-Risk Beneficiaries

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4068- P

Dear Sirs:

The National Health Policy Group appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Prescription Drug Program, on behalf of the Medicare Policy Coalition for High Risk Beneficiaries (MPC).

The Medicare Policy Coalition is an alliance of Medicare Advantage Plans and providers that have made a unique commitment to serving high-risk beneficiaries such as the frail elderly and adult disabled. MPC members have a strong interest in the Special Needs Plan designation and other aspects of the Medicare Advantage proposed rule affecting high-risk Medicare beneficiaries as they all currently offer special programs of care for these beneficiaries, many under Medicare demonstrations. Special Needs Plans offer a potential vehicle for the demonstrations to transition to permanent plan status and for non-demonstrations to intensify their focus on targeted beneficiary groups. They also provide a vehicle for more traditional plans and provider networks to develop a specialization in serving special needs beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us at 202-264-1508.

Sincerely,

Richard J. Bringewatt Valerie S. Wilbur
President Vice President
Chair, Medicare Policy Coalition Co-chair, Medicare Policy Coalition

801 Pennsylvania Avenue, Suite 245, Washington DC 20004 (202) 624-1516 Fax: (202) 737-6462 www.nhpg.org

MPC Members
? AXIS Healthcare, St. Paul, MN
? Community Care Organization, Milwaukee, WI
? Community Health Partnership, Eau Claire, WI
? Community Living Alliance, Madison, WI
? Elder Care of Dane County, Madison, WI

? Elder Health - Baltimore, MD
? Elderplan- NY, NY
? Evercare- Minneapolis, MN
? Geriatrix ? Brentwood, TN
? SCAN - Long Beach, CA

CMS-4068-P-1330-Attach-1.doc

Comments to Medicare Advantage Program
Notice of Proposed Rule Making
CMS-4068-P

Submitted by
Medicare Policy Coalition for High-Risk Beneficiaries (MPC):
October 4, 2004

Subpart A: General Provisions

§Section 422.2 Definitions

§Section 422.2 Definition of "Institutional"

CMS defines institutional as residing in a Medicare or Medicaid long-term care facility for more than 90 days as determined by the presence of a 90-day assessment using the Minimum Data Set (MDS).

MPC Comments

The MPC recommends that "institutionalized" be defined as residing in a Medicare or Medicaid long-term care facility for 30 days or longer. MPC members with extensive experience in serving an institutionalized population have found that enrolling these beneficiaries in special needs programs earlier in the admissions process enhances care outcomes by providing beneficiaries more aggressive primary care to prevent acute exacerbations of chronic illness, preventing rehospitalizations and the attendant consequences such as infections, delirium and functional decline and addressing other special care needs such as care coordination. This rule would be consistent with current practice since beneficiaries currently receive institutional status 30 days post admission at which point they are eligible for the institutional rate. Verification of eligibility, therefore, could be determined by confirmation of a resident's admission date into the nursing home and eligibility for the institutional rate. Validation of long-term status, as opposed to a short-term subacute care stay, could further be validated by the absence of an active discharge plan.

The MPC also requests that the definition of institutionalized include those residing in an Intermediate care Facility for the Mentally Retarded (ICF-MR). ICF-MRs are defined as institutional services under federal Medicaid rules. Since the current definition of "institutionalized" requires validation through the presence of a 90-day assessment, and ICF-MRs are not subject to this assessment, it appears that these institutions would be excluded from the definition. The MPC strongly supports the certification of SNPs for special needs individuals with "severe or disabling chronic conditions" which would include Medicare-eligible individuals with developmental disabilities and mental retardation, many of whom reside in ICF-MRs. Accordingly, the definition of "institutionalized" needs to be broad enough to encompass this population and verification of eligibility could be determined via confirmation of their admission date, as noted above.

§Section 422.2 Definition of "Severe or Disabling Chronic Condition"

CMS invites comments on whether to set standards for the designation of an individual with severe or disabling chronic conditions and, if standards should be set, what criteria should be used. Examples CMS offers for the definition include a threshold of four or more conditions, the need for medical management

by a specialist, qualification for a plan's disease management program, or the presence of a disability requiring a level of care similar to an institution.

MPC Comments

The MPC supports the development of criteria for defining special needs individuals with severe or disabling chronic conditions to provide a basis for determining eligibility for enrollment. We believe that four criteria should provide the basis for establishing the definition. The condition must:

1. Be based on clinical characteristics including diagnoses, functional impairment levels, and other relevant clinical factors such as cognitive impairment.
2. Be linked to standard CMS data sources including CMS-HCC diagnoses, Health Outcomes Survey (HOS) data, and Medicare Current Beneficiary Survey data.
3. Be high-cost and likely to remain high-cost.
4. Be one that would not be well served by a standard MA plan.

The MPC invested a significant amount of time in working toward a recommendation for "severe or disabling" that would meet the above criteria as discussed further below. We believe that the definition should include some combination of a specified number of medical diagnoses, specified levels of functional and/or cognitive impairment, and a specified risk score threshold. Our preliminary approach found that the presence of IADLs was a more relevant factor than we had anticipated. We also found greater variability in different high-risk populations (e.g., duals, nursing home residents) than we anticipated. As a result, we do not feel comfortable recommending a specific threshold without further research.

We therefore recommend that on an interim basis CMS restrict use of the "severe or disabling" category to specialty plans serving people who are nursing home certifiable (NHC), with the definition varying by state according to differences in state NHC definition. We believe that the only exception given to this definition are plans seeking special needs status for serving ESRD patients and beneficiaries diagnosed with AIDS. We recommend that CMS work with the MPC to continue exploring a uniform, quantitative definition of "severe or disabling" that is not program or place dependent and that can be used to identify high-risk beneficiaries across all Medicare and Medicaid programs. The MPC is the only group of specialty plans that has a high concentration of high-risk beneficiaries being served under different program arrangements and in different communities across the nation. We would welcome the opportunity to discuss our research methodology and preliminary analysis in moving toward a more uniform national definition.

We believe that clinical characteristics such as frailty, functional impairments, and multiple co-morbidities should ultimately become the basis for defining high-risk Medicare subgroups. Program-driven criteria (i.e., Medicaid) or place-driven criteria (i.e., institutional residence) make it difficult, if not impossible, to compare the effectiveness of different interventions for comparable risk groups and to evaluate the degree to which differences in outcomes are the result of different program interventions rather than differences in the make-up of the population served. Clinical criteria would allow CMS to evaluate the efficiency and effectiveness of serving the same population across programs and to establish fair and equitable payment structures across high-risk programs and communities nationwide. Toward this end, we recommend that CMS:

- ***Collect IADL Data:*** *The MPC recommends that CMS begin collecting IADL data through the Health Outcomes Survey and use this measure in conjunction with ADL measures as a criterion for identifying high-risk groups.* Research conducted by Rand and others indicates that the presence of IADLs is an important indicator of frailty, disability, or deteriorating health. The percentages of MPC beneficiaries in the three high-risk groups with two or more IADL

impairments validated this finding within the MPC population. IADLs help measure functional limitations that may be related to cognitive capacity; e.g., the ability to use the telephone and manage finances.

- ***Conduct Frailty Research:*** *CMS should pursue research to further refine the proposed definition of "severe or disabling chronic condition" by identifying frailty factors that are distinct from co-morbidities or physical disabilities.* CMS should evaluate whether these factors would increase the explanatory power of the frailty-adjusted CMS-HCC risk adjustment formula; e.g., persons with a critical mass of three or more core "frail" elements such as generalized weakness, poor endurance, weight loss, low physical activity, and slow gait speed. (Refer to the section, "New Quality/Oversight" for further discussion.)

§Section 422.2 Definition of "Specialized MA Plans"

1. MA Plans that "Disproportionately" Serve Special Needs Individuals

The statute provides CMS the authority to designate plans as special needs plans (SNPs) that "disproportionately" serve special needs individuals but does not define "disproportionate." For purposes of clarification, the MPC refers to such plans as "non-exclusive special needs plans." CMS invites comments on this definition, indicating that, at a minimum, "disproportionate" means a plan that enrolls a greater proportion of special needs individuals than exist in the service area, but that it could alternatively be defined with a discrete measure; e.g., 50% or more of a plan's beneficiaries are special needs individuals.

MPC Comments

Since the statute defines SNPs as plans that exclusively serve beneficiaries who are dually eligible, are institutionalized, or have severe or disabling chronic conditions, the MPC recommends that "non-exclusive" plans be defined as those that "disproportionately" serve one or more of these three risk groups. For purposes of identifying individuals in the third category, we define "severe or disabling" as persons who are deemed nursing home certifiable. We recommend that "disproportionate" be defined as a higher than average enrollment of one or more of the special needs individual groups as estimated for MA plans and/or the fee-for-service population. We recommend that CMS specify the "higher than average" threshold.

The MPC also supports CMS' recommendation that plans provide evidence of processes or clinical programs designed to address the unique needs of the special needs individual group. Below are examples of evidence a plan may provide to help demonstrate its intent to target and its capacity to meet the needs of special needs individuals:

- **Clinical policies, procedures, or programs** such as high-risk screening tools and care coordination procedures, contracts with medical specialists such as geriatricians and nephrologists, or protocols for managing care for a particular type of special need such as ESRD patients.

- **Indication of the uniqueness of a program** such as palliative care programs for SNPs that disproportionately enroll beneficiaries with one or more late-stage illness or family support groups for SNPs that target the enrollment of Alzheimer's patients.

- **Marketing plans or materials** targeted to special needs individual categories.

- **Program components** that reflect the presence of a critical mass of the target population such as the following:

    a) The plan employs certain specialists such as gerontologists.
    b) The plan licenses a home health agency instead of contracting for these services or provides a higher-than-average level of home health services, especially non-skilled services that assist special needs individuals with functional impairments.
    c) The plan has a defined set of clinical protocols for specified combinations of chronic conditions like COPD, CHF, and diabetes (or other sets of interaction terms included in the CMS-HCC risk adjustment methodology).

2. MA Plans that Serve Dual Eligible Subgroups

CMS indicated in the draft interim guidance on SNPs that it would require plans to serve all duals, not selectively serve subgroups such as full benefit duals. CMS invites comments on whether SNPs should be permitted to enroll certain subgroups of Medicaid or institutionalized beneficiaries.

MPC Comments
The MPC strongly supports the enrollment of certain subgroups of dually eligible beneficiaries. Specifically, we recommend that plans be permitted to serve any of the following subsets of duals:

- Frail elderly
- Children or adults who are physically disabled, developmentally disabled, or mentally impaired
- Full benefit duals, SLMBs, QMBs, or QI1s
- Nursing home certifiable or non-nursing home certifiable individuals
- Community-based or institutionalized individuals

There are several reasons for allowing plans to serve subsets of duals. First, enrollment of all Medicare beneficiaries who are eligible for Medicaid would conflict with a number of the existing programs for duals. The structure of current dually eligible demonstrations provides a clear precedent for allowing plans to select certain subgroups of duals. The Minnesota Senior Health Options demonstration (MSHO) is limited to serving seniors, and the Minnesota Disability Health Options program (MnDHO) serves an adult-disabled population. The Wisconsin Partnership Program protocol (WPP) allows plans to serve only duals that are nursing home certifiable. Within the WPP, some sites exclusively serve frail elderly, and some exclusively serve adult disabled.

Second, the needs of different subgroups may require different types or amounts of specific benefits and services. For example, the needs of frail elderly and adult disabled differ in a number of areas, as do some of the needs of different groups of adult disabled, such as physically disabled, developmentally disabled, and mentally ill.

Third, the benefit levels, services, and care management needs of full benefit duals are different from duals that are eligible for selected benefits such as state contributions to cost-sharing. Funding levels for full versus non-full benefit duals also differ. Plans would effectively need different benefits, clinical approaches, and financing for duals with different financial eligibility.

Fourth, programs serving a small number of beneficiaries may not have the financial capacity to sustain the infrastructure needed to serve several different population groups. Requiring them to do so could jeopardize chances of success. Yet a number of small, innovative programs like the Wisconsin Partnership Program demonstration and Minnesota Senior Health Options and Disability Health Options Programs have been extremely successful in developing special approaches for frail elderly and adult disabled populations. Their experience suggests that it takes significant investments of time and resources to develop operational, targeted clinical programs, care management procedures and quality assurance mechanisms for different subgroups of seniors and disabled individuals with different, complex chronic conditions. These programs should be protected and encouraged to thrive, and incentives should be provided for the expansion of these types of programs. Requiring them to serve all duals with varying health care needs could impede the ongoing development of new programs through the SNP designation.

Fifth, if the regulations prohibit the plans from targeting certain subgroups, like the frail elderly, physically disabled, mentally retarded, or other disability groups, special needs plans will fail to provide current special needs demonstrations with a vehicle for transitioning to permanency.

Plans also should be permitted to limit community enrollment to individuals who are nursing home certifiable (or, eventually, who meet more specific health-related criteria that may replace this designation) if they so choose. There are precedents for limiting enrollment to community-based plans under the PACE, WPP, and Social HMO programs. Beneficiaries receiving services in the community, including those who are nursing home certifiable, have a different set of needs than individuals residing in nursing homes. Specialty plans and providers have developed unique provider networks to serve frail and disabled individuals in the community and other networks to meet the needs of institutionalized beneficiaries. Further, community-based programs are unlikely to have the contracts and infrastructure in place to serve large numbers of nursing home residents. Medicaid capitation rates established for programs that predominantly serve community-based residents also are unlikely to support programs that serve a larger number of nursing home residents.

The MPC's recommendations on special needs plan categories are designed to accommodate existing payment and administrative policies. Members of the MPC believe that, in the long run, Congress and CMS should establish health care payment methods and administrative rules based on defined populations and the unique needs of these groups rather than care settings (e.g., nursing home versus community care settings) or interventions (e.g., acute care procedures versus long-term care services). Payment and delivery rules should be flexible enough to allow providers to deliver whatever combination of care is most clinically effective and cost-effective based on the population's need

3. Provision of Part D Benefits by Specialized MA Plans

CMS proposes that SNPs be required to offer Part D drug coverage since special needs individuals need access to drugs to manage and control severe chronic conditions. Additionally, full benefit duals who are Part D eligible will be required to obtain their drug coverage from the MA in which they are enrolled and would not have access to drug coverage if not provided by the SNP.

MPC Comments

The MPC supports the intent of this provision, contingent upon the development of an adequate risk adjustment methodology for pharmacy benefits for high-risk beneficiaries. Special needs individuals' drug costs can significantly exceed average Medicare beneficiary drug costs, putting

plans at great financial risk if the risk adjustment methods and associated drug costs are not adequately covered. For example, some of our plans average pharmacy costs in excess of $700 per member per month. In addition to direct prescription drug costs, SNPs will incur higher than average costs related to pharmacy management, such as the costs of implementing the MMA-mandated medication therapy program for targeted individuals, such as those with co-morbidities, with multiple prescriptions, and with high costs.

Subpart B: Eligibility, Election, and Enrollment

§422.52 Eligibility to Elect an MA Plan for Special Needs individuals

§422.52 Special Needs Plans for Beneficiaries with Severe or Disabling Chronic Conditions
CMS invites comments related to the development of special needs plans for several subgroups of Medicare beneficiaries. Specifically, they ask whether SNPs should be established to address the special needs of HIV/AIDS patients and whether ESRD beneficiaries should be considered to meet the requirements of special needs status.

MPC Comments
The MPC believes that in addition to the categories explicitly identified in the law, enrollment in SNPs should be limited to people with late-stage chronic conditions, people with co-morbidities, the adult disabled, and the frail elderly, with state criteria for "nursing home certifiable" used as an interim definition of severity. We believe that individuals with HIV/AIDS and ESRD fit within this general framework. We caution CMS against permitting SNPs to be used for single disease-state management. We believe that the special needs designation should be restricted to those groups where costs and quality concerns require special interventions that are beyond what is normally found in a standard managed care benefit package

§422.52 Eligibility Requirements for Enrollment in Specialized Needs Plans

1. Deeming Continued Eligibility: PACE allows individuals to remain enrolled in its plan if, in the absence of continued enrollment and access to special care, the individual reasonably could be expected to regain eligibility within a six-month period. CMS proposes to provide the same "deemed eligibility" standard to SNPs.

MPC Comments
The MPC supports this provision, as it will significantly enhance continuity of care, especially for beneficiaries who are likely to move in and out of eligibility status, such as the dually eligible. Continuity of care also will contribute to cost-effectiveness and improved clinical outcomes.

2. Exceptions:

Grandfathering: If a standard MA plan is re-designated as an SNP, CMS proposes to allow individuals already enrolled to remain in the plan, but it invites comments on whether plans should be permitted to involuntarily disenroll these individuals. A special election period would be provided to permit beneficiaries to enroll in another MA plan. New enrollees would be expected to meet the special needs individual criteria.

MPC Comments
The MPC supports CMS' proposal to allow beneficiaries to remain enrolled.

Involuntary Disenrollment: In the case of new enrollees, if a qualified individual enrolls in an SNP and later becomes ineligible, CMS proposes that the individual be involuntarily disenrolled. CMS also states that the individual be informed prior to enrollment that they may only remain enrolled as long as they meet eligibility requirements.

MPC Comments

The MPC recommends that plans be permitted to involuntarily disenroll members who lose eligibility status, but it recommends that a special election period be provided to allow the individual to enroll in another MA plan if desired. Further, we recommend that plans be permitted to maintain the enrollment of special needs individuals who lose eligibility for lapses in coverage that are expected to be temporary, i.e., six months or less. For example, dual eligible beneficiaries frequently lose eligibility on a temporary basis, sometimes related to administrative lapses or in relation to medically needy status. Alternatively, an ESRD beneficiary may lose eligibility after a transplant, but become eligible again if the transplant fails. To address such situations, plans should have the ability to maintain enrollment or involuntarily disenroll for up to six months. After six months, exclusive SNPs should be required to terminate enrollment if the individual does not regain eligibility. Non-exclusive SNPs should have the option of maintaining enrollment of such individuals since these plans serve a mix of special needs and non-special needs individuals.

3. Special Election Periods: CMS has the discretion to create new special election periods to allow beneficiaries to disenroll from one MA plan and enroll in another. CMS provides for SEPs for special needs individuals in certain circumstances, such as when beneficiaries choose to disenroll from a plan that is redesignated as an SNP. SEPs should be more broadly designated for special needs individuals.

MPC Comments

The MPC recommends that CMS create a special election period for special needs individuals that would be open for the duration of the individual's eligibility for an SNP. Special needs individuals, by definition, require flexibility in accessing SNPs when their needs become evident. Medicare beneficiaries cannot predict in advance when they may need permanent nursing home care or when they may become eligible for Medicaid benefits. Nor can they predict in advance when their health status may deteriorate to the point where access to special care interventions could mean the difference between maintaining and losing health reserves. Establishing a SEP that is open for the duration of an individual's eligibility would allow an enrollee who is eligible for an SNP to switch from a non-special needs plan or fee-for-service arrangement to an SNP at the time of need.

§Section 422.52 Other Waiver Provisions for Specialized MA Plans

The preamble states that, excepting the specific requirements that all Medicare-eligible individuals be permitted to enroll in MA plans and that ESRD beneficiaries be restricted from enrolling, all other MA provisions would apply to SNPs.

MPC Comments

The MPC recommends that CMS include a general provision in the rule that allows them to waive or modify MA requirements that conflict with the intent of the SNP provision. In its contracts with the Social HMOs, CMS has waived or modified some MA requirements that would not apply to the enrollment and marketing practices of the Social HMOs. We believe comparable waivers may be necessary for SNPs. Therefore, we believe it is important for CMS to incorporate the regulatory authority to waive requirements, as the need arises.

§Section 422.66 MA enrollees defaulting into an MA-PD plan on January 1, 2006

CMS is providing that individuals enrolled in an MA plan that, as of December 31, 2005, provides any prescription drug coverage, would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006.

MPC Comments

The MPC supports this provision as an efficient strategy for maintaining coverage and promoting continuity of care for the individual. This strategy works in cases where the premium of the MA plan does not exceed the low-income subsidy amount. We are extremely concerned about continuity for beneficiaries who are enrolled in an MA plan whose premium is higher than the low-income subsidy amount. We welcome the opportunity to work with CMS to identify strategies to enable these beneficiaries to remain enrolled in their MA plans. We urge CMS to ensure that the regulations provide sufficient flexibility to support a solution that best meets the needs of beneficiaries and is workable for MA-PD plans. The MPC recommends that CMS expand this provision to allow enrollees of an MA plan who may have drugs under Medicaid, but not the MA plan to be enrolled in the MA-PD plan.

State Relationship to Dual SNPs:

The SNP statute and regulations do not build in a role for the state, even though states have significant responsibilities with respect to the dually eligible population and have been instrumental in developing and implementing Medicare/Medicaid integration programs.

MCP Comments

Through guidance, CMS should clarify its expectations and objectives with regard to the expected state role in developing and approving SNPs that serve dually eligible beneficiaries**.** In addition, the MPC recommends that CMS give states maximum flexibility in using waiver authority to integrate Medicare and Medicaid benefits for duals under SNP programs. There are a number of "disconnects" between Medicare and Medicaid rules, such as different appeals procedures and timelines, benefit definitions (e.g., home health, DME), enrollment processes (e.g., accretion and deletion dates, member services personnel, requirements for prior authorization), payment incentives, and a host of other financial and administrative rules. We urge CMS to provide similar administrative flexibility for all special needs plans to enable them to implement special programs of care for the dually eligible that are as seamless as possible for beneficiaries. Ideally, there should be a single integrated health care system for duals, but as long as there are two separate programs, there will be two sets of rules. Special needs plans offer a permanent vehicle for addressing these challenges through better coordination of Medicare and Medicaid benefits, much as selected demonstrations are doing on a limited basis today.

Subpart D: Quality Improvement Program

§422.152: Quality Improvement Program

The MMA statute calls for a report to Congress no later than December 31, 2007, that assesses the impact of specialized MA plans on the cost and quality of services provided to enrollees. CMS invites comments on whether there are appropriate quality oversight mechanisms to improve quality for special needs individuals.

MPC Comments

The MPC recommends that CMS work with Congress to extend the evaluation period for the report to Congress to provide the time needed to develop and adequately test alternative evaluation methods tailored to the needs of special needs individuals. We request the opportunity to work with CMS in developing alternative quality assurance and performance evaluation methods that:

- Are more appropriate to the special needs populations served.
- Measure performance in relation to unique health problems and risks faced by special needs individuals and the special interventions employed by SNPs to address these problems.
- Measure SNP performance against other plans and providers in relation to comparable risk groups to ensure fair evaluation of outcomes relative to risk.

The MPC recommends that CMS establish an expert panel composed of researchers, plans, providers, consumers, and policymakers to develop more appropriate quality measures for high-risk beneficiaries.

The MPC recently conducted a survey of its members to identify the most significant barriers to effectively serving high-risk beneficiaries. Key performance and quality-of-care barriers included:

- Inappropriate quality measures for high-risk populations
- Fragmented delivery systems and lack of coordination between acute and long-term care systems and between Medicare and Medicaid programs
- Priority focus on single-state disease management, not a population-based approach to medically complex beneficiaries with multiple co-morbidities
- Lack of quantitative evidence of the costs and benefits of care management
- The need for evidence-based guidelines for clinical care for the most common chronic medical illnesses in high-risk populations
- Volume-driven reimbursement biased toward specific treatments and procedures, not quality-driven payment rewarding the critical, time-consuming, "cognitive" work required for high-risk patient management

Current evaluation methods focus almost exclusively on evaluating “measurable” medical procedures used in the treatment of acute events or episodes for single disease states. They ignore the influence of co-morbid illnesses, functional limitations, and frailty on care outcomes. They ignore the multidimensional and ongoing nature of chronic illness care and the cumulative effects of the different interventions provided as care needs evolve across time, place, and profession. Effective evaluation of plans serving high-risk Medicare beneficiaries requires a shift in orientation from treatment of acute conditions to a focus on chronic conditions. Evaluation of chronic illness care must give more focus to the effects of care interventions on preventing or delaying disease and disability

progression, maximizing functional capacity, and minimizing the "cascading" of disease and disability common among beneficiaries with multiple conditions and limited health reserves. Special needs plans should be evaluated on their effectiveness in addressing the unique risks faced by high-risk beneficiaries such as those associated with frailty, disabilities, and co-morbidities; for example:

- Beneficiaries with multiple chronic conditions taking multiple medications are at greater risk of adverse drug interactions.
- Nursing home residents are at risk of unnecessary hospitalizations for acute conditions because physician access and payment is linked to hospital settings.
- Frail seniors living alone are at risk of nursing home placement when they lose self-care capabilities.
- Beneficiaries with four or more chronic conditions are 99 times more likely to be hospitalized for preventable, ambulatory care-sensitive conditions.
- Hospitalization places seniors at significant risk for such outcomes as delirium, functional decline, incontinence, depression, pressure sores, iatrogenic illness, and other adverse impacts, which, in some cases, never fully resolve.

Modifications to our current performance evaluation systems are needed to account for these and other risks unique to high-risk beneficiaries with special needs. The MPC developed recommendations on improving performance evaluation methods for high-risk Medicare beneficiaries in response to the MMA mandate that CMS establish research priorities for Medicare, Medicaid, and SCHIP (Attachment A). We believe these recommendations are also appropriate for consideration in relation to quality oversight for special needs plans. We believe CMS has a key opportunity to develop a uniform approach to performance evaluation for plans serving high-risk beneficiaries using performance measures that are more appropriate to this population.

The MPC suggests five steps for improving performance evaluation and outcomes for SNPs:

1. Identify more appropriate indicators for evaluating quality care for high-risk Medicare beneficiaries.
2. Evaluate and enhance clinical knowledge about the relationships among frailty, disability, and co-morbidities, and further refine definitions of each clinical entity.
3. Identify and disseminate best practice guidelines for high-risk populations.
4. Enhance integration/coordination of care and oversight for the dually eligible.
5. Continue refining payment systems in support of improved quality.

Each of these recommendations is discussed further below.

1. Identify more appropriate indicators for evaluating quality care for high-risk Medicare beneficiaries (including for the over-65 senior population and the under-65 adult disabled population). MPC members indicate that current quality measures often are inconsistent with patient needs. For example, the Minimum Data Set is a more appropriate measure of quality for permanent nursing home residents than HEDIS. The Assessing Care of Vulnerable Elders (ACOVE) research project conducted by Rand validates the need for more appropriate quality measures, indicating, "Existing measures of quality or health status are often inappropriate for the elderly." Rand developed a simple questionnaire to identify vulnerable elders on the basis of age, limitations in physical functioning and functional disabilities, and self-rated health. It used a panel of geriatric experts to develop 236 quality of care indicators for 22 medical conditions that are prevalent among older adults and likely to contribute to morbidity, mortality, and functional decline. The indicators focus on four domains of care, including prevention, diagnosis, treatment, and follow-up. (Exhibit 1 lists the 22

medical conditions identified by Rand's clinical panel.) The Rand study could provide a foundation for further development of more appropriate quality measures for SNPs.

2. Evaluate and enhance clinical knowledge about the relationships among frailty, disability, and co-morbidities, and further refine definitions of each clinical entity. Medicare was designed as an acute care program, while the needs of its beneficiaries have become predominantly chronic in nature. Frailty, disability, and co-morbidities are common by-products of chronic illness. These terms often are used almost interchangeably to describe the problems of high-risk beneficiaries. Research conducted by Dr. Linda Fried and others at Johns Hopkins University suggests that these conditions are distinct, though highly interdependent clinical entities. They recommend improving our ability to distinguish among these entities, refining their definitions and criteria, developing standardized approaches to screening and risk adjustment, and promoting exploration of interventions to prevent onset and adverse outcomes for each condition. Of special interest to MPC members is further evaluation of frailty indicators, the establishment of a generally accepted definition of frailty, and evaluation of best practices for preventing or delaying the onset of frailty and disability.

3. Identify and disseminate best practice guidelines for high-risk populations. MPC members have noted the challenges of identifying evidence-based best practices for high-risk populations and for integrating care for the chronically ill, given that this type of specialization is still the exception to the rule. We recommend identifying or developing and disseminating best practice and evidence-based guidelines for clinical care of the most common chronic medical illnesses in high-risk populations. We also note the need for quantitative information about the added value of care management and other non-medical services to improve clinical and financial outcomes for high-risk beneficiaries.

CMS has administered numerous demonstrations in the past two decades testing various financing and delivery approaches for improving care and outcomes for high-risk Medicare beneficiaries. These demonstrations have developed alternative clinical approaches and protocols for serving frail elderly and disabled beneficiaries. While a uniform evaluation method was not used for these programs to allow an "apples to apples" comparison of outcomes across programs, there is much to be learned from a review of best practices developed by plans and providers under these demonstrations. The MPC recommends drawing upon the knowledge and experiences of the providers, plans, and consumers involved in these demonstrations. CMS could conduct a survey of these demonstrations to identify what industry and consumers deem best practices. SNPs provide a venue for continued testing and refining of the best practices and protocols developed under these demonstrations.

4. Enhance integration/coordination of care and oversight for the dually eligible. According to MedPAC's June 2004 *Report to the Congress: New Approaches in Medicare*, public policy for the dually eligible "creates incentives to shift costs between payers, often hinders efforts to improve quality and coordinate care, and may reduce access to care." Differences in administrative requirements for Medicare and Medicaid risk contracting such as enrollment, grievance, data collection, quality assurance, and other oversight and payment rules also hinder coordination of benefits and services and promote cost-shifting between payers. To enhance coordination between the two programs, we need to better understand how specific statutes, regulations, and interpretive guidelines hinder coordination between the two programs and how this fragmentation affects costs and outcomes. We need to: (a) identify and prioritize legislative and regulatory barriers to effective coordination of Medicare and Medicaid benefits for the dually eligible and (b) evaluate how Medicare and Medicaid linked data enhances plans' and providers' ability to better define the dually eligible population demographically and clinically, measure risk and costs, and evaluate outcomes.

5. Refine financing methods for high-risk beneficiaries in support of enhanced outcomes. The MPC survey revealed the ongoing need for payment reform to enhance care, care coordination, and outcomes for high-risk beneficiaries. Providers are rewarded for treatment and procedures, not the time-consuming cognitive work that is needed to develop and manage a comprehensive plan of care for beneficiaries with multiple, complex chronic conditions. Skilled nursing facilities are paid more for short-term rehabilitation than complex care and permanent residents. Risk adjustment models, while dramatically improved, still fail to recognize frequent geriatric syndromes—dementia, incontinence, depression, and others—that can significantly increase total medical costs.

New financial models are needed that support and provide incentives for multi-practice groups, coordinated care, and quality outcomes. Managed care payment methods have the potential to enhance quality, outcomes, cost-effectiveness, and client satisfaction since providers can direct dollars to whatever interventions and services they deem most clinically effective and economically efficient. To the extent that this flexibility enhances coordination of care among providers caring for the same patient, reduces medical errors, and improves outcomes, managed care payment methods have the potential to produce savings and reduce inefficiencies. The MPC recommends a more targeted evaluation of the impact of capitated payment methods on clinical decision-making, care interventions, and treatment approaches and a determination of how changes in treatment methods affect outcomes for frail elderly, disabled, and beneficiaries with serious chronic conditions.

Subpart F: Submission of Bids, Premiums, and Related Information and Plan Approval

§422.254: Submission of Bids

General Concerns

All Medicare Advantage (MA) plans and demonstrations must participate in the bidding process with the exception of PACE, which is exempt from bidding on Part A and B benefits. MPC members are concerned that the bidding process could significantly disadvantage many SNPs by forcing them to prepare a bid for a substantially different product offered, and under a different organizational structure than the typical MA plan. This may result in certain unanticipated consequences for special needs plans and individuals that CMS did not intend. We also recognize that, at this point in time, there are a number of uncertainties regarding the process and final risk adjustment methods for Part A, B and D benefits that make it difficult to fully understand or evaluate the true impact on all plans.

The starting point for our concerns regarding the impact of the bidding process is that SNPs enroll a different beneficiary population and offer a richer package of services. These differences are most significant for Medicare/Medicaid integration demonstrations for the dually eligible. SNPs offer a comprehensive package of primary, acute, and long-term care benefits that, under demonstration programs, have been financed through a combination of Medicare and Medicaid payments. Second, SNPs serve a higher risk population, creating greater reliance on the accuracy of the MA risk adjustment methodologies. An analysis of the CMS-HCC model in the most recent *Health Care Financing Review* indicates that the model continues to underpredict costs by 14% for the highest cost quintile, 23% for the top 5% of beneficiaries and 31% for the top 1% of beneficiaries. SNPs that exclusively serve special needs individuals have a significant portion of their risk spread across beneficiaries in the upper risk ranges where the CMS-HCC model underpredicts risk. Even if the frailty adjuster is incorporated into the overall MA risk adjustment, it is uncertain if the full costs of care will be covered. In addition to higher

utilization, many SNPs are small plans with significantly smaller beneficiary populations that lead to higher fixed administrative costs. Finally, for dual eligible demonstrations that historically have integrated Medicare and Medicaid benefits and funding, the process of accounting for Medicare and Medicaid costs separately will be a significant challenge and is inconsistent with the goals and structure of these programs.

Each of these considerations may lower the estimate of savings necessary to buy-down cost-sharing requirements and could result in new premiums for the services currently offered under specialty plan models. As the MPC understands the bidding process, the ability to produce savings will be affected by the bidding process in 3 ways:

1. **Costs of Part A/B Benefits:** Plans develop their bids for A/B services on the basis of their actual utilization experience and then "normalize" the bid to reflect the national average risk level of 1.0. For example, if the cost of offering hospital services to a plan with a risk score of 1.5 were $600 pmpm, the cost for an average beneficiary with a risk score of 1.0 would be normalized at $400 pmpm (i.e., $600 /1.5). When plans develop their A/B benefit package, it is based on standard A/B covered benefits (plus administrative costs and retained earnings or profits) and the estimated cost-sharing amount. If this total amount is at or below the benchmark (i.e., county rate), plans can offer a zero-based premium. If the cost is above the benchmark, the plan must charge the difference in an A/B premium. (For duals, some states may cover all or part of this premium.)

2. **Supplemental Benefits:** Supplemental benefits are funded with 75 percent of the difference, if any, between the benchmark and the plan bid for Part A/B benefits or through a supplemental premium. SNPs typically have provided more generous benefits than standard plans. If there are little or no savings from the estimated costs for the provision of A/B benefits, the concern is whether our plans can continue to provide these benefits without a substantial increase in member premiums.

3. **Part D Premium:** If the Part D bid is above the benchmark, it results in an additional premium. For duals, if the low-income subsidy for Part D benefits were lower than the plan's beneficiary premium, the beneficiary would have to pay the premium since states cannot fund the Part D premium.

In summary, because SNPs' use of A/B services is higher than average and the payment methodology does not fully account for the higher resultant costs, the higher utilization is likely to be reflected in limited savings to the plan or a premium for the beneficiary. If there are no savings, the plan cannot offer supplemental benefits, or it has to charge a premium for the supplemental benefits. If the bid for Part D benefits exceeds the benchmark, which is based on a weighted average of MA-PD and PDP drug bids, there would be a third premium added to the mix. If there were no savings from Part A/B benefits to buy down the excess drug premium, the beneficiary would have to pay that premium, including duals.

Since many of the specialty plans operating under demonstration status serve dually eligible beneficiaries, premiums are not an option for a number of special needs individuals. While some of the states participating in Medicare/Medicaid integration demonstrations historically have provided cost-sharing for duals, if the cost-sharing levels increase as a result of the new bidding process, mandatory cost-sharing requirements, and other changes in the MMA, states may not be able to continue providing a level of cost-sharing that reduces beneficiary premiums to zero. This current state budget crisis underscores this concern. To the extent that states cannot fully fund cost-sharing, risk is shifted to the plans, further exacerbating the financial risk related to risk adjustment methods.

The bidding process creates the greatest difficulties for dually eligible demonstrations due to their program structures. These models were designed to integrate Medicare and Medicaid benefits and pool

funding so that providers can allocate benefits on the basis of beneficiary need, not payment policy. Accordingly, these programs have not been required to track Medicare and Medicaid costs separately and file ACRs like standard plans. The bidding process will require these programs to begin accounting for individual services based on Medicare and Medicaid payment policy, which is inconsistent with the intent of the demonstration. The whole purpose of Medicare/Medicaid integration programs is to look at the totality of a person's need and optimize costs across the two funding sources rather than sub-optimize costs within each program, with cost shifting an integral strategy to cost savings. Over the long term, the result is invariably an *increase* in costs for *both* programs, not to mention the added cost burden of fragmented administration and adverse effects on quality of care. It is possible that these programs will need to modify their benefit packages and approaches to care if forced to segregate funding and operate more like a fee-for-service model. For small programs serving hundreds or a few thousand beneficiaries, the accounting and information systems requirements also will be extremely onerous administratively and financially in relation to total revenue.

MPC Comments

Part A/B Bidding Process

Option 1: *The MPC recommends that CMS exempt SNPs that exclusively serve special needs individuals from the bidding process for Part A and B benefits*. Our preliminary evaluation of the bidding process suggests that the bidding process is inconsistent with the design of special needs programs for special needs individuals. For programs that have worked hard to integrate Medicare and Medicaid benefits into a seamless package of services for the dually eligible, we are concerned that this process would impede, not facilitate the integration. If beneficiaries disenroll from these programs as a result of higher costs of participation, their health status would be compromised, leading to higher costs for the federal and state governments under these programs. In fact, these programs have been successful to date in reducing inpatient hospital use through more sophisticated approaches to complex care management and reducing nursing home use through the substitution of community-based services. We also believe that plans exclusively serving individuals living in a nursing home or those with severe or disabling chronic conditions could face similar financial risks since they offer different benefit packages and their utilization experience could increase their bid amount in relation to costs for average beneficiaries.

Congress established the precedent for this approach by exempting PACE. CMS could use the program's existing demonstration authority to waive this requirement in the short run and work with Congress to expand the PACE exemption to dual SNPs. The rationale for exempting PACE from Part A and B bidding applies to dual SNPs as well. First, the purpose of the competitive bidding provisions is to provide programs the financial incentive to maximize efficiency in producing health care services. A key difference between Medicare and the commercial market, however, is that commercial plans are competing primarily for healthy people where the principle of insurance risk is at work. But MA plans, in general, and special needs plans, in particular, are "competing" for an "at-risk" population. Second, under the new payment methods, the Medicare rate is determined to be actuarially sound, thereby reducing concerns regarding overpayment or inappropriate payment. Third, the availability of Medicaid funding and the use of interdisciplinary teams and intensive care management facilitate access to and appropriate use of services. The orientation of each program (e.g., acute care orientation for Medicare and long-term care orientation of Medicaid) enables an integrated program to appropriately tap into the value of each clinical model and integrate care in relation to the interdependent care needs of patients served. For example, the pooled financing promotes greater efficiency by substituting more cost-effective service use such as skilled nursing services for inpatient hospital care or home and community-based services as an alternative to nursing home care. The net sum is a win-win for everyone—for the patients, providers, payers, and purchasers of care.

Option 2: A second option would be to establish a separate class for bidding for special needs plans and demonstrations to create a level playing field on products, benefits, risks, and costs. This may be more difficult to accomplish in the short run than an exemption, however, since there are likely to be a limited pool of special needs plans, and there are only a few demonstrations at this time.

Option 3: A third option would be to use waiver authority to delay implementation of the bidding process, providing time to explore alternatives that are consistent with the intent of dually eligible integration programs. However, we believe that the issues involved for special needs plans that exclusively serve a high-risk population are sufficiently consistent with PACE, which are already exempted from bidding, and that CMS should adopt the same policy for SNPs that exclusively serve special needs individuals.

Part D Bidding Process

The MPC also requests a delay in the implementation of the Part D bidding for exclusive special needs plans to provide time to work with CMS to develop an appropriate process for calculating payment for prescription drugs. While Congress did not exempt PACE from the Part D bidding process, we believe that the problems enumerated above affect the entire bidding process for SNPs and PACE. In the interim, we recommend that CMS payments for Part D covered drugs for all special needs individuals be based on amounts currently paid to dually eligible organizations by Medicaid for drug coverage. While we do not know with certainty that Medicaid funding levels for duals and non-duals are identical, we assume that the costs of the high-risk populations serving dual and non-dual high-risk beneficiaries would be similar.

Specialty M+C plans, providers, and demonstrations have provided rich laboratories for enhancing clinical care systems and financing methods for the highest-cost and most vulnerable Medicare beneficiaries. We urge CMS to make every effort to help preserve these programs so that we can continue learning how to improve outcomes and consumer satisfaction and control health care costs for Medicare's highest-cost and fastest-growing service group. In the event that the above recommendations are not workable, we would request that CMS carefully evaluate whether the bidding process was fair and equitable for SNPs and determine if the process unintentionally creates distortions or unanticipated changes in the way the plan sets benefits and premiums, receives payments, or delivers. Further, we would request that CMS conduct this evaluation as soon after the bids are submitted as possible so that adjustments can be made prior to January, if necessary.

§422.254: Appropriateness of Treating A/B Costs as Supplementary Costs for Bid Purposes

The preamble indicates that CMS will direct MA organizations to adjust their supplemental benefit bids to reflect the costs of "induced demand" for additional Part A and B services driven by the supplemental benefit. That is, since supplemental benefits such as reduced cost-sharing decrease the cost of accessing Part A and B benefits, beneficiaries will use more of these services. Accordingly, CMS indicates that the additional costs should be included in the supplemental bid, not the A/B bid.

MPC Comments

The MPC opposes this requirement and requests that CMS reconsider this policy for several reasons. First, the policy would be difficult to comply with and would require a subjective evaluation of which Part A or B services would have been used without the supplemental benefit and which were driven by the supplemental benefit. Second, under the new bidding process, Congress has effectively capped payments for A/B services by establishing a benchmark against which plans must bid. This benchmark is based on A/B services provided in the fee-for-service sector where over two-thirds of beneficiaries carry Medigap or supplemental policies. Accordingly, since "induced demand" is

already accounted for in the benchmark, requiring plans to shift these costs to the supplemental benefit package appears to set up a "double-dipping" phenomenon.

Third, it would be particularly difficult for SNPs, coupled with the fee-for-service cost-sharing mandate. While attribution of "induced demand" costs to the Part A and B benefit package would increase the cost of the bid and reduce potential savings, shifting these costs to the supplemental benefit package would result in increased premium costs for SNP beneficiaries. Since MPC members are concerned that their benefit design and cost structure may limit opportunities for rebates, these plans may have limited opportunities for buying-down these premiums. This would result in cost shifting to plans or, in the case of duals, to states that cover cost-sharing amounts. Further, assuming savings are produced, the rebate would not fully fund the increase in the supplemental premium since, under the new bidding rules, plans must return 25% of the savings to Medicare.

§422.254: Actuarial Equivalence for Mandatory Cost-Sharing

Beneficiaries are required to pay cost-sharing in an amount actuarially equivalent to Medicare FFS cost-sharing requirements for Part A and B benefits. The way actuarial equivalence is determined will significantly affect a plan's cost structure, and CMS invites comments on how actuarial equivalence should be determined.

MPC Comments

The MPC examined methods for determining actuarial equivalence for SNPs. While a plan-specific method may be the most accurate, upon further review and discussion with our actuaries, we believe that it would be extremely burdensome to implement, due to data collection requirements, and it would not produce enough additional accuracy of the cost-sharing obligations to warrant this cost and effort. Accordingly, we believe that AHIP's recommendation to use the proportional method developed at the local level may be in the best interest of our plans and members. We also support the recommendation that CMS explore the local establishment of proportions by service category, which would result in cost-sharing proportions more closely aligned with the mix of services used in each geographic area.

SNPs experience may differ quite substantially from regional averages in some cases due to their unique membership characteristics and benefit design. Accordingly, we entreat CMS to help us more fully evaluate the impact of the proportional method and others on SNPs. We look forward to the opportunity to explore these issues further with CMS and may submit additional comments as we clarify the impact of the various methods for determining actuarial equivalence on SNPs.

§422.256 Negotiation and Approval of Bids: Adjustments for Rebate

CMS proposes to allow adjustments to rebate dollars related to the Part D bid and the MA regional plan bids because the beneficiary premium and the benchmark respectively are not known prior to bid submission.

MPC Comments

The MPC supports this proposal as well as AHIP's recommendation that CMS allow adjustments to rebate dollars to further reduce their Part D premiums to match the low-income premium subsidy. The creation of specialized MA plans is intended to afford special needs individuals enhanced, specialized services that meet their needs. As noted throughout our comments, MPC members have large dually eligible and frail elderly populations. The success of these programs would be seriously

undermined if their Part D premiums exceed the applicable low income Part D subsidy because their dually eligible enrollment, which includes frail elderly individuals, would have an incentive to disenroll from these plans. The MPC recommends that SNPs also be permitted to reallocate rebate dollars to ensure that dually eligible beneficiaries would not need to pay a premium for Part D if they enroll or remain enrolled in these MA plans.

§422.264: Calculation of Savings: Selection of Methodology to Adjust Savings

Any savings generated by plans that bid below the benchmark are risk adjusted, since the original bid is based on the national average risk profile of 1.0. The savings could be risk adjusted, based on the statewide average or individual plan level risk scores.

MPC Comments

The MPC requests that CMS use a plan-specific risk adjustment. Since the statewide average is likely to be lower than plan-level risk scores for SNPs, a plan-level adjustment would more accurately reflect the plans' actual costs. In addition, the rebate will be used to provide supplemental benefits or reduced cost-sharing requirements. Plans with higher-risk beneficiaries need additional revenue to provide the same level of supplemental benefits as a plan with enrollees with lower risk scores. This will be especially important for dually eligible SNPs to help reduce drug premium costs. MPC members are concerned that prescription costs will exceed the low-income subsidy for Part D benefits, yet states are prohibited from contributing to the drug premium. Since duals do not have the financial capacity to finance these benefits, they will either be forced to disenroll, since full benefit duals must obtain their drug coverage from their MA plan, or the costs will be shifted to the plan. Plans serving high-risk beneficiaries already are at increased financial risk since they disproportionately enroll beneficiaries in the risk ranges that the CMS-HCC model underpredicts.

422.266 Beneficiary rebates: Use of rebate dollars to fund supplemental drug benefits

MPC Comments

The MPC recommends that CMS revise proposed §422.262(b)(2) to allow rebate dollars to be used both to pay for the Part D premium and to provide supplemental drug coverage at no cost to the beneficiary. This latter discretion is authorized by Section 1860D-21(a)(2)(B). This change is needed to clarify that MA plans have the right to use rebate dollars to fund supplemental prescription drug benefits at no cost to the beneficiary as part of the basic Part D prescription drug benefit offered by the MA plan. This provision is critical given the risks faced by dually eligible SNPs described in our comments at §422.264.

Subpart G: Payment for Medicare Advantage Organizations

§Section 422.308: Adjustments to Capitation Rates, Benchmarks, Bids, and Payments

§422.308(c): Risk Adjustment

The MMA did not provide CMS explicit authority to pay SNPs differently from standard MA plans, and the proposed rule states that SNPs will be paid the same. CMS research indicates that the diagnostic risk adjuster alone does not fully account for costs related to functional impairment. On an interim basis, CMS is using waiver authority to pay selected demonstrations a frailty adjuster to account for these residual costs.

CMS-HCC Risk Adjustment Methodology
While the CMS-HCC risk adjustment methodology significantly improves predictive accuracy over the demographic model, the MA risk adjustment methods need to be further refined to fully account for the costs of high-risk beneficiaries. As indicated earlier, an analysis of the CMS-HCC model in the most recent *Health Care Financing Review* indicates that the model continues to overpredict costs by 23% for the lowest-cost quintile of Medicare beneficiaries and underpredict by up to 31% for the highest-cost beneficiaries (top 1% of beneficiaries). This study suggests that plans serving high-risk populations will continue to be underpaid by the CMS-HCC model. MPC members exclusively or disproportionately enroll high-risk populations including those who are dually eligible, permanent nursing home residents and people with serious and disabling chronic conditions, which we recommend to be defined as nursing home certifiable beneficiaries. Several MPC members have plan-level risk scores at or above 2.0 for their predominant high-risk groups. Specific concerns regarding the CMS-HCC model that suggest the model may not fully account for SNP costs include the following:

- There is only one HCC risk level for COPD and CHF, while many SNP enrollees have late-stage conditions for which costs may not be fully accounted.
- The HCC for depression relates to psychiatric conditions, not clinical depression common among seniors and disabled individuals with serious health problems.
- The HCC excludes a code for osteoarthritis, which is extremely disabling and common among frail seniors. The HCC model also excludes codes for common geriatric syndromes such as Alzheimer's disease and incontinence.
- The HCC includes only a limited number of interaction codes for co-morbid conditions; additional codes may be appropriate for specific disease clusters.

MPC Comments
CMS has continued to refine the CMS-HCC model and has added additional HCC codes since the model originally was finalized. We applaud the efforts of CMS to refine the CMS-HCC model to more fully account for high-risk beneficiaries. The MPC urges CMS to continue these efforts and further evaluate the adequacy of the HCC method for high-risk beneficiaries and do whatever is necessary to increase the predictive power for the frail elderly; those with multiple, complex chronic conditions; and other high-risk subgroups. For example:

- To account for varying levels of intensity for conditions like COPD, CHF, and other HCCs common among frail elderly, it may be appropriate to have a code for late-stage conditions that triggers a higher risk score.
- There may be additional disease interactions more common in high-risk groups that would further enhance predictive accuracy.

- HCC codes should be expanded to include key geriatric syndromes like Alzheimer's disease and related disorders, clinical depression, severe osteoarthritis, and other conditions that can significantly increase medical costs.

The MPC also urges CMS to consider a methodology for further enhancing the predictive value of the CMS-HCC risk adjustment that the MPC began to evaluate last year. Research conducted by Dr. Gifford, Willing Manning, David Knutson, and others suggests that a "semi-square root" prediction function or "complexity" adjustment can significantly enhance predictive performance for high-risk populations. The complexity adjustment methodology builds upon the current CMS-HCC model but includes an additional calculation to correct for the underprediction bias characteristic of high-cost plans, where predictive accuracy decreases as case complexity increases. Because this model builds upon the existing CMS-HCC model, it would not require the collection of additional diagnostic codes or information.

Dr. Gifford has tested the complexity adjustment model for Medical Assistance recipients with disabilities in Minnesota and found it predicts acute care utilization remarkably well for selected high-risk subpopulations. The MPC, working with Gifford, Knutson, and others, tested the model on MPC member Medicare data. The results were inconclusive but encouraging, and we believe further analysis is warranted. Our preliminary analysis found that the model has greater predictive accuracy than the standard CMS-HCC model for beneficiaries with two to three or more HCCs. Because the model is designed to address the underprediction bias associated with medical complexity, one would expect the variation in risk scores to increase between the CMS-HCC and complexity adjustment models as the number of HCCs increases. This, in fact, happened. The Minnesota Department of Human Services also has tested the complexity adjustment model (on disabled populations) and found promising results. Accordingly, we urge CMS to work with the MPC and other interested parties in further evaluating this model.

Frailty Adjustment

The MPC is aware that CMS is in the process of conducting additional research on the frailty model to determine if the model should be implemented across the board for all MA organizations. We also understand that the model may be refined as a result of the research and that the structure and weights could change. The frailty adjuster is critical to SNPs due to the higher prevalence of functional impairments among enrollees.

MPC Comments

The MPC urges CMS to reconsider its position on the frailty adjuster and apply this adjustment to special needs plan enrollees whether or not it is implemented for all MA plans. If Congressional authority is required to extend special payment rules to SNPs, we urge CMS to work with the MPC in support of legislation that explicitly provides for payment of the frailty adjuster to SNPs. CMS has indicated that it must pay all MA plans the same, that it does not have the authority to pay certain classes of MA plans differently, except under demonstration authority. This position appears to be in conflict with Section 422.3049(c) of the MMA that provides for alternative payments for ESRD enrollees, MSA plan enrollees, and RFB plan enrollees under special rules. Without this adjustment, special needs plans would be penalized for targeting and specializing in the care of high-risk, high-cost beneficiaries, and CMS efforts to contain costs while maintaining quality outcomes would be impeded. Immediate application of the frailty adjuster for specialty needs plans would not only provide SNPs with a more fair and equitable payment, but it would enable CMS to gain further knowledge of its application before expanding its use in other plans and would expedite the process of improving the efficiency and effectiveness of care for Medicare's most vulnerable and costly population.

While the majority of Medicare beneficiaries are not functionally impaired, for most MPC members, the majority of their beneficiaries do have some level of functional impairment. Many of the Coalition members' enrollees are severely functionally impaired due to frailty or physical disabilities. Virtually all of the frail elderly and duals demonstrations include a special disability adjustment, and it should be made available to these demonstrations as they transition to SNPs. If CMS modifies the frailty adjustment, it will be important to provide SNPs impact estimates as soon as possible so that plans can evaluate the impact of changes in the methodology.

Pharmacy Risk Adjustment

Since SNPs' average per member drug costs are higher than standard MA plans due to the enrollment of high-risk beneficiaries, the adequacy of the pharmacy adjustment is critical to SNPs' financial viability, especially since CMS proposes to mandate Part D pharmacy benefits for SNPs. One MPC member serving the adult disabled has average per member per month drug costs of $700. Two other members serving the frail elderly have drug costs of $400-$500 per member per month. The pharmacy risk adjustment must be sensitive to the types and costs of prescription drugs required by special needs individuals, including the high medication costs associated with end-of-life care that may not be recovered under a prospective payment approach.

MPC Comments

To ensure that the pharmacy adjustment will be adequate, CMS should test its pharmacy risk adjustment methodology on plans and programs serving high-risk populations. Further, we urge CMS to collect data from state Medicaid programs to analyze the impact on high-risk subgroups, including duals, frail elderly, and disabled adults. State dually eligible data on drug utilization would be a more accurate reflection of true costs than the FEHBP database that we understand is being used for evaluating pharmacy costs, since the FEHBP data relates to drug costs for a much younger population. We also request that CMS evaluate whether there is a relationship between functional impairment and higher drug costs that may not be accounted for by diagnosis alone and to determine if the frailty adjuster needs to be further modified to account for higher pharmacy costs.

§422.308(e): Adjustment to Plan Premium

If the plan bid exceeds the benchmark, the difference becomes the plan premium. Since the bid is based on national average risk, however, plan premiums should be adjusted to reflect the plan's revenue needs in relation to actual beneficiary risk.

MPC Comments

We understand that CMS proposes to provide for an adjustment of payment to account for the fact that the beneficiary premium is not risk-adjusted. The CMS payment would be adjusted upward or downward, depending on the plan's risk in relation to the national average risk profile. We appreciate CMS' recognition of the need for this adjustment and support the CMS proposal in this regard.

Subpart J: Special Rules for MA Regional Plans

Regional Plans

CMS indicated on their open door forum that SNPs would not be permitted to participate in regional plans.

MPC Comments

The statute does not appear to explicitly exclude SNPs from participating in regional plans. The MPC seeks clarification regarding why CMS believes SNPs cannot participate in regional plans. While MPC members do not presently anticipate forming regional plans, we request that CMS make this option available to SNPs in the event that some wish to participate through a consortia arrangement at some point in the future.

EXHIBIT 1

ACOVE TOPICS

Appropriate Use of Medication
Chronic Pain
Continuity and Coordination of Care
Dementia
Depression
Diabetes Mellitus
End-of-Life Care
Falls and Mobility Problems
Hearing Loss
Heart Failure
Hospital Care
Hypertension
Ischemic Heart Disease
Malnutrition
Osteoarthritis
Osteoporosis
Pneumonia
Pressure Ulcers
Preventive Care
Stroke and Atrial Fibrillation
Urinary Incontinence
Visual Impairment

Submitter : Carmen Hooker Odom **Date & Time:** 10/04/2004 09:10:26

Organization : NC Department of Health and Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 212440-8014

Re: Proposed Rule with Comment Period, Medicare Program: Medicare Prescription Drug Benefit

Dear Dr. McClellan:

I respectfully submit the following comments regarding the proposed Medicare Prescription Drug Benefit regulations, published in the Federal Register on August 3, 2004.

Enrollment Process: ?Background?

Item II. B.2. (FR, Vol.69, No. 148, p. 46639) discusses whether CMS or the state or a contracted entity should perform the automatic enrollment function. North Carolina believes this is a CMS responsibility (either directly or by contract with an outside entity) because the Part D benefit is a federal benefit. Further, CMS will have data links to the PDPs and MA-PDs and is responsible for notifying PDPs and MA-PDs about low-income subsidy individuals

Enrollment Process: Automatic Enrollment Provisions

The new Medicare Part D benefit offers many beneficiaries their first opportunity for prescription drug benefits. However, this is not the situation for Medicaid enrollees who meet the definition of `full benefit dual eligible?. These beneficiaries already have comprehensive prescription drug benefits. It is crucial that their transition from Medicaid coverage to Medicare Part D has no break in coverage.

Section 1860-D-1(b)(C) requires that a process be established for enrollment in a Part D plan when a `full benefit dual eligible? has failed to enroll. This section does not define at what point the `failure? occurs and gives the beneficiary the right to `decline or change? the enrollment. The proposed regulation at 42 CFR 423.34(d) creates an automatic enrollment process at the end of the initial enrollment period. This means a `full benefit dual? may be without any prescription drug coverage beginning January 1, 2006, through whatever date the auto enrollment occurs. By definition the `full benefit dual eligible? is either elderly or disabled and poor. An inability to obtain necessary prescriptions clearly endangers the health of the most vulnerable population groups.

We recommend that automatic enrollment occur prior to January 1, 2006, with notification to the beneficiary that he may change plans during the initial enrollment period should he not want to remain with the assigned plan.

Low Income Subsidy Determinations (LIS)

Since publication of the proposed regulations, we learned that Social Security agreed to complete the `LIS? determinations for individuals who are

not deemed `LIS? based on their Medicaid or SSI status. Individuals would still be able to apply at a local Medicaid office, but the application will be shipped to a Social Security office for the eligibility determination. Under this arrangement recipient notices, as well as appeals of the decision, should be handled by Social Security We strongly support this plan and ask that you revise the proposed regulations at 42 CFR.774 to accurately reflect the agreed upon procedures. . It will of course be necessary to establish a screening process for Medicaid benefits when the LIS individual does not file his application at a Medicaid office.

Definition of `Institutionalized Individual?

Please clarify that the proposed definition of `long term care facility? at 42 CFR 423.100 and the definition of `institutionalized individual? at 42 CFR 423.772 include residents of ICF-MRs.

I appreciate the opportunity to make comments on the proposed regulations. Should you have questions or wish to discuss any of these issues further, contact Barbara Brooks at Barbara.Brooks@ncmail.net.

Yours truly,

Carmen Hooker Odom

CMS-4068-P-1332

Submitter : Mr. Carmen Catizone **Date & Time:** 10/04/2004 09:10:30

Organization : National Association of Boards of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

CMS-4058-P
Letter to CMS on Proposed Regulations

CMS-4068-P-1332-Attach-1.doc

NABP 100 YEARS
1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

October 4, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

Dear Dr McClellan:

Thank you for the opportunity to submit the following information in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the proposed regulations implementing Title I of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). Our response is relevant to pharmacists' provision of services within Medication Therapy Management Programs (MTMPs) and its impact on the public safety and state regulation of the practice of pharmacy.

The National Association of Boards of Pharmacy (NABP) was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. The purpose of NABP is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. I am submitting these comments as executive director of NABP.

Although the concept of MTMP services is presently an area of considerable attention due to the enactment of the MMA of 2003, the state boards of pharmacy and NABP have been involved in defining the scope of pharmacy practice and the standards and competencies associated with licensure of pharmacists for more than 100 years. The state boards of pharmacy were the first entities to legally define the practice of pharmacy and establish regulations to regulate pharmacy practice and pharmacists. It is through the state boards of pharmacy that pharmacists are assessed as competent to practice and the scope of the practice of pharmacy amended as standards and practice therapies change.

National Association of Boards of Pharmacy

700 Busse Highway · Park Ridge, IL 60068 · Tel: 847/698-6227 · Fax: 847/698-0124
Web Site: www.nabp.net

NABP serves its member boards of pharmacy by developing and administering competency assessment examinations required by the states for licensure (NAPLEX and MPJE[1]), maintaining disciplinary and licensure transfer clearinghouses for the states to allow for the interstate transfer of licensure of pharmacists' licenses, and working with the states to produce model laws and regulations to address issues and concerns which the state boards of pharmacy are charged to regulate. Model regulations developed by NABP and subsequent state laws and regulations adopted by the states outline the parameters of the scope of practice of pharmacy. The state boards of pharmacy and NABP recognize the importance of pharmacists providing MTMP services within a regulatory framework that focuses on patient safety and complies with existing states' definitions of the practice of pharmacy and scope of authority of the pharmacist.

Legal Authority of the State Boards of Pharmacy

The "Board of Pharmacy" or "Board" in each state is the legally constituted governmental regulatory body charged to regulate the practice of pharmacy and licensure of pharmacists and pharmacies. As defined in the various practice acts of the state boards of pharmacy, the purpose of the State Practice Act and regulations is clear:

"It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the Practice of Pharmacy; the licensure of Pharmacists; the registration of Pharmacy Technicians; the licensure, control, and regulation of all sites or Persons, in or out of this State, that Distribute, Manufacture, or sell Drugs (or Devices used in the Dispensing and Administration of Drugs), within this State, and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual."

When implemented, MTMP services will fall under the consideration of the state boards of pharmacy and how the states have defined the practice of pharmacy and scope of services which pharmacists are legally able to provide to patients. NABP requests that CMS work with the states and NABP to ensure that the definition of the practice of pharmacy and allowable activities of the pharmacist do not conflict with the proposed implementation of the MTMP services.

NABP Addresses Practice of Pharmacy in the *Model Act*

Many elements of the MTMP outlined in the MMA fall under the scope of pharmacy practice. *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* defines the scope of pharmacy practice as:

[1]NAPLEX is the computer-adaptive North American Pharmacist Licensure Examination, which is a requirement of all states for licensure. NABP has developed and administered the North American Pharmacist Licensure Examination (NAPLEX) since the mid 70s. Every pharmacist who wishes to practice pharmacy in the Unites States of America is required to pass the NAPLEX. The NAPLEX Blueprint (Appendix A) outlines the competency statements that reflect the knowledge, judgment, and skills expected of entry-level pharmacists. Upon review of those competencies, it is evident that pharmacists are equipped with the knowledge and skills to successful implement MTMS.
MPJE is the computerized Multistate Pharmacy Jurisprudence Examination required by 47 states.

> The "Practice of Pharmacy" means the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Reviews; the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of proper records for them.

The definition of the "Practice of Pharmacy" in the states is the critical factor of the state practice acts and regulations. Boards of pharmacy must have full knowledge of the whereabouts of Drugs and provision of services by pharmacists in the legitimate stream of intrastate and interstate commerce in order to protect patients from incompetent or dangerous practitioners, prevent diversion, effectuate recalls, ensure the quality of Drugs Dispensed or Administered to patients, and effectively protect the public. Again, NABP is requesting that CMS work with the states and NABP to determine how the definition of MTMP services impact or are impacted by state practice acts and regulations and to work closely with state boards of pharmacy to provide for effective supervision and regulation of MTMPs.

Collaborative Pharmacy Practice and MTMPs

In recent years, the concept of collaborative practice has evolved and codifies the relationship between pharmacists and other health care practitioners utilizing a multidisciplinary health care team approach. The *NABP Model Act*, and more than 40 state practice acts, similarly define collaborative pharmacy practice as the "Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol whereby the Pharmacist may perform certain patient care functions authorized by the Practitioner or Practitioners under certain specified conditions and/or limitations."

The purpose of entering into a collaborative pharmacy practice agreement is for pharmacists to work in collaboration with other practitioners to provide drug therapy management to patients. The ultimate goal is to provide the best possible services to the patients to ensure they are receiving the best possible therapy for their condition. Patient safety should be the pillar of any program or service developed by CMS or any other entity providing healthcare services to the public.

The *NABP Model Rules* contain a comprehensive list of elements that should be included in a Collaborative Pharmacy Practice Agreement (Appendix B). For clarification purposes, collaborative practice is separate and independent of prescriptive authority. This is a significant clarification. In some reviews of the MTMP services, there is the mistaken belief that state practice acts and regulations must grant pharmacists prescriptive authority in order to participate in the provision of MTMP services. This is simply not true.

The more relevant areas for consider when reviewing whether MTMP services will be allowed in a state is the definition of the "Practice of Pharmacy" and "Collaborative Practice" regulations.

The ultimate determining factor will be the definition of the "Practice of Pharmacy." Again, there is a misconception that in order for MTMS to be allowed in a state, the state must have "Collaborative Practice" regulations in place. This is not true if the definition of the "Practice of Pharmacy" is modeled after the *NABP Model Act* definition or broad enough to allow for the inclusion of MTMP services. The impact of "Collaborative Practice" regulations is to further define the scope of services allowed under the "Practice of Pharmacy." In regard to MTMP services, "Collaborative Practice" regulations could serve to enhance and assist pharmacists in implementing MTMP services.

Although not specifically listed, NABP is currently researching the practice acts and regulations of these states to determine if the act and regulations are broad enough to allow for MTMP services and do not restrict the provision of these services. It is NABP's opinion that a broad definition of the "Practice of Pharmacy" and no specific prohibition for providing MTMP services or MTMP-like services should allow for the implementation of this pharmacist activity.

Evaluation of Non-Resident Pharmacy License for Remote Caregivers

Although those defining and implementing MTMPs may envision that the provision of these services will follow traditional therapy patterns, consideration must be given to the extent and impact of interstate activities. The immediate questions that should be addressed are whether states will allow for the practices of telemedicine and telepharmacy and what requirements and restrictions are in place for these variations from traditional, face-to-face care. For pharmacy practice and regulators non-resident pharmacies and related services are a primary focus.

A "Non-Resident Pharmacy," as defined in the *NABP Model Act* and state practice acts, means a Pharmacy located outside of the State. Nearly every state requires non-resident pharmacies to be licensed or registered in the state where they are shipping medications. An example of a non-resident pharmacy is a mail order facility that is located in one state but ships medications to patients in another state.

Regulatory activity regarding non-resident pharmacies has significantly increased in the past year, closely associated with importation issues, counterfeit drugs, and patients purchasing medications from the internet. In order to determine the non-resident requirements and the similarity/variation among the states, NABP recently conducted a survey of the state boards of pharmacy to determine which states have specific requirements for nonresident versus resident pharmacies, how the states assure quality and compliance, whether or not the state requires an inspection, and the number of complaints and how they are investigated.

NABP's survey found that nearly every state requires non-resident pharmacies to be licensed in their state; most do not require the individual pharmacists to be licensed in their state. The nonresident pharmacies comparison chart (Appendix C) included with this statement highlights examples of similarities and variances that exist in the nonresident pharmacies between the states.

Pharmacists must be licensed in the state in which they are physically located. Only a handful of states require non-resident pharmacists to be licensed in their particular state. NABP is not sure

at this time how states will view the provision of MTMPs across state lines. It would appear that if non-resident pharmacists begin performing specific MTMP services, the state boards may, upon evaluation of their regulations and the pharmacist scope of practice, require non-resident pharmacists to become licensed in the state where the patient resides.

Provision of MTMPs by Non-Pharmacist Practitioners
A standard, which will essentially be the standard of practice defined and regulated by the boards of pharmacy for pharmacists, must be required for non-pharmacist practitioners providing MTMP services. Basic MTMP services could be performed by ***all*** pharmacists licensed in good standing with their state board of pharmacy without additional education or certification. The monitoring of these services from the health and safety of the patient would fall within the realm of current state regulation and provide a valid safeguard for patients. The same cannot be said if non-pharmacist practitioners engage in the provision of MTMP services.

In closing, NABP cannot underscore the importance of patient safety as it pertains to MTMP services and the need to work closely with the states to define the scope and implementation of MTMPs. CMS must develop regulations to ensure that the MTMP services provided to the Medicare beneficiaries are executed by pharmacists or other qualified non-pharmacist, healthcare professionals. While many arguments can be made to support the rapid adoption of MTMP services, careful consideration should be given to the details of the structure of MTMPs to ensure the focus is on patient safety, public protection, and the provision of quality health care. Both NABP and the state boards of pharmacy are willing to assist CMS in any capacity to help ensure that the services provided are within the scope of practice of pharmacy and that every patient benefit from the services provided to them.

Thank you, once again, for the opportunity to address this important issue.

Sincerely,

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

CAC/eza

Enclosures: Appendix A – NAPLEX Blueprint
Appendix B – Collaborative Pharmacy Practice Excerpt
Appendix C – Nonresident Pharmacies Comparison Chart

Submitter : Mr. E. Clyde Buchanan **Date & Time:** 10/04/2004 09:10:28

Organization : Emory Healthcare

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

1. CMS rules must allow for all pharmacists to be included not precluded. Pharmacists at Emory Healthcare are an integral part of the health care team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary hospitalizations and ER visits. Examples include anticoagulation therapy management, parenteral nutrition monitoring and patient teaching, immunosuppressant drug monitoring and organ transplant patient teaching, anemia and chemotherapy monitoring and cancer patient teaching, dosing of medication therapies in the elderly, compliance.
2. All pharmacists practicing within a region (regardless of practice setting) should be afforded the opportunity to provide and be paid for MTM services such that plan sponsors should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service. Furthermore, all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

3. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services. They should not be allowed to discriminate and leave pharmacists out in the cold.
4. Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services and be eligible to provide MTM services to these patients. Identification of targeted beneficiaries should not be left solely to the plan. Plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription.
5. MTM services should be able to be provided in conjunction with and outside of product dispensing.
6. An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.
7. Plan sponsors should be required to establish at CMS-specified set of MTM services. The specified set of services should be a minimum set while additional services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management and adverse drug event assessment and prevention should be included.
8. CMS should consider developing a program to accredit plans that agree to meet the above stated conditions that add value to and lower the cost of care.

CMS-4068-P-1333-Attach-1.doc

EMORY HEALTHCARE

October 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

To Whom It May Concern:

I am writing to offer comments regarding the proposed Medicare Part D rules. As Senior Director of Pharmacy at Emory Healthcare in Atlanta, I am deeply concerned with the rules as they are currently proposed and the negative impact they could have on the services provided to Medicare beneficiaries.

In order for this program to be successful, I urge CMS to incorporate rules that will 1) ensure compensation for all pharmacy providers that perform medication therapy management (MTM) services, and 2) allow for all willing pharmacists to serve as a prescription product providers for Medicare beneficiaries. Below are my specific and detailed recommendations for rules concerning MTM services and prescription access that will ultimately do the right thing for the patient:

MTM Services

1. **CMS rules must allow for all pharmacists to be included not precluded**. Pharmacists at Emory Healthcare are an integral part of the health care team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary hospitalizations and ER visits. Examples include anticoagulation therapy management, parenteral nutrition monitoring and patient teaching, immunosuppressant drug monitoring and organ transplant patient teaching, anemia and chemotherapy monitoring and cancer patient teaching, dosing of medication therapies in the elderly, compliance.
2. All pharmacists practicing within a region (regardless of practice setting) should be afforded the opportunity to provide and be paid for MTM services such that **plan sponsors should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service**. Furthermore, all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.
3. **MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist**. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services. They should not be allowed to discriminate and leave pharmacists out in the cold.

4. **Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services** and be eligible to provide MTM services to these patients. Identification of targeted beneficiaries should not be left solely to the plan. Plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription.
5. MTM services should be able to be provided **in conjunction with and outside of product dispensing**.
6. **An efficient electronic MTM claims process** should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.
7. **Plan sponsors should be required to establish at CMS-specified set of MTM services**. The specified set of services should be a minimum set while additional services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management and adverse drug event assessment and prevention should be included.
8. CMS should consider developing a **program to accredit plans** that agree to meet the above stated conditions that add value to and lower the cost of care.

Access to Pharmaceuticals – Drug Product Provisions within Part-D

1. Plans should be required to offer standard contract language to all pharmacies willing to participate in the program as a prescription and MTM services provider. **Plans need to make it easy for patients to have convenient access to their pharmacy of choice**. They should not be able to limit the number of pharmacy providers as this would negatively impact patient access to needed medications and pharmacy services.
   Georgia, like many states, has a number of rural counties where access to health care is often limited. The isolation and transportation issues faced by the elderly may be exacerbated if access is defined at the county or regional level. Furthermore, in order to provide the highest quality care and service to Medicare beneficiaries who receive their care at Emory, it is absolutely essential that our pharmacies are able to dispense prescription medications for beneficiaries as an approved/preferred pharmacy provider.
2. **Co-payment reductions should not be provided to coerce beneficiaries into using "preferred" pharmacy providers solely on the basis of pricing or cost**. This will provide incentives for beneficiaries to use low cost, low quality providers and ultimately increase the cost of patient care and will produce a "chasm" in that it will disrupt existing pharmacist-patient relationships resulting in improved drug therapy outcomes. While steering patients to a limited number of pharmacies that are willing to accept deep-discount reimbursement rates may result in reduced “drug-silo” costs for the plan (which under the current legislation may in fact be in the plan’s best interest as they may only be at risk for the cost of the drug product), this savings will undoubtedly be offset by much higher medical costs to Medicare as a result of poor quality pharmaceutical care and poor patient medication therapy management and medication regimen non-compliance. This practice could also result in pharmacies that specialize in accepting the lowest reimbursement formula but develop “schemes” to shift patients to high-profit margin regimens that ultimately increase costs to the plan.
3. CMS must act responsibly by assuring an **adequate reimbursement formula** that at a minimum covers the average cost of filling a prescription or providing a service.
4. It would be an acceptable approach for plan sponsors to provide beneficiaries with incentives for using “preferred” pharmacies over others based on **well-defined quality principles**

related to providing a high level of pharmaceutical care and MTM services for patients. It would be advantageous for all pharmacy providers to strive to achieve and adhere to the defined quality standards and they should be allowed to become designated as preferred when they achieve those standards, as compared to being excluded.

5. **Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies**. There are safety and medication management concerns when beneficiaries are required to use mail order pharmacies. If mail service is offered as an incentive to lower costs, all pharmacies should be offered standard contract language and allowed to participate as a mail service provider. Beneficiaries should not be required to use mail service pharmacies.
6. To prevent conflict of interest, **plan sponsors should be prohibited from promoting or requiring the use of pharmacies in which they have an ownership interest**.

In closing, pharmacies must be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful. Medicare must make specific requirements of the plan sponsors otherwise many of the nation's foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully, and all licensed pharmacists within a designated region should be considered an MTM provider. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration, and please feel free to contact me if I can be of further assistance in helping to craft specific rules.

Sincerely,

Clyde Buchanan, M.S., R.Ph.
Senior Director
Pharmaceutical Services
Emory Healthcare
1364 Clifton Rd.
Atlanta, GA 30322
U.S.A.

CMS-4068-P-1334

Submitter : Mr. Carmen Catizone **Date & Time:** 10/04/2004 09:10:37

Organization : National Association of Boards of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

CMS-4068-P
NABP Appendix B

CMS-4068-P-1334-Attach-1.doc

Appendix B

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

June 2003

Collaborative Pharmacy Practice Excerpt

(Pages 91-93)

Model Rules for Pharmaceutical Care

Section 3. Pharmacy Practice.

J. Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement.

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct Drug Therapy Management activities approved by the Practitioner. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents.

The Collaborative Pharmacy Practice Agreement shall include:

(a) Identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(b) The types of Drug Therapy Management decisions that the Pharmacist is allowed to make, which may include:

(i) A detailed description of the types of diseases, Drugs, or Drug categories involved, and the type of Drug Therapy Management allowed in each case;

(ii) A detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting Drug Therapy Management; and

(iii) A detailed description of the activities the Pharmacist is to follow in the course of conducting Drug Therapy Management, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;

(c) A method for the Practitioner to monitor compliance with the Agreement and clinical outcomes where Drug Therapy Management by the Pharmacist has occurred and to intercede where necessary;

(d) A description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes.

(e) A provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

(f) A provision that allows either party to cancel the Agreement by written notification;

(g) An effective date; and

(h) Signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3) Initiation of the Collaborative Pharmacy Practice Agreement

The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate Drug Therapy Management for any particular patient.

(4) Documentation of Drug Therapy Management.

Documentation of Drug Therapy Management must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to received it. Documentation of Drug Therapy Management shall be considered Protected Health Information.

(5) Review.

At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

CMS-4068-P-1335

Submitter : Mr. Carmen Catizone **Date & Time:** 10/04/2004 09:10:08

Organization : National Association of Boards of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

CMS-4068-P
NABP Appendix C

CMS-4068-P-1335-Attach-1.doc

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	Do you have specific requirements for non-resident vs. resident, if so, please list-	How do you assure quality and compliance?	Do you require an inspection component such as copy of last inspection, etc.?	How many complaints do you receive each year against nonresident pharmacies?	Describe how are they investigated-	Do you rely on VIPPS or another national accreditation program?
AZ	No, requirements are the same except pharmacists are not required to be licensed in Arizona. (See regulation R4-23-607. Nonresident Permits.)	Arizona State Board of Pharmacy assures quality and compliance by verifying out of state license/permits.	No	Less than 2 (two)	Arizona forwards complaints to the agency in the jurisdiction.	No
AR	All requirements are the same except counseling and exemption. (See out-of-state regulations at www.arkansas.gov/asbp)	Arkansas assures quality and compliance by requiring a licensed pharmacist on staff (physically) at each location.	Yes			
CA	In addition to the ownership information required for all applicants, non-resident pharmacies are also required to provide: a copy of their last inspection report; a statement indicating that they maintain records of controlled substances or dangerous devices dispensed to California patients, so that those records are readily retrievable from other drugs dispensed; two prescription labels that include a toll free number; a list of pharmacists and their license numbers for those who fill prescriptions for California residents; an original letter from your state board verifying your state license is current and in good standing with the state seal embossed on the letter.	California requires a letter from your state board verifying your state license is current and in good standing or with any disciplinary action. California may also visit the home state's website.	Yes	24	California conducts an investigation via letter. If the information received is substantiated, the board may cite and fine the pharmacy. Once resolved, the board will notify the licensing agency in the state the pharmacy is located in.	VIPPS is sometimes used.

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	Do you have specific requirements for non-resident vs. resident, if so, please list-	How do you assure quality and compliance?	Do you require an inspection component such as copy of last inspection, etc.?	How many complaints do you receive each year against nonresident pharmacies?	Describe how are they investigated-	Do you rely on VIPPS or another national accreditation program?
CO	Prerequisite for registration of out of state pharmacies is that non-resident pharmacies must submit a copy of the most recent board inspection.	Colorado relies on the state where the pharmacy is located.	Yes	Less than 5 (five)	Colorado refers to the state board where located.	No
CT	See Connecticut regulations: Section 20-627. Nonresident pharmacy. Definitions. Certificate of registration. Requirements; Section 20-628. Shipping, mailing or delivering legend devices or drugs; Section 20-629. Suspension or revocation of certificate; Section 20-650. Advertising.	Connecticut assures quality and compliance by current licensure.	Connecticut requires a copy of the most recent inspection report.	Not documented	Complaints are investigated by referring to the state of licensure.	No
DE	Yes, resident and non-resident requirements are listed in statute and regulation. (See Web site at www.professionallicensing.state.de.us)	Delaware assures quality and compliance through licensure, license procedure and complaints addressed.	Yes	1 (one)-5 (five) a year - Non-resident complaints have routinely centered around quantity dispensed issues.	Complaints are investigated by contact made and complaint discussed with licensee.	Yes
DC	No					
FL	See Statute 465.0156 Registration of nonresident pharmacies	Florida relies on the state where pharmacy is located to assure quality and compliance.	No	12-15 per year	Most complaints are referred to the state of residence.	No

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	***Do you have specific requirements for non-resident vs. resident, if so, please list-***	***How do you assure quality and compliance?***	***Do you require an inspection component such as copy of last inspection, etc.?***	***How many complaints do you receive each year against nonresident pharmacies?***	***Describe how are they investigated-***	***Do you rely on VIPPS or another national accreditation program?***
HI	Out-of-state pharmacies who fill prescriptions for individuals residing in Hawaii must be permitted under our miscellaneous permit. Hawaii requires that the out-of-state pharmacy be already licensed/permitted in another state. Hawaii does not license individual pharmacists for out-of-state pharmacies. (See Web site at www.state.hi.us/dcca/pvl - Requirements and instructions for filing – Miscellaneous Permit)	Verification from the state of domicile that the pharmacy and pharmacists are in good standing, unencumbered, etc.	No	This information is not readily available. Complaints and investigations are handled by the Regulated Industries Complaints Office.	See answer to question #4.	No
ID	See statute 54-1740 through 54-1750 – "Out-of-State Mail Service Pharmacy Licensing Act"			We receive very few formal complaints (which are what we act on).We have had 2 (two) $1000 fines for violation of our product selection rules.	Complaints are investigated by our compliance section - we have not really had to rely on another state.	No
IN	See Indiana law IC 25-26-17 Chapter 17. Nonresident Pharmacies	Indiana assures quality and compliance based on "home" state licensure and inspection. Law requires that the "home" state's requirements are equivalent to Indiana's in-state requirements.	Yes, we require a copy of last inspection.	Average of 6 (six) over the past 4 (four) years	Complaints are investigated by the Indiana Office of the Attorney General, usually in cooperation with the "home" state's Attorney General.	We recognize VIPPS, but it is not a requirement.

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	***Do you have specific requirements for non-resident vs. resident, if so, please list-***	***How do you assure quality and compliance?***	***Do you require an inspection component such as copy of last inspection, etc.?***	***How many complaints do you receive each year against nonresident pharmacies?***	***Describe how are they investigated-***	***Do you rely on VIPPS or another national accreditation program?***
KS	Pharmacy has to be licensed in good standing in the state it is located. Each pharmacist dispensing drugs in Kansas has to be licensed in state where he is practicing. Pharmacy has to provide the name of responsible pharmacist who shall receive communication from board, pay a registration fee, and keep records of drugs dispensed in Kansas available on request. They must have an incoming toll free phone number, be open normal business hours with a minimum of 40 hours – 6 days a week, and must have resident agent. We also review all complaint and conviction data of owners.	Facilities and records of pharmacy are subject to inspection. Satisfactory inspection reports by the licensing entity using similar standards as Kansas may be accepted in lieu of inspection by the board.	No	Approximately 2 (two) - 5 (five)	Contact resident state board of pharmacy for assistance. We also make direct contact with responsible pharmacist in charge, and ask for written response to complaint. Phone contact with responsible pharmacist.	We rely on VIPPS for all internet mail order accreditation.
LA	No, we expect them to comply with all of our laws and rules to the extent that does not place them in violation of their resident state's rules.	Louisiana relies on resident state board of pharmacy.	Yes	Louisiana has about 340 such permits. In fiscal year ending, June 30, 2004, the board logged approximately 20 complaints; about 1/3 were internet operations, another 1/3 were late renewals, and another 1/3 were failure to pay Medicaid fees.	Louisiana in-house counsel works via telephone and mail, calling on other boards as needed.	No
MD	(See Pharmacy Act Ho, § 12-403. Required standards.)	Maryland relies on Board in state of original license.	Yes, a copy of last inspection.	Few, actually rare.	Information given to home state.	No

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	Do you have specific requirements for non-resident vs. resident, if so, please list-	How do you assure quality and compliance?	Do you require an inspection component such as copy of last inspection, etc.?	How many complaints do you receive each year against nonresident pharmacies?	Describe how are they investigated-	Do you rely on VIPPS or another national accreditation program?
MS	Mississippi has no specific requirements for resident vs. nonresident pharmacies.	Mississippi assures quality and compliance by verifying that a pharmacy license is in good standing with the state in which it is located before issuing a nonresident permit.	Mississippi does not require a copy of the last inspection.	Not sure how many nonresident complaints the board gets, but probably less than 10. Most pertained to a mail order pharmacy and cost or product selection. (Most seem to be insurance problems, not pharmacy problems.)	Agents in this office phone the facility about the complaint. If a phone call is not sufficient, we call the Board of Pharmacy in that state.	Mississippi does not rely on VIPPS.
MO	(See Rule 4 CSR 220-2.020 Pharmacy Permits, and 4 CSR 220-2.025 Nonresident Pharmacies.)	Random check of host state inspection reports.	No, not on the application, but we are planning to.			
NE	Yes, Nebraska licenses nonresident pharmacies as Mail Service Pharmacies. They are required to employ a Nebraska licensed pharmacist to assure compliance with the Mail Service Pharmacy Act.	Nebraska licensed pharmacist requirement to assure compliance with the Mail Service Pharmacy Act.	Yes, requirement of last 2 (two) inspections unless they are new (opened recently) in their state, so they have only had one inspection.	No, but we do ask whether their pharmacist in charge or the pharmacy has been disciplined since their last renewal. The board can discipline their license for past discipline.	Either Nebraska pharmacy inspectors or Nebraska Investigation Division.	Only that we check VIPPS, but not very many are found to have VIPPS.
NV	No specific differences, except resident pharmacies must report controlled substance dispensing to prescription monitoring program.	Nevada relies on the state of situs that licensure and standards are met. We request confirmation.	No	Very minimal, 1 (one) or possibly 3 (three) per year.	Nonresident pharmacies are investigated by forwarding the complaint to the regulatory agency appropriate for that pharmacy.	Yes, Nevada's regulations require either the VIPPS certification or attestment. The pharmacy has adopted the same standards.

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	***Do you have specific requirements for non-resident vs. resident, if so, please list-***	***How do you assure quality and compliance?***	***Do you require an inspection component such as copy of last inspection, etc.?***	***How many complaints do you receive each year against nonresident pharmacies?***	***Describe how are they investigated-***	***Do you rely on VIPPS or another national accreditation program?***
NH	Yes, as specified in RSA 318:37, II and Chapter Ph 900 of the board's administrative rules. (See New Hampshire rules)	Rely on VIPPS certification and the cooperation of boards of pharmacy where the non-resident mail order pharmacy is domiciled.	Yes, New Hampshire requires a copy of the most recent inspection, conducted by the domiciled board of pharmacy, to be submitted with the annual renewal application.	Not more than 12-15 per 12 month period.	Vast majority of concerns/complaints are resolved by speaking with the patient. If necessary, a call to the mail order pharmacy provides an explanation and/or resolution.	Yes
NY	Yes, see regulation S 63.8 Registration of nonresident establishments; S 6808-b. Registration of nonresident establishments.	From the state board from their home state.	No	Very few	No	No
NC	Yes, see regulation §90-85.21A. Applicability to out-of-state operations; 21 NCAC 46.1607 Out-of-State Pharmacies.	Investigate complaints; communicate with board in state where located; legislation in process to require permit holder to employ a North Carolina licensed pharmacist.	No	Approximately 10	North Carolina asks the host state to investigate.	Yes
ND	Yes, see Law – Article 61-08 Out-of-State Pharmacies.	North Dakota relies on the resident board's inspection, and requires a copy of the last inspection, and also a copy of the pharmacy's license.	Yes	One a year	North Dakota writes to the pharmacy for an explanation of the incident; a copy of the explanation goes to the resident board. The board cooperates with the resident board in acquiring evidence and prosecuting the complaint.	North Dakota uses VIPPS as one of the components in their licensing review.

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	***Do you have specific requirements for non-resident vs. resident, if so, please list-***	***How do you assure quality and compliance?***	***Do you require an inspection component such as copy of last inspection, etc.?***	***How many complaints do you receive each year against nonresident pharmacies?***	***Describe how are they investigated-***	***Do you rely on VIPPS or another national accreditation program?***
OK	Yes, see Rule 535:15-3-9. Non-resident pharmacies.	Oklahoma relies on the state board where the pharmacy is located.	Oklahoma reserves that right, but again relies on the state of origin.	Less than 12 a year.	Oklahoma turns information over to the state board of the state they are located in.	No
OR	Yes, Oregon requires the nonresident pharmacies to send verification from their licensing state, current status with the state, and any actions taken against the pharmacy.	Oregon leaves the quality and assurance to each state and uses certification by the resident state.	No	4 (four) to 5 (five)	Complaints are investigated as a normal case with correspondence.	No
PA	Pennsylvania State Board of Pharmacy has no authority to license/regulate nonresident pharmacies.					
SC	South Carolina has the same requirements for nonresident pharmacies vs. resident pharmacies.	South Carolina assures quality and compliance through the state board in which the facilities are located.	Yes	Last year South Carolina received 8 (eight) complaints on nonresident pharmacies, and that is about average.	All cases are investigated by a pharmacist investigator. Necessary files and records are obtained for review from the facility in question as well as other regulatory entities that may be involved. Cases are reviewed by an investigative review committee that approves any recommendation for disciplinary action. Any actions (formal or non-disciplinary) are reviewed and approved by the full board.	South Carolina utilizes VIPPS.

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	*Do you have specific requirements for non-resident vs. resident, if so, please list-*	*How do you assure quality and compliance?*	*Do you require an inspection component such as copy of last inspection, etc.?*	*How many complaints do you receive each year against nonresident pharmacies?*	*Describe how are they investigated-*	*Do you rely on VIPPS or another national accreditation program?*
SD	Go to www.state.sd.us/doh/pharmacy, see Law SDCL-36-11-19.2 to 19.8	South Dakota requires a copy of state license, pharmacy address, contact person, pharmacist-in-charge phone number, report any license restrictions, and list of owner phone number for public access 800 number.	South Dakota requires a copy of the latest inspection, and sometimes makes contact with the state to verify information (spot check).	Most complaints are against mail-order located in this state.	If South Dakota has a complaint outside this state, the state where the licensed non-resident pharmacy is located is contacted.	South Dakota asks the question if VIPPS certified. Some are, most are not.
TN	Must have a pharmacist-in-charge who is licensed in Tennessee. Must submit a copy of most recent inspection and subsequent inspections. (See Rule 1140-1-.08)	See question #1.	See question #1.	Less than 1% of overall complaints.	Complaints that require a response are handled directly. Complaints requiring investigation are deferred to the board of jurisdiction. Boards are copied on all correspondence.	No
TX	See Board Rules 291.101-291.105	The board relies on the state board of pharmacy where the pharmacy is located to assure compliance.	At the time of initial application, the pharmacy must provide a copy of its most recent inspection as well as a statement from the resident board of pharmacy which verifies the license of the pharmacy and the license of the pharmacist-in-charge.	In FY2003 (September 1, 2002 – August 31, 2003) the Texas State Board of Pharmacy closed 56 complaints on non-resident pharmacies.	Usually complaints involving non-resident pharmacies are referred to the state board of pharmacy where the pharmacy is located for action. See the Texas Pharmacy Act, Section 565.053.	No

Appendix C

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey

34 Boards Responded

State	Do you have specific requirements for non-resident vs. resident, if so, please list-	How do you assure quality and compliance?	Do you require an inspection component such as copy of last inspection, etc.?	How many complaints do you receive each year against nonresident pharmacies?	Describe how are they investigated-	Do you rely on VIPPS or another national accreditation program?
VA	See Law §54.1-3434.1. Nonresident pharmacies to register with Board. Virginia is planning to propose changes next legislative session.	Rely currently on resident state board.	Yes, this is a problem with states that do not inspect prior to opening new pharmacies.	Approximately 20-30	Referred to resident state currently.	No, require resident state licensure.
WA	Yes, Washington has specific laws, which address the application and licensing requirements for nonresident pharmacies – RCW 18.64.350 through 450.	The board assures quality and compliance through: Verification of license status; providing applicable rules and regulations to licensed pharmacies – education; and customer service – a uniform process for receiving, investigating and determining appropriate actions.	Yes, the original application packet submitted to the board for consideration for licensure requires a copy of the most recent inspection conducted by the state's licensing/regulatory agency.	The Washington Board receives approximately 6 (six) -10 complaints per year for nonresident pharmacies.	The nature of the complaint would determine what actions/investigation is pursued. A violation of pharmacy law would be referred to the state board/regulatory agency in which the pharmacy is located. Actions limiting the resident license would directly impact the license issued by Washington State. If the complaint is not a violation of pharmacy law, the board sends a letter informing the licensee of the complaint and the case is closed.	No, to date Washington has not relied on any national accreditation programs; however, if necessary we have contacted individual boards via telephone or Internet for license verification.
WV	West Virginia's requirement is a toll free phone number.	Generally rely on home state to ensure legitimate practice.	Yes	Generally 4 (four)-5 (five), usually about delayed delivery or switching of products.	Contact mail order PIC, if needed work with home state board of pharmacy.	No, have sought legislation to require it. No success yet.
WI	Wisconsin does not license non-resident pharmacies.					

34 Boards Responded

State	*Do you have specific requirements for non-resident vs. resident, if so, please list-*	*How do you assure quality and compliance?*	*Do you require an inspection component such as copy of last inspection, etc.?*	*How many complaints do you receive each year against nonresident pharmacies?*	*Describe how are they investigated-*	*Do you rely on VIPPS or another national accreditation program?*
WY	Yes, a copy of state license, a copy of most recent board inspection, a copy of DEA registration and an application which is a little different from resident.		Yes	Very few complaints.	Contact pharmacy, communicate back and forth.	No

Submitter : Mr. Beau Washington **Date & Time:** 10/04/2004 09:10:51

Organization : Mr. Beau Washington

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1336-Attach-1.rtf

October 4 , 2004

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-4069-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Comments on Proposed Rule -- Medicare Part C, Medicare Advantage Program
Potential Impact on American Indians/ Alaska Natives and Indian Health Programs
Notice of August 3, 2004, 69 Federal Register 46866
File Code CMS-4069-P

Dear Administrator:

I am writing to express my great concern that the final regulations for the Medicare Advantage Program and any related prescription drug benefit address the unique status of American Indian and Alaska Native people and the Indian health programs. Decision in regard to the health care of Native people must take into consideration the Federal Trust Responsibility, the promise of health care in Indian Treaties, the Indian Health Care Improvement Act, and principles of Tribal Self-Determination. The proposed regulations could cause a significant loss of Medicare Part A and Medicare Part B reimbursement revenue for Indian health programs, which may not be adequately replaced by the Medicare Advantage Program. Medicare Advantage plans will be run by private companies and could charge elderly and disabled tribal members significant premiums and other costs (including costs for prescription drugs) for health services now available without charge through Indian health programs.

The regulations governing the Part C must be revised to achieve the following goals:

- Encourage MA enrollment by elderly and disabled tribal members by removing financial barriers and allowing their voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, or selection of an Indian health program plan.

- Ensure that Indian health programs, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to elderly and disabled program users who also enroll in a Medicare Advantage plan; reimbursements should not be less than are available under Medicare Parts A and B.

- Indian health programs the flexibility to sponsor their program users in Medicare Advantage plans under a special group payer arrangement.

- In the future, develop a special Medicare Advantage plan for elderly and disabled Native people that includes the active participation of Tribes in its design and implementation.

- Explicitly exempt “special needs” elderly and disabled dual eligible Indian health program users from mandatory participation in a State Title XIX MA or MA-PD Plans and coordinate services with the Indian programs.

There are no “Indian provisions” in the proposed Medicare Advantage Program. If elderly and disabled tribal members and their Indian health programs are to really gain some advantage from the program it must take into account the unique status of Native people and the federal obligation to enhance, and not diminish, Indian health programs.

I further incorporate by reference the comprehensive comments developed by the National Indian Health Board and submitted on this record in behalf of many Tribes and regional Indian Health Boards.

Sincerely,
Beau Washington, MA

CMS-4068-P-1337

Submitter : Dr. Charles Curry **Date & Time:** 10/04/2004 09:10:21

Organization : International Society on Hypertension in Blacks, I

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

See attached letter from Dr. Charles L. Curry, President - International Society on Hypertension in Blacks, Inc.

CMS-4068-P-1338

Submitter : Dr. Beth Young **Date & Time:** 10/04/2004 09:10:26

Organization : Dr. Beth Young

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

What requirements and/or guidelines should CMS formulate for MTM?

I understand that you will be conducting further research into this issue. I believe that the best practices that should be followed are guidelines that are published by such agencies as AHCRQ, JCAHO and other healthcare/professional organizations. These guidelines are already followed to monitor for quality and safety in hospitals and other health care organizations. The data that should be collected is the same data that is collected by these organizations. When it comes to selecting a Medicare provider by the patient, does CMS monitor their providers for meeting "best practices gudelines." If so, how is this information given to its' beneficiaries?

2. Regarding MTMPs and the Medicare Chronic Care Improvement Programs

I believe that CMS should have opened the CCIP bid to pharmacists as a healthcare provider group.

CMS needs to establish the eligibility determination language of beneficiaries that receive MTM. For each plan to establish their own criteria leaves too much variablitiy and interpretation. MTM should be opened to all patients that are on 5 or more chronic medications and not restricted by disease state. MTM services should be provided by degreed individuals only; this would exclude medical assistants, nursing assistants, emergency medical technicians or LPNs.

3. MMTPs and administrative costs

This should not be categorized as administrative costs. Patients should pay a copay as part of a healthcare provider visit. Services provided are for the management and improvement of a patient's health and as such are comparable to services provided by any other recognized provider.

CMS-4068-P-1339

Submitter : Dr. Harriet Fetner **Date & Time:** 10/04/2004 09:10:03

Organization : Medi Home Infusion

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed Medicare Part D to cover infusion drugs without covering nursing or supplies would be impossible for providers to provide this service. In the state of South Carolina, a CON is required to provide skilled nursing service, without reimbursement for the nursing visit to administer the medication, the patient would not be able to receive the medication and would end up staying in the hospital where the cost for Medicare would be much higher. Home Infusion companies would have to "pay" to service these patients. Medicare needs to reevaluate what is covered, ie nursing, supplies, and drug, to ensure that their memebers are able to receive this lower cost administration method.

Submitter : Mr. Peter Wittmann **Date & Time:** 10/04/2004 09:10:58

Organization : Mr. Peter Wittmann

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

10/1/04

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

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 (Regulation C: Benefits & Beneficiary Protections).

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

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 (Cost Control & Quality Improvement Requirements for Prescription Drug Plans).

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I am currently a pharmacy student at Ohio State University, but plans should be made to help my future patients make the best use of their medications.

In conclusion, I urge the CMS to revise the regulation to revise benefits & beneficiary protections to meet the TRICARE pharmacy access requirements on a local level, and to consider pharmacists as primary providers of MTM services.

Thank you for considering my view.

Sincerely,
Pete Wittmann
49 West 9th Avenue
Columbus, OH 43201
Apt. #2

Submitter : Miss. Marie Ganski **Date & Time:** 10/04/2004 09:10:48

Organization : Pharmacy Student

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

My main concern is with the MTMS inclusion in Subpart D. This component of healthcare is essential for patients and must be supported, developed, and enacted to the fullest extent the bill will provide. A continuum of care must be established for the patient, ensuring optimal healthcare, from nursing, to physician, to pharmacist, to home care. Keeping the patient central will ensure improved health, decreased costs, and success of the Medicare Modernization Act.
Thank you for this opportunity to submit my views.

CMS-4068-P-1342

Submitter : Mr. Benjamin Gross **Date & Time:** 10/04/2004 09:10:33

Organization : Tennessee Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed 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.

CMS-4068-P-1343

Submitter : Ms. Kathleen Jaeger **Date & Time:** 10/04/2004 09:10:14

Organization : Generic Pharmaceutical Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the same letter we submitted earlier today. However, it includes an attachment which we were unable to include at that time because of technical difficulties.

Submitter : Dr. Charles Curry **Date & Time:** 10/04/2004 09:10:02

Organization : International Society on Hypertension in Blacks

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

4 October 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: File Code CMS ? 4068-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: File Code CMS-4068-P

Dear Dr. McClellan:

As you may know, the International Society on Hypertension in Blacks, Inc., (ISHIB) is a not-for-profit, professional, medical membership society devoted to improving the health and life expectancy of ethnic populations. As such, we would like to take this opportunity to offer our perspective on the United States Pharmacopeia?s Draft Model Guidelines and the draft regulations proposed by CMS for classification and coverage of medications for Medicare beneficiaries under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as they relate to African American Medicare beneficiaries.

The primary focus of the ISHIB with regard to the Draft Model Guidelines and the proposed regulations is to ensure that Medicare beneficiaries have access to antihypertensive medicines they need to treat and cure their disease and to maintain their health and quality of life. We are specifically concerned that the special needs and requirements of the African American Medicare community are not currently reflected in the guidelines and ask that these needs are recognized and successfully addressed.

As is well documented, elderly African Americans are at a significant greater risk for hypertension. In fact, a new report from the American Heart Association notes that the prevalence of high blood pressure in African Americans in the United States is among the highest in the world. Compared with Caucasians in the United States, African Americans develop high blood pressure earlier in life and their average blood pressures are much higher. As a result, compared to Caucasians, African Americans experience a greater rate of nonfatal stroke (1.3), fatal stroke (1.8), death due to heart disease (1.5) and end-stage kidney disease (4.2). (Fifth and Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure). The rationale for lowering blood pressure to a specified goal is to protect target organs from hypertension-related damage and to reduce cardiovascular morbidity and mortality. Given the increased prevalence of co-morbidities, this patient population requires that physicians and patients have access to all available medications and therapies that have demonstrated benefit in treating these conditions.

With regard to cardiovascular medications, the current Draft Model Guidelines could limit access to the full range of high blood pressure medicines that have demonstrated positive health outcomes among the African American Medicare community. Currently, the guidelines fail to provide proper classification for whole classes of drugs, such as angiotensin II receptor blockers (ARBs), angiotensin converting enzyme inhibitors (ACEs), aldosterone antagonists (AAs), beta blockers, or calcium channel blockers.

Specifically, the different mechanisms of action of ACEs and ARBs offer physicians important choices in prescribing medications that best meet the needs of their individual patients. That flexibility is extremely important for elderly patients, whose response to medications vary considerably, either because of their frailty, other illnesses, multiple medications, or as sometimes is the case, because of their ethnic heritage.

Additionally, there is no consideration given in the current Draft Model Guidelines given to fixed-dose combination therapies, which have also

proven effective in managing hypertension. It has been well documented that, as monotherapy or in the absence of a diuretic or beta blocker, ACEs and ARBs do not lower blood pressure to the same extent in African American patients that they do in white patients with hypertension.

CMS-4068-P-1345

Submitter : Mr. MARTIN PETROFF **Date & Time:** 10/04/2004 09:10:14

Organization : LAMSON & PETROFF

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

WE SUPPORT THE POSITION OF NEW YORKERS FOR ACCESSIBLE HEALTH COVERAGE IN A LETTER SENT TO THE CENTERS FOR MEDICARE & MEDICAID SERVICES ON OCTOBER 1, 2004 FROM DAVID C. WUNSCH, DIRECTOR, AND MARK SCHERZER, LEGISLATIVE COUNSEL.

Submitter : Ms. Sharonann Kushinka **Date & Time:** 10/04/2004 10:10:24

Organization : Tides Foundation - Community Clinics Initiative

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

This comment summarizes the opinions of several safety net providers and community health centers in California, all of whom serve the underserved and many of whom also serve rural communities. In these organizations, the challenges and barriers to technology adoption extend far beyond the development of industry standards or the cost of devices. They also include day-to-day cultural and organizational factors, equal access to skilled technology professionals, and meeting the demands for federal, state, county and individual grant reporting. Implementing e-Rx or a full electronic health record is far more than a technological endeavor; it is a change in the way care is delivered. Any program seeking to encourage physician adoption of technology cannot succeed without addressing the factors of cost, culture, organizational effectiveness and functionality.

Many California community clinics and health centers have found that regional collaborations can help to lower the financial risk of implementing technology. Risk-taking, innovative clinics and consortia need to be rewarded either through expanded grant-making or increased reimbursement for these initiatives. Overwhelmingly, CCHCs and safety net providers in California feel that new models of collaboration need to be fostered and this can only be accomplished by eliminating some of the financial risk for progressive organizations. HHS could consider revising the requirement for 50% matching funds for technology infrastructure grants and instead, have this requirement based on a sliding scale. Criteria such as evidence of the ability to implement systematic process change - either with technology or other programs - should weigh in favor of the grant recipients.

While the e-prescribing aspects of the Medicare Drug Program will be one more positive step in the overall encouragement of electronic patient management - bringing with it administrative cost savings and reduced medication errors - the safety net providers need help in removing some of their specific barriers to adoption. While we believe the barriers are somewhat higher in our segment of the healthcare delivery system, so are the opportunities for remarkable benefits realization.

CMS-4068-P-1347

Submitter : Miss. Brooke Whitmore **Date & Time:** 10/04/2004 09:10:36

Organization : Tennessee Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-4068-P-1348

Submitter : Dr. Charles Curry **Date & Time:** 10/04/2004 10:10:01

Organization : International Society on Hypertension in Blacks

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

To support the use of fixed-combination therapies, a Consensus Statement of the Hypertension in African Americans Working Group of the International Society on Hypertension in Blacks published in the Archives of Internal Medicine of March 2003 concluded that to reach appropriate blood pressure goals, most individuals will likely require combination antihypertensive therapy. In fact, large randomized trials among African Americans have demonstrated that 2 to 4 antihypertensive agents are required to achieve DBP and SBP goals in adults with uncomplicated hypertension. Clinical trial data also show that patients with diabetes or renal disease require from of 2.6 to 4.3 different antihypertensive medications to achieve a satisfactory blood pressure goal. Thus, it is imperative that proper classification of these medicines is established in the guidelines to accommodate appropriate combinations of drug therapy that ensure access.

Additionally, given the prevalence of institutional barriers that limit African American?s access to quality health care, management of these diseases in African American patients is extremely difficult and complex. The current guidelines would impose restrictive formularies on individuals already disadvantaged by low-income status or disability, the ?dual eligibles? whose current ACEIs, ARBs, and AAs are provided by Medicaid or Social Security Disability Insurance but may not be when they are switched over to Medicare. Dual eligibles should be ensured continuity of care either through being granted access to open formularies or through the provision of continuous coverage of a drug that is part of a prescribed therapy until such prescribed therapy is no longer medically necessary for any covered person under such policy.

Not having these vital medicines available on their formularies, African American Medicare beneficiaries? only recourse to obtain their needed medications would be through an appeal to the Centers for Medicare and Medicaid Services, a process that would be costly, time-consuming, and particularly burdensome to non-native English speakers of African decent or individuals whose culture and customs dissuade confrontation or conflict with governmental authority. At the very least, relying on the appeals process to ensure access to needed medications would present a substantial drain on valuable time and resources at a number of points along the bureaucratic path.

Finally, we recommend that cardiology specialists and African American patient advocacy group representatives are well represented on the Plans P&T committees to ensure that African American
Medicare beneficiaries? special needs are met within the formulary. As stated earlier, this is a group of the Medicare population that has special health requirements and lack of representation may lead to negative health outcomes.

A comprehensive formulary that includes full ranges of medications will ensure that African Americans will have access to these medicines and will not have to undergo a complicated appeals process that could lead to poor patient compliance of needed medicines and negative health outcomes.

We sincerely appreciate your consideration of these concerns that disportionately affect African American Medicare beneficiaries. We urge CMS to use its discretion outlined in ?423.120b to require revisions to the current Draft Model Guidelines. While we realize that the USP and CMS have a daunting task, we are confident that the issues above will be addressed to ensure that Medicare beneficiaries and physicians will have an arsenal of medicines available to them to treat disease and to improve quality of life.

Sincerely,

Charles L. Curry, MD, FACC
President

CMS-4068-P-1349

Submitter : Dr. Anne Marie Murphy **Date & Time:** 10/04/2004 10:10:45

Organization : Illinois Department of Public Aid

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4068-P-1349-Attach-1.doc

Illinois Department of Public Aid

201 South Grand Avenue East
Springfield, Illinois 62763-0001

Rod R. Blagojevich, Governor
Barry S. Maram, Director

Telephone: (217) 782-1200
TTY: (800) 526-5812

October 4, 2004

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

Re: CMS Proposed Rule – 4068-P

Dear Dr. McClellan:

Enclosed please find comments and recommendations regarding 42 CFR Parts 403, 411, 417, and 423, the Medicare Program; Medicare Prescription Drug Benefit; Proposed Rules, which were released for comment on August 3, 2004. These comments reflect the views of the Illinois Department of Public Aid (IDPA), which is the single state Medicaid agency in Illinois and also the administrator of claims for the Illinois State Pharmaceutical Assistance Program, known as Circuit Breaker or Illinois Pharmaceutical Assistance Program (IPAP). These comments first lay out background and the Department's general concerns and later address the Notice of Proposed Rule Making (NPRM) section by section.

Unlike many other states, Illinois currently has a rich array of pharmaceutical assistance programs designed to help our residents with the cost of prescription drugs. Consequently, the implementation of the Medicare drug bill in a manner that in any way impinges upon Illinoisans' current ability to access affordable prescription drugs is of grave concern to the state.

Using Medicaid and the State Children's Health Insurance Program (SCHIP) combined, Illinois provides comprehensive drug coverage to approximately 1.8 million Illinoisans. Of the 1.8 million enrollees, 181,219 are dually eligible for Medicare as of 8/1/04. Children covered by the Illinois Medicaid program have no cost sharing requirements. Children covered by SCHIP have very modest cost sharing. Adults covered by Illinois Medicaid and our HIFA waiver have very modest cost sharing requirements with a $3 copayment for brand name drugs and no copayment for generics.

In addition to the comprehensive Medicaid program outlined above, seniors in Illinois whose incomes are below 200 percent of the federal poverty level (FPL) and who meet the nonfinancial eligibility standards for Illinois Medicaid may avail themselves of the SeniorCare program. There were, 201,585 seniors enrolled in this program as of 8/1/04. SeniorCare is an 1115 Medicaid Pharmacy Plus waiver, which provides comprehensive prescription drug coverage. Cost sharing is generally minimal with no premiums, no copayments for those whose income is below 100 percent FPL, and for those whose income is above 100 percent FPL $4 co pays for brand name drugs and $1 co pays for generics for the first $1,750 of drug spending. After $1,750 of drug spending has been reached, a senior pays a coinsurance of 20 percent in addition to the co pays. This program is significantly more generous than the program to be enacted in the MMA. The Department estimates that for those beneficiaries whose incomes are above the low-income subsidy level in the Medicare part D program, the difference is on average as follows: for an individual with $1,855 worth of drug spending, the Department estimates the average out-of-pocket costs through Senior Care is $120, whereas the out-of-pocket costs through Medicare would be $1,045; for an individual with $5,100 worth of drug spending, the Department estimates average out-of-pocket costs through SeniorCare are $988 and through Medicare would be $4,020. Therefore, the Department strongly supports CMS' interpretation of the Medicare drug law to allow for the continuation and renewal at state discretion of Pharmacy Plus waivers. In addition, the Department continues to desire to expand the Illinois SeniorCare program to those whose income is up to 250 percent FPL. The Department hopes that there will be flexibility to modify the SeniorCare program to coordinate benefits with Medicare part D when this is in the best interest of beneficiaries and the state and federal government with respect to maximizing coverage and minimizing costs. The Department also suggests that at a minimum state spending on SeniorCare count toward a beneficiary's out-of-pocket costs. The NPRM allows state spending from a State Pharmaceutical Assistance Program (SPAP) to count toward a beneficiary's out-of-pocket costs but precludes equal treatment for Medicaid waivers. This appears discriminatory and will deter SeniorCare enrollees from signing up for Medicare part D.

In addition to these federally funded programs, Illinois also operates an SPAP known as Circuit Breaker or Illinois Pharmaceutical Assistance Program (IPAP). IPAP has been in operation since 1985 and provides coverage of prescription drugs for ten specific health conditions, including heart disease, osteoporosis, and arthritis. IPAP is available to seniors and persons with disabilities whose income is below approximately 240 percent of the federal poverty level. Therefore, seniors whose incomes are above the SeniorCare limit or whose immigration status precludes them from SeniorCare are eligible for this

program. In addition, persons with disabilities of any age whose income is below the limit are also eligible. Approximately 50,000 individuals are enrolled in IPAP. The Department supports the requirement that the new Medicare Prescription Drug Plans (PDPs) and Medicare Advantage drug plans (MA-PDPs) coordinate with SPAPs. Nonetheless, the Department is concerned about the section of the regulations (Section 423.464(e) 3) that allows PDPs and MA-PDPs to charge SPAPs for coordination as this could unnecessarily strain the finances of IPAP and other SPAPs. SPAP contributions and coordination of benefits enhance Part D benefit packages and such coordination should not carry a financial penalty. The Department is also concerned about CMS' interpretation of the antidiscrimination language in the law at Sec. 1860D-23(b)(2) (proposed regulations Sections 423.4 (SPAP definition (2) and 423.464(e)(1)(ii)), which would preclude the use of a preferred PDP. The Department believes this is not in the best interest of SPAP beneficiaries as it precludes offering them a specific tool that could maximize their benefits. The Department will address this issue in greater detail in our comments on specific sections.

The state of Illinois also operates a prescription drug discount card known as Save Rx. This card is available to seniors and persons with disabilities. Generally, the card costs $25 but this fee is waived for IPAP enrollees and IPAP enrollees are autoenrolled in the program so as to facilitate their receiving discounts on the drugs that are not covered in IPAP. Average savings from this program are 20 percent.

To summarize current prescription drug coverage in Illinois for the 1.6 million Illinoisans enrolled in Medicare, approximately 500,000 Illinoisan have retiree health benefits with prescription drug coverage[1], 181,219 are fully dual eligible Medicaid beneficiaries, 360,000 are eligible for SeniorCare with 201,585 enrolled, 50,000 are enrolled in IPAP. Put another way, Illinois Medicare beneficiaries over the age of 65 with income less than 200 percent FPL, are currently eligible for comprehensive drug coverage through SeniorCare. Illinoisans under the age of 65 who have a disability with an income of less than 100 percent FPL, are eligible for comprehensive drug coverage through Medicaid or if their income is above 100 percent FPL but less than approximately 240 percent FPL, they are eligible for the less comprehensive IPAP program and state drug discount card. This would suggest that the group that will benefit most from enactment of the Medicare drug law will be seniors whose income is above 200 percent FPL who do not have retiree health benefits that cover prescription drugs and persons with disabilities whose incomes are above the eligibility level for Medicaid (100 percent FPL). Our concerns, therefore, are broadly trifold; given the current presence of generous state programs, the Department advocates for implementation of the new Medicare drug law in a manner that will not undermine current coverage, secondly, that Part D benefits for those who have limited current coverage be maximized, and thirdly, those who do not have current coverage receive the most generous coverage possible.

The state of Illinois under Governor Blagojevich's leadership has been improving ease of access for Illinoisans with respect to prescription drug coverage. To do this, the state has

[1] Ken Thorpe "Implications of a Medicare Prescription Drug Benefit for Retiree Health Care Coverage," November 17, 2003

created a single point of entry for SeniorCare, IPAP and Save RX through the Department on Aging (DoA). The state has many years experience with beneficiaries and recognizes that many people prefer to access such coverage through the extensive Aging network. The Department hope that CMS will recognize states' experience in this area and will allow states flexibility to create the point of entry for access, in particular the low-income subsidy, which works best for each state individually. Our interest here is in providing our residents with an entry point that works for them and that will optimize their ability to receive both the low-income assistance and other benefits for which they are eligible including the Medicare Sharing Program.

The area of greatest concern to the Illinois Medicaid program is the transition of the dual eligibles to coverage by Medicare part D. While the Department supports the concept of autoenrolling those who do not choose a plan with an opt-out mechanism, the Department is particularly concerned about a potential gap in coverage between the time that the Medicare part D goes into effect (January 1, 2006) and the time that autoenrolling would happen (May, 2006). This population does not have current experience in choosing such plans and some may find it particularly difficult to make such choices. This is particularly true for certain nursing home residents or those who have impaired cognitive function. According to MedPAC, 39 percent of dual eligible individuals suffer mental illness.[2] There are two potential solutions to this problem. Either CMS could allow for temporary Medicaid coverage until autoenrollment is effective or CMS could do autoenrollment prior to the start of the program so as to ensure that a safety net was provided to these beneficiaries who are the most vulnerable and unable to afford prescription drugs without such a safety net. The Department realizes that the Medicare law may preclude the first option. However, the Department believes that consideration should be given to modifying the law in this area in particular for the group mentioned above.

Full benefit Medicaid, SeniorCare and SCHIP enrollees currently enjoy access to all prescription drugs for which the Department of Health and Human Services (DHHS) has a rebate agreement. Illinois Medicaid coverage goes beyond the coverage mandated by federal statute, covering drugs such as smoking cessation agents, certain barbiturates and benzodiazepines, which under Sec. 1927(d)(2) of the Social Security Act could be restricted. While IDPA does employ the use of a Preferred Drug List (PDL), drugs that are not on the PDL are available to enrollees when medically necessary through the use of a prior authorization system consistent with Sec. 1927 (d)(4) and (5) of the Social Security Act.

As the Department describes in more detail in our comments on Subpart P, we are very concerned that the NPRM does not address ongoing eligibility for full subsidies for dual eligible individuals. It appears that CMS has focused its attention primarily, and we admit understandably, on program implementation. The Department urges CMS to consider that maintaining full subsidies for dual eligible persons will be critical to preserving their health.

[2] MedPAC "A Databook: Healthcare spending and the Medicare Program," June 2004

Illinois Medicaid and SCHIP provide comprehensive drug coverage at a total cost of $1.8 billion in FY04. Per capita prescription drug expenditures have been rising rapidly over the last several years in the United States. While Illinois Medicaid has also seen increases, IDPA has engaged in aggressive cost containment in order to achieve reduction in growth of prescription drug costs. So while the per capita increase in prescription drug expenditures nationally was 14.3 percent in 2002, 12.3 percent in 2003 and is projected to be 11.9 percent in 2004 and 11.3 percent in 2005, here in Illinois Medicaid's increases were 12.2 percent in FY2002, 8.7 percent in FY2003, and are projected to be 12.4 percent in FY2004 and 8.2 percent in FY2005. The Department is particularly concerned that the "phase down state contribution" (423.908 and 423.910 of the NPRM) may not fully take into account these recent cost containment measures and so the amount charged to Illinois for the cost of dual eligibles may be inflated. In fact, while congressional intent was to phase down state contributions, usage of a growth factor that overstates cost increases in the Medicaid program may actually result in states paying more rather than less for prescription drug coverage for dual eligibles under Medicare part D. While it is true that states did seek to transfer responsibility of providing dual eligibles with drug coverage to the federal Medicare program, this was not advocated with the idea of states retaining financial responsibility for such a program. The Department would suggest that the Medicare Part D law in this area is particularly unfair to states, which will no longer have any control over spending in this area and yet will be financially responsible for the costs of a fragmented and potentially less competitively priced program. The Department urges Congress to revisit this provision and further suggests that CMS utilize the most appropriate growth factor that actually is representative of Medicaid program prescription drug cost increases.

Additionally, while the Department supports enrolling those individuals eligible for Medicare cost sharing, The Department anticipates an increase of up to 20,000 new Illinois beneficiaries in the Medicare cost sharing programs and is concerned about the likelihood of Illinois Medicaid costs rising by between $10-20 million annually as a result.

The Department is concerned about the structure of the Part D law, which fragments drug coverage among many PDP sponsors. The Department knows from its own experience that successful acquisition of competitively priced prescriptions drugs requires a large purchasing pool. This is consistent with CMS' recent initiatives to promote multi-state purchasing pools. Therefore, the Department suggests that creating the largest regions possible across which PDPs may operate is likely to be in the best interest of both states and the federal government, which are financially liable for this new program. The Department also suggests that CMS consider contracting with some of the largest states as either PDP or fallback plans, due to the extensive experience that states have operating cost-effective, comprehensive drug programs and the leverage that such states have due to the large size of their purchasing pool.

While the Department understands that promoting choices for beneficiaries is also an important goal, the Department suggests that the experience with the Medicare discount card has been instructive in this area. It is clear from that program that when individuals

are confronted with a wide array of choices, it is often very difficult to compare them all and that this promotes confusion and inaction. Furthermore, there are some beneficiaries who spend time in different geographic areas, including different states, during the course of a year. The Medicare program is a national program and currently, those beneficiaries enjoy their Medicare benefits throughout the entire United States. Consideration should be given to making some Part D plans available that can be accessed in all parts of the United States. Such portable coverage is consistent with the overall Medicare national program.

Detailed comments on the sections of the proposed rules

Subpart A – General Provisions

Section 423.4 - Definitions

PDP sponsor

The NPRM limits PDP sponsors to nongovernmental entities. The Department does not believe that CMS has legal authority to so limit choice of sponsors. The MMA does not include a provision to so limit the choice of PDP sponsors.

It is curious that CMS would choose to limit PDP sponsors to nongovernmental entities, given the enormous experience that states have in providing prescription drug coverage. Private sector companies do not currently provide stand-alone prescription drug coverage as an insurance option. Instead, drug coverage is generally integrated within other insurance coverage. In contrast, the states have created stand-alone drug coverage programs both in the form of SPAPs and 1115 Pharmacy Plus waivers. The stability of the state run programs is in marked contrast to the instability of many private sector insurance products including the Medicare + Choice insurance products. The Department suggests that CMS reconsider this definition. In some areas of the United States, it may be difficult to contract with an appropriate PDP sponsor. However, a governmental entity may be willing to provide such a benefit. This is particularly true in states where a large SPAP or 1115 waiver program currently exists. There may be significant benefits to both the federal government, the state government and to beneficiaries from the utilization of a structure that has been in operation for several years and that is well known to beneficiaries.

In addition, states are required to continue to contribute to the cost of prescription drug coverage for the dual eligibles. However, states will have no control over the costs of such coverage. Furthermore, states will be giving up a certain proportion of their population and may lose some bargaining power, which will also negatively affect a state's ability to control prescription drug costs for the rest of its Medicaid program. Therefore, some states may be eager partners with the federal government to provide such coverage to Medicare enrollees, especially to the dual eligibles. This option may prove to be a much more stable and reliable option for the federal government compared to other options.

Subpart B – Eligibility and Enrollment

The Department recognizes that the task of educating Medicare beneficiaries about how to enroll in this new benefit will be enormous. The structure of the part D benefit itself is in many ways designed to be fragmented by its use of many PDPs and MA-PDPs as opposed to a uniform national program with single point of entry. This new design will be very different for beneficiaries compared to the traditional Medicare part A and B enrollment process. The Department is consequently concerned that sufficient attention be directed to outreach to the many different populations served by the Medicare program. In particular, the Department is concerned about outreach to persons with disabilities and those who reside in nursing homes or institutions for mental disease (IMDs).

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. These organizations are staffed primarily by volunteers who are already overburdened. Moreover, SHIPs are primarily focused on assisting seniors and generally do not have the capacity to address the special needs of individuals with disabilities.

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 most appropriate plan available. The conference report for the Medicare Modernization Act, 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.] States have had significant experience in enrolling individuals suffering from mental illness in to state mental health programs and their experience 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.

Additionally, experience with the Medicare discount card is clearly instructive. While many low-income individuals are eligible for transitional assistance, very few have signed up by themselves. Seventy five percent of enrollment has been via autoenrollment.[3]

The Department suggests that CMS partner with and finance 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. Here in Illinois, the Department has great experience in this

[3] Kaiser Family Foundation report "Medicare discount cards: A work in progress," July 2004 and found at www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

area. The Department has partnered with community-based organizations to enroll children and families in our KidCare and FamilyCare program. The Department has over 1100 KidCare Application agents (KCAA). IDPA provides KCAAs with $50 for every complete application they submit that is approved. Similar groups or even some of the same organizations are likely to be known and trusted by Medicare beneficiaries with disabilities.

CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (Preamble discussion of 423.48 at pages 46642-46644). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources and training. Here in Illinois, the Department provides our KCAAs with on-going training so that they are familiar and up to date on our programs.

While information on the Internet may be useful to some beneficiaries, in general such a mode of communication will not be suitable for the majority of the Medicare population. The Kaiser Family Foundation has done some surveying in this area and finds that 70 percent of those over 65 report never using the Internet. Of those who do go on line, just 2 percent have visited CMS' Medicare.gov site. In addition, use of the Internet is stratified by income. For those with incomes below $20,000 per year, only 15 percent have ever visited the Internet.[4]

The Department suggests that CMS develop very specific plans for facilitating enrollment of beneficiaries with disabilities and other particularly vulnerable populations such as those residing in institutions in each region that incorporates collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. CMS should also consider providing additional grants to SHIPs, Departments on Aging, Area Agencies on Aging, state agencies providing assistance to persons with disabilities and Medicaid agencies for the purpose of providing public education and information on this new program. In addition, in their bids, PDPs and MA-PDs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness.

423.30 - Eligibility to enroll

Consistent with the MMA at 1860D-1(a)(1)(B), the NPRM restricts Medicare Advantage enrollees to MA-PD plans. However, as pointed out in the preamble, this could under certain circumstances present CMS with a quandary with respect to low-income individuals, if the Medicare Advantage plan does not offer a plan at or below the low-income benchmark premium. This would be contrary to the clear intent expressed by

[4] Kaiser Family Foundation report "Medicare discount cards: A work in progress," July 2004 and found at www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

Congress at 1860D-14(b)(3), to avoid a situation where there are no plans available to those people qualifying for a low cost plan. The Department recommends that CMS require all MAs to offer an MA-PD at or below the low-income benchmark premium.

In addition, due to the restriction of choices for enrollees of Medicare Advantage plans, the Department suggests that CMS notify all such enrollees of such restriction and give them the opportunity to return to Medicare Fee for Service if they desire to enroll in a PDP plan.

423.34 (b) - Enrollment.
The final rule should clearly provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual. This is most appropriate for those Medicare enrollees who will find it hard to enroll by themselves.

423.34(c) – Denied Enrollment Notice Requirement.
The notice should be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

423.34(d) - Enrollment requirement for full benefit duals
As mentioned earlier, the Department supports the provision in the law to allow for autoenrollment of full benefit duals in a PDP or MA-PDP if they fail to choose a plan. However, the Department is concerned about the timing of this autoenrollment, which may leave this very vulnerable population without coverage for several months. In the absence of a law change to provide transitional Medicaid coverage, the Department suggests that CMS take the precautionary approach of pre-autoenrolling them in a plan as a fallback. Beneficiaries can then move to the plan of their choice at any time due to the availability of "special enrollment periods" for the dual eligibles under 423.36 (c) (4). However, enrollees would have the guarantee of a safety net plan under such a proposal.

In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. The Preamble suggested that states have more experience with auto-assigning beneficiaries. This may be true in states that operate mandatory managed care programs. However, in states such as Illinois this is not the case. While it is true that states have more readily available data identifying the dual eligibles in their state and they will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment, they are currently suffering significant budgetary and staffing challenges and MMA only provides a limited match for administrative costs imposed on the states by this law. Additionally, the states may have no relationship with the new PDP sponsors and their only involvement for enrollment will be enrollment in the subsidy rather than enrollment with a specific PDP sponsor. CMS is in fact in the best entity to do autoenrolling because it has relationships with the PDP sponsors and is funded to administer the program. Furthermore, if CMS chooses to insist on the states performing this task, then 50 different entities (states) will have to find solutions for this task. This has the potential for far more disruption. Each state has a different computer system and significant system changes would be necessary

in a relatively short time period to effectuate this autoenrollment. It is highly likely that many states would be unable to perform this function within the time period needed. Medicare is a national program and this issue is most efficiently dealt with once by the federal government.

If CMS does, however, decide to impose this new mandate on the states, the administrative match should be 100 percent and CMS should provide the states with technical staff to assist in this implementation including staff for necessary system changes.

423.36(c) - Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the provisions for involuntary disenrollment (see comments under section 423.44). CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties.

The special enrollment provisions should be clarified to ensure that dual eligibles would not be subject to a late enrollment fee if the complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

423.38 (c) - Effective dates for special enrollment periods
The Department supports the principle of determining effective dates for coverage in a manner consistent with protecting the continuity of health benefits coverage.

423.42 (e) – Maintenance of enrollment
The Department supports the principles contained in this section. CMS should develop a methodology for ensuring that no beneficiary loses coverage if a PDP is discontinued, including perhaps temporary autoenrollment into another plan until such time as a beneficiary chooses a new PDP.

Certain beneficiaries may lack the ability to address future changes due to instability or discontinuance of coverage. While they may receive assistance with initial enrollment due to the large amount of public awareness surrounding the initiation of the program, in the future when only a portion of enrollees are affected by a change, their need for assistance may go unnoticed. It is therefore, incumbent upon CMS to ensure that if there are changes in PDP sponsors, that enrolled beneficiaries do not fall through the cracks and therefore lose coverage.

423.44(b)(2)(i) - Required involuntary disenrollment by the PDP.
CMS stated that it was "particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area." (Preamble, p. 57).

The disenrollment requirement in this section raises the issue of "snowbirds"—the large number of Medicare beneficiaries who move for large parts of the year. The churning—the enrolling and disenrolling—that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination (as described in the June, 2004 MedPAC report to Congress), the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

The Department suggests several ways that CMS can better address this issue:

- **Create certain PDP options that are available throughout the United States**.

- **Require traveler benefits policies and require plans to provide information on their traveler benefits.** Unlike Medicaid, Medicare is a completely federally funded and administered program. Medicare beneficiaries are currently able to access their benefits in all parts of the United States. Therefore, the Department believes that CMS should require as a condition of participation that plans have a system of visitor or traveler benefits. In addition to requiring traveler benefit policies, CMS should require plans to provide prospective enrollees with specific information on traveler benefits and "out-of-plan service policies." In many cases, 90-day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. Beneficiaries who are traveling and need emergency pharmaceutical services need to know how their plan will (or will not) reimburse for those services.

- **Allow PDP exceptions.** Consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement. At a minimum, beneficiaries must have a clear understanding of how a plan will serve people temporarily out of the service area.

- **Define time period.** The regulations should also clearly define the time period that a plan could consider an enrollee as "no longer reside(ing) in the PDP's service area." This should be defined to accommodate seasonal travelers who maintain a residence in the service area.

423.44(d)(2) - Disenrollment for disruptive or threatening behavior.

The Department is particularly concerned about beneficiaries who currently receive their prescription drug coverage through Medicaid. There are no provisions in the Medicaid statute to allow a state to disenroll an individual due to disruptive or threatening behavior. Therefore, dual eligible individuals could experience less protection under this section compared to their current coverage.

The NPRM allows Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44). CMS' authority to allow such disenrollment is questionable. The MMA does not include

any mention of disenrollment of beneficiaries for disruptive behavior who are enrolled in PDPs. While the MMA does under Sec 1860D-1(b)(1)(B) allow for the establishment by the Secretary of rules for enrollment for MA-PDs similar to those in effect for current MAs, this provision is limited to MA-PDs. Section 1851(g) of the Social Security Act allows Medicare + Choice plans to terminate enrollment for individuals who have engaged in disruptive behavior. However such termination allows the individual to return to traditional Medicare. MMA does not include a provision to extend such disenrollment to traditional Medicare or PDPs.

CMS' inclusion of these provisions creates 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.

Further, the NPRM does not allow a process by which a beneficiary can appeal an involuntary disenrollment due to disruptive or threatening behavior. This lack of an appeal right opens the door for abuses resulting in a PDP eliminating beneficiaries with above-average costs from its program. Further, this lack of an appeal right may result in the denial of due process.

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.

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 would appear 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.

As the provider of other health care services for dually eligible population, the Department is particularly concerned about the effect this may have on our beneficiaries who may be hospitalized due to the deterioration of their health due to the denial of drug coverage.

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. The term "threatening" is not defined. The Department is concerned about how such an undefined term might be interpreted.

Reenrollment. In the preamble, CMS asks 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. Individuals who are subject to involuntary disenrollment may have no resources to pay for their medications. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify one 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 minimized. 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 or dementia, 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. The Department questions 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 the Department urges 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.

Protections to include. While the Department believes that CMS lacks authority to allow for disenrollment of beneficiaries from PDPs due to disruptive behavior, if CMS insists on maintaining these provisions, 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, the Department strongly recommends 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":

- CMS is strongly encouraged to prohibit PDPs and MA-PDPs from disenrolling any low-income subsidy eligible individuals unless the beneficiary is enrolling in another PDP or MA-PDP. It is essential that PDPs and MA-PDPs be prohibited from disenrolling any dual eligible individuals unless the beneficiary is enrolling in another plan. These individuals will not have means available to purchase drugs out-of-pocket and they should never experience gaps in pharmacy coverage. Beyond the personal suffering that will result, if dual eligibles lose pharmacy benefits, it can be expected that they will become more acutely ill and require other, probably more expensive, Medicare or Medicaid covered acute care services.

- 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 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.

- Enrollees should have the opportunity to appeal such disenrollment;

- If, upon establishment of the appropriate process, an enrollee appeals this involuntary disenrollment, the disenrollment should not be effective until the appeal has been decided.

Section 423.46 - Late enrollment penalty.

The Department urges CMS to delay implementation of this section for all enrollees for at least one year. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or will not understand that they must choose a plan and enroll. This is particularly true for non-deemed low-income beneficiaries who will have to know to apply through two separate processes, one with the PDP sponsor and one for the low-income subsidy.

IDPA has observed from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them. The Department also sees from our own experience providing prescription drug coverage to Illinoisans that many people who desperately need prescription drug coverage and who are eligible for prescription drug coverage do not necessarily know how to access it. For instance, the Department estimates that close to 360,000 Illinois seniors are eligible for SeniorCare, a comprehensive drug program without a premium or deductible. Yet only approximately 200,000 are enrolled. The state has engaged in extensive outreach to make the public aware of this program, which unlike the Medicare part D benefit has a no cost for enrollment.

The Department understands CMS' concern that healthy beneficiaries will not apply and will instead wait until they need prescription drug coverage to apply. This would result in adverse selection in the program and has the potential for driving up the cost of the program. However, the Department believes that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness. The Medicare Part D program is new and confusing. The Department knows from the experience with the Medicare endorsed discount card that people delay enrollment in a drug card because they do not understand the program and find the choices overwhelming. Many Medicare beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug

plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

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

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complexity. CMS should recognize that persons who have previously received Medicaid drug benefits may not realize the relevance of the MMA to them. It will take extra effort to assure they know that the Medicaid benefit is ending.

Omissions in this section.
Beyond that general comment, The Department have several more specific concerns regarding omissions in this section.

- **Add appeals opportunity.** There should be an opportunity for enrollees to appeal late enrollment penalties. This should be noted in this section and should be incorporated as part of the general system for appeals outlined in Subpart M.

- **Coordinate with "special enrollment periods."** Late enrollment penalties should be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties. The exemption of time during special enrollment periods from late penalties should be stated in this section.

- **Exemption for individuals involuntarily disenrolled.** Unless CMS adds special enrollment opportunities for individuals who are involuntarily disenrolled—as strongly recommended under our comments on section 423.36(c)—those who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period. At that point, they may be subject to a late penalty and increased premiums. For those disenrolled due to "disruptive behavior," this may have resulted from denial of access to needed medications. Where disenrollment was not related to failure to pay premiums, the Department suggests that the late enrollment penalty be waived.

- **Late enrollment penalties and people with disabilities**. CMS should incorporate an enrollment "grace period" for individuals with disabilities. The rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to beneficiaries with disabilities, and these beneficiaries might well require additional time to make a selection and complete the enrollment process. Therefore, CMS should incorporate a late enrollment "grace period" for this population.

Section 423.48 - Information about Part D.

Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references the role of SHIPs in relation to this section (as well as section 423.30). As noted in our introductory comments to our discussion of Subpart B, the reference is inadequate and, in general, insufficient attention is being given to what will be the very difficult task of adequately disseminating information on this program to ensure that, at the least, those with coverage—particularly dual eligibles—do not experience a gap in coverage or late enrollment penalties.

An extensive network of local, face-to-face counseling services will be needed. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate. SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. The Department believes that the SHIPs and Area Agencies on Aging, and related local counseling services are significantly under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, is about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. The Department urges a further increase in funding for SHIP/AAA/Departments on Aging/Medicaid agencies.

Information plans must provide. This section states that "each PDP and MA-PDP plan must provide…information necessary" to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient.

Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance.

In addition, CMS needs to require plans to make information available in alternative formats for people with disabilities and in languages other than English to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. The Department suggests that CMS develop a comparative brochure that can be provided to each beneficiary so that beneficiaries can compare options. The Department realizes that a different brochure would be necessary for each region. However, without independent, unbiased comparative information, beneficiaries are likely to be unable to make informed choices. CMS should continue to make information available upon written request and through 1-

800-Medicare but the Department believes an additional annual mailing by CMS is also necessary. The Department also asks CMS to continue to work to improve information sources, as they sometimes are difficult for consumers.

Minimal information plans should be required to provide. While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on the benefit itself that potential enrollees will need in order to make a choice among plans. This minimum set of information should be specified in this section. Specifically, beneficiaries will need to understand:

- Premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay;
- The benefits structure and comparative value of the plans available to them;
- The coinsurance or copayment they will need to pay for each covered Part D drug on the formulary;
- The specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage;
- Formulary structure, the actual drugs on the formulary, and information on whether the formulary can change during the plan year and if such changes are allowed on how this will be take place;
- Participating pharmacies, mail order options, out-of-service options;
- Appeals and grievance processes;
- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans. Plans should also be required to provide this information to potential enrollees (see comments on section 423.50, below). Therefore, the Department urges CMS to specify the minimal information that plans will need to provide. As noted, guidance is insufficient.

Specifically, the Department urges CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees, who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. The Department urges CMS to require

plans to publish, as part of their marketing materials, price information. This could be provided in a manageable format.

For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish in a standardized format, and post on the Internet, their negotiated price for each of those drugs. Such a list would be easy to prepare and take only about one page in marketing materials.

Information and outreach for dual eligibles. In the Preamble, CMS states that "prior to [this] automatic enrollment process, a widespread education and information campaign (described later in this subpart at Section 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled" (Federal Register, Vol. 69, No. 148, Tuesday, August 3, 2004, Proposed Rules, page 46638). Such an education and information campaign targeted to dual eligible individuals and that does equip them to select among plans and enroll prior to automatic enrollment is critical. However, the proposed regulations may be insufficient.

In the Preamble, CMS discusses education and information materials that it will provide to beneficiaries. This discussion focuses on support through the Internet sources and the 1-800-Medicare number. Both are necessary but, as noted above, insufficient to meet the needs of the Medicare population and particularly insufficient to meet the education and information needs of dual eligibles. This is a difficult to reach population with limited Internet access and, in many cases, limited telephone access.

The Department recommends that CMS involve community-based organizations and providers who serve and work with dual eligibles in this enrollment process. In addition, CMS should devote resources to helping these organizations and providers inform dual eligibles that Medicaid drug benefits are ending, of their choices and what they need to do to sign up. These organizations can help duals find the best plan available to them and let them know that they can switch plans through the special enrollment provision in § 423.36 of the regulations if they have been automatically enrolled in a plan that is not the best for them. The Department further recommends that CMS develop brochures or guidebooks for each region, which are mailed to each beneficiary and are also made available to community-based organizations. This material should provide comparative information on the available plans in each region. This compilation of information is critical to the success of this program.

423.50 - Approval of marketing material and enrollment forms

Experience in this area in both Medicare and Medicaid is extensive and development of the marketing rules for the PDPs and MA-PDPs should be based on that experience. Most recently, Illinois has seen fraudulent marketing with respect to the Medicare drug discount card.[5,6] The Department urge CMS to be vigilant and to identify and prohibit these problematic areas and practices as it develops final regulations.

[5] "Medicare Drug Cards: Illinois accuses 2 firms of fraud" Chicago Tribune, September 19,2004
[6] "Medicare Drug Cards may trigger headaches, consumer groups warn" Chicago Tribune, March 8, 2004

423.50(c) - Guidelines for CMS review.
This section vaguely states benefit information that plans must provide in their marketing materials in subparts (i), (ii), and (iii). The Department urge CMS to include more specific requirements. It will be important that beneficiaries have comprehensive information on plan benefits and drug prices, since the drug co-pays, coinsurance and donut hole costs they might have to pay could be substantial. The Department recommends that CMS add to this list the requirement that plans make available the following information on benefits and benefits structure, in written format and on the Internet:

- **Information on the formulary**: What the formulary is; information on the fact that the formulary might change; notice that will be provided if there is a formulary change; and, at the least, formulary and cost-share tier information for 25 to 50 drugs frequently prescribed to Medicare beneficiaries (see section 423.48 above).

- **Information on drug prices.** A description of the "negotiated price," and a list of the negotiated price for 25 to 50 frequently prescribed drugs (again, see section 423.48 above).

- **Premium information**. Information on plan benefits and the premium (for the basic benefit and any other benefits offered). If a plan offers multiple benefits, marketing material should include a side-by-side comparison of those benefits. For each benefit offered, plans should be required to note, clearly and conspicuously whether individuals qualifying for the low-income subsidy will have to pay a premium and, if so, the amount that will have to be paid.

This information will be critical if beneficiaries are to make informed choices among plans. It should be part of standard marketing materials; potential enrollees should not have to request this basic information.

423.50 (e) - Standards for PDP marketing.
Prohibit telemarketing. Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. There have been numerous reports of telemarketing fraud under the Medicare Drug Discount Program.[7] The Part D benefit is susceptible to even more fraudulent business practices. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

Prohibit marketing of other services. In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit

[7] "Medicare Scams Prey on Seniors," Chicago Sun-Times, News Special Edition at 8, May 24, 2004

cards) in conjunction with Medicare prescription drug plan services. CMS seems to believe that this would encourage entities such as financial services firms to participate as prescription drug plans. The Department finds such a proposal alarming. The MMA clearly lays out the purposes for which a PDP sponsor may market. The law is silent on additional purposes and The Department believes that such silence was intentional. Congress did not envision allowing PDP sponsors to use the information they receive on Medicare enrollees to market other products. PDP sponsors should be participating in this program based on their ability to provide covered benefits not on their desire to tap into this market for other non-Medicare related activities. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. This would be inadvisable for several reasons:

- Having plans offer added services would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved card"; the difficult task of comparing plans would become even more complex for potential enrollees; beneficiaries might mistakenly believe that they need to take an entire package of offered services when they sign up for the drug plan. This section prohibits marketing activities that could "mislead or confuse." Allowing plan sponsors to market added services is so apt to create situations that confuse and mislead beneficiaries that it is in direct conflict with the provisions of this section.

The Act intends the use of beneficiary information to be solely for facilitation of marketing of plans and enrollment of beneficiaries, and the Preamble notes the disclosure of this information is permissible under the HIPAA Privacy Rule. However, permitting PDP sponsors to use detailed health information to market other products to beneficiaries violates the intention of the Act. PDP sponsors that seek to market other products would be subject to the marketing restrictions of the HIPAA Privacy Rule, including being required to obtain a beneficiary's prior authorization to market those products to that beneficiary. However, there is enormous potential for marketing abuses by a PDP sponsor when the PDP sponsor attempts to obtain that prior authorization, in the same way door-to-door and telemarketing may open the door to deceptive marketing practices. In soliciting authorizations to market other products, PDP sponsors may bundle those products with plan information creating confusion about what the beneficiary is authorizing the PDP sponsor to do.

Prohibit single-contract pharmacies from marketing.

CMS asked for comment on the applicability of MMA marketing requirements for PDP marketing. The Department recommends that PDP marketing be much more severely constrained. There is the potential for pharmacies to market certain PDPs more aggressively, regardless of whether or not that PDP is the best for the beneficiary. The Department can easily foresee this occurring if a pharmacy has a contract with only one PDP or has more favorable contract terms with a specific PDP. Providers with relationships with a PDP plan might market that plan more heavily. The Department urges CMS to consider the potential for provider and pharmacy-based marketing to steer beneficiaries into inappropriate PDPs and to

make marketing requirements more limited than those for the Medicare Discount Card and also to specify marketing limits in the regulations.

At the very least, pharmacies with only one PDP contract should not be allowed to market the program; other pharmacies (those with multiple contracts) should be required to provide equal space to materials from all PDPs with which they contract.

Do not allow plans to use Medicare discount card enrollee and applicant information. The regulations should prohibit prescription drug plans from obtaining and using Medicare Drug Discount Card enrollee and applicant information, and information collected from any other card programs the company might sponsor.

It is foreseeable that many Discount Card sponsors will apply to be prescription drug plans. As Discount Card plans, these entities will have beneficiary-level information on drug use, creating the potential for prescription drug plans to use Discount Card information to target marketing to low-cost beneficiaries, either directly or through marketing firms.

Section 423.50(e)(2) prohibits drug plans from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." The regulations should:

- Specifically prohibit prescription drug plans from obtaining or using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor.

- Prohibit others from using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor to market on behalf of a prescription drug plan sponsor.

Specify whether and how the Secretary can provide information to prescription drug plans. The MMA added section 1860D-1(b)(4)(A) to the Social Security Act. This permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."[8]

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

The proposed rule does not contain any provision governing whether and how this information will be provided and in the Preamble, CMS seeks comments on a number of operational issues as well as on the provision in general.

The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair information practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. The Department recognizes that there may be some benefit in the Secretary's providing information to prescription drug plans if the plans send information to eligible individuals information that would actually be useful in determining which plan to select. The Department recommends the following in the disclosure of identifiable information:

- If the Secretary provides information to prescription drug plans, the information provided should be limited to the minimal amount necessary: the potential enrollee's name and address. No health or financial information should be disclosed.

- The Secretary should disclose identifiable information to prescription drug plans to facilitate marketing or enrollment only if the plan's marketing materials contain formulary and drug pricing information or are accompanied by an application form. This approach could help balance privacy concerns with the need for beneficiaries to obtain important plan information.

- The Secretary should not disclose telephone numbers. Telemarketing should be prohibited; there is no need for plans to have beneficiary phone numbers unless provided by the beneficiary.

- Beneficiaries should be given the choice of whether they want this information disclosed. The Department suggests that an opt-out approach be used to ensure that beneficiaries have the ability to limit their exposure to such marketing. Ordinarily, the Department would suggest an opt-in rather than opt-out approach. However, from our own experience with asking beneficiaries for responses, the Department realizes that many will not read the opt-in/out notice and therefore, will not make any choice. Setting the default to opting-out (ie a beneficiary is considered to have opted-out unless they affirmatively opt-in) will result in many beneficiaries not receiving information on the plans when in fact they had not chosen to opt-out, rather they had not acted at all. The opt-out notice should be clear; written with the Medicare population in mind; state what will be shared; and clearly state that even if a beneficiary elects to opt-out, they can still enroll in the benefit, they will still receive information about the benefit from CMS, and they can still request information directly from plans.

423.56 - Creditable coverage
The Department supports inclusion of Medicaid coverage under Title XIX of the Act or under a waiver under section 1115 of the Act.

Given the long history of fraudulent sales of insurance products billed as meeting certain federal standards, the Department strongly supports the provision in Sec. 423.56(f) allowing an individual to apply to CMS to have coverage treated as creditable coverage for the purposes of applying 423.46 when the individual can show that they were not adequately informed that coverage was not creditable.

Subpart C – Benefits and Beneficiary Protections

423.100 - Definitions
Long Term Care Facility
Definition of "long-term care facility" to explicitly include Supportive Living Facilities, Assisted Living Facilities, ICF/MRs and ICF/DDs, the State of Illinois operates a home and community based waiver for supportive living facilities. This innovative program provides Medicaid services to individuals in an assisted living like setting. Due to federal law that precludes receipt of food stamps in a licensed facility, these facilities are certified as supportive living facilities rather than licensed as assisted living facilities so that the beneficiaries may receive nutritional support in the form of food stamps. The Department recommends that the final rule include a definition of "long-term care facility" that explicitly includes such facilities and their counterpart assisted living facilities along with inclusion of intermediate care facilities for persons with mental retardation or developmental disabilities (ICF/MRs and ICF/DDs). The Department believes that many mid to large size ICF/MRs, ICF/DDs, supportive living facilities and some assisted living facilities operate exclusive contracts with long-term care pharmacies. Other states may have other types of facilities that are similar in nature but that contract with long-term care pharmacies and so a broad definition that can encompass the widest variety of settings that utilize such long-term care pharmacies, the Department believes would be advantageous to beneficiaries.

Incurred Costs
The Department support the inclusion of payments made by SPAPs as counting toward a beneficiary's incurred costs.

A state's contribution to a Pharmacy Plus waiver authorized under an 1115 Medicaid waiver should also count toward incurred costs. It does not make sense to allow certain state contributions for drug coverage to count toward incurred costs but to exclude other state contributions. States that were in the forefront of maximizing prescription drug coverage for seniors prior to a Medicare benefit should not be penalized. Illinois raised this issue in its negotiations with CMS over its SeniorCare waiver, the first Pharmacy Plus program in the nation. This is also true of other state programs such as state contributions to ADAP programs for people with HIV. If Pharmacy Plus waiver expenses are not included in incurred costs, then enrollees in these plans will never reach

catastrophic coverage and there will be no reason for them to enroll in the Medicare part D program.

423.104(e)(2)(ii) - Establishing limits on tiered co-payments.
The MMA is a law whose goal is to provide voluntary prescription drug coverage to Medicare beneficiaries. The provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit" is counter to that goal. Allowing a plan to subject a beneficiary to 100 percent cost sharing runs counter to the concept of drug coverage. While the Department understands that describing a prescription drug as covered even when it has 100 percent cost sharing allows the cost to be counted toward the beneficiaries true out-of-pocket costs, which is advantageous to the beneficiary reaching the full catastrophic benefit, it is difficult to justify such a practice as consistent with coverage.

Section 1860D-2(b)(2)(B) of the MMA permits tiered cost sharing provided it is consistent with 1860D-2(b)(2)(A)(ii), which requires actuarial equivalence to a 25 percent coinsurance. This allows Part D plans to incentivize the use of preferred drugs within a class, when it is clinically appropriate. However, 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 and the 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.

The absence of reasonable limits on cost-sharing tiers combined with a difficult to navigate exceptions process could result in certain Medicare Part D enrollees in effect being uncovered. 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. 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. Therefore, the Department suggests that allowing such unlimited cost sharing is inconsistent with Sec.1860D-11(e)(2)(D)(i) of the MMA.

It should also be noted that this practice would be outside the mainstream of current private sector practice. In 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers.[9]

[9] *Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004

The Department recommends that the final rule 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. A limit on the highest tier of cost sharing is also necessary to ensure that coverage is meaningful. This would bring the proposed regulations into closer alignment with Sec.1860D-11(e)(2)(D)(i) of the MMA.

423.104 (h)(3)(i) – Negotiated prices – Disclosure
The NPRM states that a PDP sponsor or an MA organization offering a qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals, or in the form of lower monthly beneficiary premiums and lower covered Part D drug prices at the point of sale as specified in 423.336 (c)(1) and 423.343.(c)(1). It is in the best interest of the program to require PDP and MA-PDP sponsors to disclose ALL negotiated price concessions not those passed on to the beneficiaries and CMS in the form of lower prices. This is essential if CMS is to really address the true costs of the program and its actuarial value in the long run.

423.112 – Establishment of prescription drug plan service areas.
As mentioned earlier, it is in the best interest of the financial integrity of the Medicare part D program to create as large regions as possible, while maintaining beneficiary choices. In addition, CMS should look at contracting with certain PDPs that are available to enrollees all across the United States.

423.120 (b) 5 – Notice regarding formulary changes
The proposed time for notifying beneficiaries of changes in a formulary are too short. Many beneficiaries will not have sufficient time to make an appointment with his or her doctor so as to discuss alternative medications or to seek an exception.

The Department recommends a 90-day notification period with receipt of notification acting as a coverage determination that may then be appealed.

423. 124 (a) – Special rules for access to covered Part D drugs at out-of-network pharmacies
When a beneficiary cannot reasonably be expected to obtain drugs at an in-network pharmacy, then the out-of-network cost should be the same for the beneficiary as the in-network costs.

<u>Subpart J – Coordination Under Part D with Other Prescription Drug Coverage</u>

423.464(a) – Coordination of Benefits with Other Providers of Prescription drug coverage
The Department supports the requirement that PDP sponsors must permit SPAPs to coordinate benefits with the prescription drug plan or MA-PD plan.

423.464 (f)(3) – Imposition of fees
The Department strongly objects to the provision in the NPRM that allows PDP sponsors to charge SPAPs with coordination fees.

423.578 (a) and (b) Exceptions Process for a PDP's tiered cost-sharing structure
These sections differentiate between exceptions from tiered cost sharing and exceptions involving non-formulary drugs. The Department would suggest that in light of the current proposed rules to "apply tiered co-payments without limit" (see discussion under 423.104(e)(2)(ii)) this is a distinction without a practical difference for beneficiaries. If tiers are going to be allowed to be so high as to confer no real benefit, the criteria or threshold for approving a tiered copayment exception should be no different than for approving a non-formulary drug. In either case, the issue at stake is financial access to the drug. This is particularly true for beneficiaries of more modest means.

The Department recommends that criteria or the threshold for approving a copayment exception should be no different from that used for approving a non-formulary drug. In fact the law at Sec 1860D-4(g)(2) clearly states that "denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h)" of that section.

Subpart M—Grievances, Coverage Determinations and Appeals

As the current provider of prescription drug coverage to Medicaid enrollees including dual eligibles and the claims administrator of the Illinois SPAP program, The Department are particularly concerned about this section of the proposed regulation. The Department recognizes that the law as written is difficult to navigate. However, the Department believes that CMS has some scope to improve this section and to create a more consumer friendly system that does not rely on two separate tracks depending on whether a person personally pays for a drug and files an appeal or instead does not obtain the drug and then files an appeal.

The timeframes laid out in this section are far too long. Gaps in coverage are guaranteed under the NPRM as it stands. For certain types of patients, such gaps in coverage can be life threatening or at the very least hazardous to the enrollee's health.

Pursuant to federal Medicaid law (Section 1927(d)(5) of the Social Security Act), a 72-hour supply of medications is available to beneficiaries while they await a decision on a prior approval request. Beneficiaries are also entitled to a fair hearing and administrative review of an adverse hearing decision when a prior approval is denied.

Sections 1860D-4 (f), (g) and (h) require PDPs and MA-PDs to establish a grievance, coverage determination and reconsideration, and appeals process in accordance with Sections 1852 (f) and (g) of the Social Security Act. Section 1852 (f) and (g) of the Social Security Act are the sections that deal with grievances and coverage determination appeals in the Medicare + Choice program. So it would appear that Congress intended the existing Medicare + Choice grievance and appeals system to be used as a model for this new benefit.

Case law provides some guidance as to how the system should operate. In the case of Grijalva v. Shalala[10], the court dealt with the issue of notice for denials of coverage. The court originally found that HMOs failed to provide adequate notice of coverage denials, that the notices were at times illegible and failed to specify the reason for the denial, and failed to inform the beneficiary that he or she had the right to present additional evidence to the HMO. Further, the court found that the Secretary of HHS was under an obligation to insure that appropriate notice was given. The court suggested that to be considered legible, notice should be at least 12-point type. The notice should state clearly the reason for denial, inform the enrollee of all appeal rights, explain hearing rights and procedures, and provide instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician. The Department recommends that greater specificity be given in the NPRM as to the requirements for grievance and appeals. Beneficiaries are in danger of being denied their rights because the system as currently described by CMS is excessively cumbersome and confusing.

423.560 - Definitions
This section defines an authorized representative as someone authorized by the enrollee to deal with appeals. Given the fact that SPAPs will likely be at risk for coverage in the absence of Medicare coverage, this definition should be modified to clearly include SPAPs in this definition.

423.562 – General Provisions
This section states that "if an enrollee has no further obligation to pay…a determination regarding these services is not subject to appeal." CMS has verbally indicated that this could prohibit SPAPs from appealing if they pay for a drug. The Department believes that such a proposal would be unfair to states and to beneficiaries.

SPAPS have the mission of assuring that their enrollees have uninterrupted access to needed medications. As the party responsible for payment, the SPAP should have the right to appeal. The enrollee who has coverage whether Medicare pays or not, will have no incentive to appeal if the SPAP is picking up the tab. Such a situation could lead PDP sponsors to deny SPAP enrollees full coverage with impunity, while SPAPs are left defenseless. If SPAPs were to change their policies so as to no longer pay until after an appeal is filed by the beneficiary, this would result in considerable delays for many low-income beneficiaries.

The Department, therefore, recommends that this language be revised to exempt payments from SPAPs from resulting in any abridgement of appeal rights.

Section 423.562 (c)(2) precludes an enrollee from challenging a denial of coverage for a drug when it is accessed from a non-network provider, except in those situations where a PDP sponsor is required to provide such coverage. This section lacks clarity and could lead to a PDP sponsor denying an enrollee their appeal rights when there is a dispute as to whether the PDP sponsor is required to provide such coverage. In the interest of

[10] Grijalva et al v. Shalala 946 F. Supp. 747 (D. Ariz. 1996)

simplifying these rules, CMS should delete this section. While doing so may increase the number of appeals, it will be easier to administer and explain to enrollees. Simplification should be a goal for CMS in this section.

423.566 – Coverage determination
Greater clarity as to what constitutes a coverage determination is needed. CMS should consider how this system will be implemented. When a pharmacist first submits an electronic claim and receives an electronic admittance advice, this should be treated as a request for coverage. If such a request is denied, it should trigger the appeals process.

Section 1860 D-4 (g)(1) states that "a PDP sponsor shall meet the requirements of paragraphs 1-3 of section 1852 (g) of the Social Security Act… in the same manner as… an MA organization." Under such a system for other non-drug benefits, the initial claim denial is the coverage determination and it results in a written notice of appeal rights. Re-determination follows. Medicare + Choice rules for plans that include drugs do not vary between drugs and non-drug benefits on this matter. Therefore, CMS' construction of an alternative system under Medicare Part D, whereby after a pharmacy submission is denied the beneficiary must request a coverage determination appears on its face to run counter to the MMA statutory language. It also exacerbates the complexity of this system.

The Department recommends that an initial claim denial at the pharmacy be considered a coverage determination and the exceptions process should be considered the redetermination.

423.568 – Standard timeframe and notice requirements for coverage determinations
This entire section is again premised on the notion that the initial submission of a claim by the pharmacy is not a coverage determination. As mentioned above, this must be remedied by CMS for this system to work for enrollees.

In the absence of remedy, when a claim is denied at a pharmacy, the PDP is not required to send a notice of such denial to the beneficiary. It is in the best interest of the enrollees to receive such notice in a timely fashion at point of sale. PDPs should be required through their contracts with participating pharmacies to provide enrollees with such notice upon initial claim denial. These notices should include the remedies available to the enrollee, including the enrollees right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or is on too high a tier.

One might argue that this is a burden on the pharmacy. However, the pharmacies and the PDP sponsors must be in close contact so as to keep up-to-date with formularies, coinsurance and calculations of an enrollee's out-of-pocket expenses.

Denials of drug claims can be just as detrimental to the health of an enrollee as other denials of benefits and can result in large out-of-pocket expenses. It does not make much sense to treat such drug claims in a manner that differs from other health services claims.

In addition to providing enrollees with notice of such a coverage determination, The Department also suggest that if the enrollee is also in a SPAP, that notice be provided to the SPAP so the SPAP can also appeal a coverage denial on behalf of the beneficiary.

423.568 (a)(1) – Timeframe for requests for drug benefits
Fourteen days is far too long for exception requests.. Normally these requests are completed in 2-3 days for commercial plans and 24 hours for Medicaid. Most drugs for Medicare enrollees will be for chronic illness, which may deteriorate if there are lapses in coverage. As the provider of medical benefits for dual eligibles, the Department is particularly concerned about lapses in coverage for this group, who often suffer from multiple chronic illnesses. For certain groups such as those with HIV/AIDs or mental illness, gaps in coverage can be particularly dangerous.

Similar to the Medicaid program, in cases of acute illness or urgency, the pharmacist should be authorized to issue a 72-hour supply of a denied medication to enable the patient time to return to their physician to discuss options.

Without this safety measure, dual eligibles will see their protections eroded with implementation of the Medicare drug law.

The Department recommends that the timeline for PDP sponsors to make a decision on a request for an exception be no more than 3 days, unless the beneficiary or physician failed to supply needed information. Dual eligibles or those covered by SPAPs or other low-income beneficiaries should be able to receive a 72-hour emergency supply of denied medications, if the pharmacist determines that they are necessary for the health of the patient.

Additionally, low-income beneficiaries who will be unable to pay out-of-pocket as a stopgap measure during an appeal, should receive a temporary supply while the appeal is being decided. Again, this would be consistent with Medicaid policy.

Finally, those who are currently on a particular medication when a formulary or other change in coverage policy occurs, should receive a 90 day supply of the drug until they can see their physician to discuss their medical options or can pursue an appeal. The NAIC model act on prescription drug benefits provides a workable template with respect to this issue.

423.568 (c) – Notice of denials
In the interest of promoting an easier to navigate system, the Department suggests that CMS eliminate the differential treatment in the NPRM for drug benefit denials versus drug payment denials. However, in the absence of such a change, both situations need denial notices for enrollees.

423.570 and 423.590 – Expediting Certain Coverage Determinations

The Department understands the concept behind differentiating between appeals where a prescription drug has not been provided versus where the beneficiary has paid for the drug and is now appealing non-payment. One could argue that in the first instance, access to health care is being denied and so urgency may be necessary but in the second instance the care has been provided and so urgency is not necessary. In reality, this may be a distinction without a difference for enrollees of modest means. In many cases, the need for the prescription drug is ongoing. In others, while the beneficiary may have paid, they may be in urgent need of reimbursement so that they can pay for rent, food or other necessities.

If one is to penalize an enrollee who pays out-of-pocket because they believe their health is at risk, then the system is promoting the prolonging of denial of care. This is not good public policy and is not in the best interest of Medicare beneficiaries.

CMS should revise these sections to eliminate the differential treatment accorded beneficiaries who pay for their prescription drugs out-of-pocket and then seek to recoup those costs through the appeals process. Neither commercial PBMs nor Medicaid make a distinction in a person's right to a speedy appeal of a prescription drug denial based upon whether they paid out-of-pocket for a stopgap supply.

423.578 and 423.584 – Exceptions Process and Expediting Certain Redeterminations
SPAPs should be entitled to act on behalf of their enrollees to pursue all levels of exceptions. Likewise an authorized representative or a prescribing physician should be able to seek a standard redetermination and any other appeal that is in the best interest of the patient. Many older patients will look to their doctor for assistance with the appeals process. It is likely that the overall system will be confusing and intimidating to many enrollees who have no current experience with managed care.

523.578 – Exceptions process
The preamble considers requiring PDP sponsors to provide "continued access" to a drug at the old copayment rate if the copayment is increased midyear. The Department supports this proposal as it will deter "bait and switch" tactics by PDP sponsors. The Department does, however, support allowing pricing changes in the event a generic alternative becomes available. Generic drugs are approved by the Food and Drug Administration and are required to be fully substitutable for their brand name counterpart. The promotion of the use of generics is essential to maintain cost controls on the Medicare part D program.

The Texas insurance code (Art 21.52J) provides useful model language for this purpose: "A (PDP) shall make a prescription drug that was approved or covered for a medical condition or mental illness available to each enrollee at the contracted benefit level until the enrollee's plan renewal date, regardless of whether the prescribed drug has been removed from the (PDP's) formulary or moved to a higher copayment tier.

423.578 (a) Exceptions for tiered copayments

CMS should develop rules to more formally lay out the rules for tiered copayments. If there are no limits on the way that tiers can operate, there is great potential here for massive confusion. If tiers can vary based on a drug being preferred versus non-preferred and also between whether the pharmacy is preferred, mail order, or non-preferred, there may be too many variables for enrollees to comprehend. Such confusion will deter beneficiaries and SPAPs from appealing the high cost tiered products.

The Department recommends that CMS work with NCPDP to establish a standard claims processing field that all payors and pharmacies would be required to use for purposes of communicating which tier is applied. This information can then be shared at the point of services with the beneficiary, as well as on written explanations of benefits (EOBs).

423.578 (C)(2) Untimely exceptions decisions
If an exception decision on a formulary deletion case is not made in 14 days, then the PDP must cover a 1-month supply. If the PDP still fails to act, then a continued supply must be covered until the PDP makes a decision. Even with this continued supply, the beneficiary will have been 14 days without coverage. No similar provision appears to be available for enrollees when a beneficiary is denied access to a drug due to a closed formulary. Yet such an enrollee has exactly the same access problems as those described in the first example. This is particularly worrisome for low-income beneficiaries who are unable to purchase prescription drugs due to lack of income.

The Department recommends that dual eligibles and other low-income beneficiaries including SPAP enrollees have access to at a minimum a 72-hour emergency supply of denied medications, if their doctor or pharmacist determines that they are necessary for their health This will give the enrollee time to file an exception request. Additionally, low-income beneficiaries should be able to access a supply of medication until the exception or appeal is resolved. As mentioned earlier, for certain types of patients gaps in coverage can be particularly dangerous and CMS should do everything in its power to avoid such gaps.

423.578 (c)(3) –Approved exceptions request
The restriction on applying a special tier for drugs approved on exceptions should be broadened to include drugs approved through redetermination, IRE, ALJ, or MAC. Additionally, a stipulation should be included that the preferred drug formulary drug copayment be the operative copayment when exceptions are approved.

423.600 – Reconsideration by an Independent Review Entity (IRE)
This section provides that if the redetermination is denied, the enrollee may submit a written request for reconsideration by the IRE. The preamble distinguishes this process from the process available for non-drug benefits, wherein a referral to the IRE is automatically made by the MA plan.

The Department suggest that this differential treatment is unwarranted. The preamble suggests that interruption in this referral is necessary so as to get information from the physician regarding medical necessity. However, in practice, drug plans require the

prescribing physician to submit their justification for denied drugs during the exception process. Therefore, this argument appears without merit.

The preamble indicates that many drug appeals will involve small monetary amounts. However, no data is provided to back such an assertion up. In many instances, the drugs are likely to be for a chronic disease and will over time add up to significant amounts of money.

The Department recommends that requests for redetermination, which are denied by the PDP, be automatically forwarded to the IRE by the PDP. The IRE should be authorized to review the cases de novo and to use its own clinical judgment. This is particularly important given the MMA's rather weak provisions with respect to conflicts of interest. CMS should not require that all requests to the IRE be in writing as this will restrict some beneficiaries' access.

423.610 –Right to an ALJ hearing

To determine whether the threshold for accessing the ALJ has been met, CMS should require that the calculation of drug costs include the costs of the drug over the period for which the drug is needed during the contract year. Thus, if the drug is a maintenance drug, then the cost might be the annual cost of the drug. To arbitrarily limit the calculation to a 30 or 60 day supply of the drug would limit beneficiaries' rights under this section.

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

The family size, income and resource definitions established in this Subpart vary significantly from those Illinois uses for its Medicaid program. Forcing the state to establish separate processes to make determinations of eligibility for low-income subsidies is a burden the Department is not in a position to afford. The Department strongly supports efforts to enable states to assist applicants to efficiently use SSA's application processes. If, however, CMS determines that states must independently determine eligibility, the Secretary must exercise the discretion established in 1860D-14(3)(E)(iv) of the Act to permit them to use the same resource methodologies as are used for Medicare cost-sharing even though this will result in variable determinations of eligibility among the states. Barring that, Subpart S should be amended to reimburse states for 100 percent of costs associated with establishing and operating eligibility determinations under the MMA.

Illinois is particularly interested in preserving the benefits of SeniorCare, our existing Pharmacy Plus waiver, for our residents. CMS is urged to modify the proposed rule to clarify that Medicaid FFP will continue to be available to states for the operation of Pharmacy Plus waivers.

423.772 - Definitions

Family Size. This definition is vague as to whether relatives of the spouse of an applicant can count toward family size. This should be made explicit.

This definition of family size will greatly complicate the actual determination of eligibility by states. This is a point that argues strongly for states to be permitted to support applicants in using or applying to SSA but not operating an independent eligibility determination process. Operating its own system will cost Illinois in both systems development and ongoing time spent in application processing – it will add further workload to already strapped eligibility workers.

There is no guidance in the rules as to how a state would determine that a relative was dependent on the applicant or spouse for half of their financial support. For example, could a state rely upon the declaration of the applicant or alternately require documentation that the dependent was claimed on the applicant's or spouse's tax return? This will be a difficult determination to document in other ways and the Department urges CMS to allow states flexibility in this area.

Full Benefit Dual Eligible Individual. Illinois interprets this definition to include persons participating in the state's Medicaid Buy-In under the provisions of the Ticket to Work and Work Incentives Improvement Act and persons eligible pursuant to the state's decision to disregard certain income through section 1902(r)(2). If this is not CMS's intention, the rule must be clarified.

This definition does not take into account the fluctuating nature of Medicaid eligibility. CMS should state clearly in the rule that a person who qualifies as a full benefit dual eligible in the month of application stays in this category for a full 12 months regardless of changes in Medicaid status. This is essential to avoiding confusion and to carry out the simplification mandate of the MMA. Current state and federal systems supporting Part B premium payments by states to SSA on behalf of individuals are not sufficiently efficient and information can lag for months. This is at best a nuisance for dual eligibles receiving Part B subsidies but it will have far more dire consequences if it causes delays in access to essential medications for persons who need Part D subsidies. The fluid nature of Medicaid eligibility is common, especially for persons who spend down to become Medicaid eligible and for persons in group care. CMS must clarify the rules to ensure that eligibility for Part D low-income subsidies will not be similarly erratic.

The rules also fail to account for the retroactive eligibility required for Medicaid. The rules must make clear that persons who were dually eligible during a retroactive period are deemed eligible for the low-income subsidy as well even if the subsidy does not become effective until the month in which they apply for it.

Notwithstanding these changes, for purposes of calculating state participation under Subpart S, only the actual periods of Medicaid eligibility should be counted toward the state's contribution to the program.

Subpart P is silent concerning how or when states must notify CMS or CMS must notify states that an individual qualifies as a full benefit dual eligible individual. Expectations for these transmissions should be made explicit.

Institutionalized Individual. Regarding institutionalized persons, the rules make no provision for persons who may move from institutional to community settings. These transitions are difficult and will be complicated by the imposition of cost sharing once a person is back at home. The rules should provide for phasing out of subsidies for persons who will lose them as a result of leaving an institution. (Many persons are eligible for Medicaid through spend down because of the high cost of institutional care. Often such persons would not be Medicaid eligible in the community.)

It would be appropriate to apply the same cost sharing requirements that are available to institutionalized individuals to those who are enrolled in Home and Community-based waivers, including the Illinois Supportive Living Program. In recent years, there has been a move to assist seniors and persons with disabilities in their desire to remain or return to their home or other community setting. This concept is embodied in the President's new Freedom Initiative. However, for those who have significant prescription drug needs, the application of copayments for prescription drugs may act as a barrier for such community living.

Resources. Defining resources for the purposes of the MMA to mean only liquid assets provides another argument in favor of CMS permitting states to support subsidy applicants through assistance to apply to SSA but not requiring states to operate independent eligibility determination processes. This definition of countable assets does not match Illinois' existing Medicaid rules and operationalizing the difference will require extensive system changes as well as unfunded additional staffing resources. Such extra work will materially degrade service to other Medicaid eligible persons.

Other Subsidy Eligible Individuals. Similarly to the dual eligible population, persons who are not dually eligible for Part D and Medicaid but who otherwise are eligible for full subsidies as well as other low-income subsidy individuals, should be made eligible for a full 12 months, regardless of change in status, or income or resources during that period.

423.774 - Eligibility determinations, redeterminations, and applications
General Comments
As noted previously, Illinois strongly urges CMS to extend flexibility to states to fulfill their obligations to make determinations of eligibility through assisting individuals to use SSA application process.

Application Requirements. The rules are vague on the timing within which individuals applying for subsidies must supply all required information. Reasonable time periods for response and notice of missing information should be specified. Also, no standards are established for the amount of time SSA or a state has to complete a determination of eligibility for subsidy.

423.780 - Premium subsidy
The structure of the premium subsidy virtually assures that in regions with larger numbers of PDPs and MA-PDs, persons receiving subsidies will have fewer choices of plans.

Sliding Scale Premium. Illinois has employed a stepped premium structure for its Medicaid Buy-In program rather than a scale based on strict percentage of income. The state's experience has been positive with regard to this approach and The Department recommend that CMS adopt it for Part D. Using a finite set of established premiums is easier to display in a table and consequently makes it easier for beneficiaries to understand what their contributions will be.

Premium Subsidy for Late Enrollment Penalty. The premium subsidy for late enrollment should by 100 percent for at least the first year of the program

Recognizing the complexity of enrolling in and applying for the Part D benefit and subsidy, CMS must acknowledge that large numbers of subsidy eligible persons will fail to apply for the benefit in a timely manner. They must not be penalized for late enrollment. Similarly, the rules must provide that persons who were initially deemed eligible for the subsidy but subsequently lose dual eligibility may not be penalized for late enrollment. These are the poorest and sickest among us and successful negotiation of the complexity of Medicaid compounded by the complexity of Part D subsidy eligibility will require resources and sophistication that CMS cannot reasonably expect them to possess. They should not be penalized for having difficult lives.

423.800 - Administration of Subsidy Program
The rules are silent concerning how quickly PDPs and MA-PDs must act to extend subsidies once notified by CMS of an enrollee's eligibility. Illinois urges CMS to set standards for such action because failure to act promptly will materially affect the health and well being of beneficiaries.

Similarly, the rules are silent as to how quickly reimbursement for prior periods of subsidy eligibility must be made by the PDPs and MA-PDs. The Department urge CMS to set explicit time limits.

Subpart S – Special Rules for States

423.904 - Eligibility determinations for low-income subsidies
CMS should state clearly that states could satisfy their obligations to make determinations and redeterminations through taking applications and submitting them on behalf of applicants to SSA. Furthermore, the rules should offer states the flexibility to take or process subsidy applications through state agencies or other entities that are not the single state Medicaid agency, so long as such other agency or entity are operating under the terms of an interagency agreement with the single state agency. For example,

in Illinois, DoA is widely regarded by seniors as the agency that serves them and DoA is currently conducting outreach and enrollment for both the state's Pharmacy Plus and SPAP. It is essential for the success of Medicare Part D in Illinois that DoA be permitted to play a key role in educating seniors, assisting them to complete applications and perhaps in making determinations of eligibility for low income subsidies.

423.904 (c) - Screening for Medicare Cost Sharing
The rules are vague as to states' obligation to screen individuals for eligibility for Medicare cost sharing when those individuals apply to SSA for low income subsidies. States have no ability to screen persons unless they apply to the states. Illinois gladly accepts responsibility to consider persons eligible for any Medicaid program when that person contacts the state for information or to apply. The rule should be clarified to assure states are not called to account for something they cannot reasonably accomplish.

Illinois anticipates increased costs due to increased enrollment in Medicare cost-sharing programs. The Department anticipates up to 20,000 new enrollees at a cost of between $10-20 million for the state. While The Department fully support enrollment of eligible Illinoisans in to these programs, the Department wishs to point out that it will put a significant financial strain on the entire Medicaid program. The Department suggests that Congress should consider providing states with either an enhanced match or full federal subsidy for this expanded enrollment.

423.904 (d) - Application Process
In instances where states do make determinations of eligibility for low-income subsidies, the rules should clearly provide state flexibility to accept all information from applicants or their representatives on the basis of the applicant's declaration of the validity of the information. That is, states should be permitted great flexibility in defining the documentation necessary for the information in the application.

423.906 - General Payment Provisions
Regular Federal Matching
As mentioned previously in our comments on Subpart P, the Department strongly supports efforts to enable states to assist applicants to efficiently use SSA's application processes. If, however, CMS determines that states must independently determine eligibility using family size, income and resource definitions established in Subpart P, CMS must amend Subpart S to reimburse states for 100 percent of costs associated with establishing and operating eligibility determinations under the MMA.

423.908, 423.910 – Phased-down State contribution ("the Clawback") to drug benefit costs assumed by Medicare
Enactment of this section of the MMA represents an alarming new way of doing business with respect to the Federal government's imposition upon states. In what the Department believes is an unprecedented move, the U.S. Congress will create a federal benefit and will require states to provide significant financing without allowing states to control in any way the program's costs. In fact, under the NPRM states are excluded as potential

PDP sponsors and yet the law requires states to pay for coverage of a large portion of the enrollees of this program.

The Congressional Budget Office estimates that states will pay $88 billion toward Part D coverage between 2006 and 2013.[11] These payments will likely be the largest single flow of funds from state to federal government in the years after program initiation. Neither the House or Senate passed versions of the MMA contained "the clawback."[12] However, "the clawback" was inserted during conference negotiations as a way of off-setting the expense of this new federal benefit. In fact, "the clawback" represents 25 percent of the offsets contained in the bill over the time period of 2006 to 2010.[13]

It may be suggested that states advocated for the transfer of responsibility for prescription drug coverage of dual eligibles to Medicare and that is true. However, states did not advocate transferring control with state retention of financial responsibility. While state contributions are phased-down in the MMA, they are far from eliminated. At full phase-down, states are still responsible for 75 percent of their share of current funding for dual eligibles. This state contribution, unlike previous proposed House of Representative's legislation, is permanent.[14]

While it is true that states contribute to the cost of certain Medicare cost-sharing programs, in those instances there is a clear benefit to states from such a contribution as Medicaid is the payor of last resort and enrolling beneficiaries in Medicare reduces states' overall health care costs throughout the Medicaid program. In contrast, Medicare beneficiaries enrollment in part D has no overall effect on Medicaid beneficiary's enrollment in Medicare generally. Furthermore, the portion of Medicare part B that the states subsidize is limited to only 25 percent of the part B cost. In the case of part D, the only entity that benefits from state contributions is the federal government.

Additionally, enrollment of dual eligibles into part D will hurt states' ability to negotiate competitive drug prices for their entire Medicaid program. Currently, 80 percent of prescribed Medicaid drugs are for enrollees over the age of 65 and persons with disabilities. Fifty two percent of Medicaid drug spending is attributable to dual eligibles nationally.[15] For states to loose such a large amount of purchase and with it the ability to negotiate better prices, without their being relieved of the responsibility of paying for the dual eligibles is to the detriment of state's fiscal health.

There are a variety of other aspects of "the clawback" that are particularly unfair to certain states, including Illinois. First "the clawback" is based on the number of fully dual eligibles that a state has. So states that have more generous coverage for dual

[11] see www.cbo.gov/showdoc.cfm?index=5668&sequence=2&from=0
[12] Health Policy Alternatives "Prescription Drug Coverage for Medicare Beneficiaries: A Side-by-Side Comparison of S.1 and H.R. 1 and the Conference Agreement (H.R.1)," November 26, 2003
[13] Kaiser Family Foundation ""The Clawback:" State Financing of Medicare Drug Coverage" by Andy Schneider, June 2004.
[14] H.R. 4954 "Medicare Modernization and Prescription Drug Act of 2002."
[15] Kaiser Family Foundation "Medicaid Prescription Drug Spending and Use," by Brian Bruen and Arunabh Ghosh, June 2004

eligibles are penalized with increased costs. Illinois expanded coverage through the Assistance to Aged, Blind and Disabled program (AABD) over the last several years. Whereas coverage was previously limited to those with incomes below 40 percent FPL, current coverage extends to those with incomes up to 100 percent FPL. Today, 87,000 Illinoisans covered under AABD have incomes above the federal minimum coverage level.

Second, "the clawback" is calculated based on a state's Per Capita Expenditures(PCE) on prescription drugs in 2003 for full dual eligibles. States that provided the most generous coverage are, therefore, again penalized. In 2002, Illinois spent $1,237 per dual eligible. This was the 8th highest level of spending per person nationally. Unlike many other states, Illinois does not limit Medicaid beneficiaries' access to prescription drugs by limiting the number of prescriptions they may have each month. Some states limit the number of prescriptions a beneficiary may fill to as few as 3 per month. However, "the clawback" does not differentiate between states that have comprehensive benefits and those that have a far more limited benefit. In fact, "the clawback" rewards states with the most limited coverage.

The Department recognizes that the points listed above require congressional action and The Department urges Congress to revisit this issue. Our first preference would be a full elimination of "the clawback." Failing such a revision, The Department would suggest that "the clawback" be revised to only count federally mandated dual eligibles and the 2003 figure be adjusted to reflect coverage levels comparable to the Medicare part D benefit.

Our third area of concern is one that CMS has authority to address under the NPRM and it relates to the applicable growth factor used to inflate PCE in 2003 to 2006. Section 103(b) of the MMA specifies that the applicable growth factor for 2004, 2005, and 2006 will be based on the most recent National Health Expenditure projections for the years involved with respect to increases in the per capita amount of prescription drug expenditures. The Department suggests that CMS consider whether the per capita increases in National Health Expenditures for Medicaid prescription drugs are in fact lower than the general per capita increases in National Health Expenditures. CMS has verbally indicated that they might be willing to consider this option. Illinois' per capita drug spending in Medicaid as a whole over the last several years has been lower than the National Health Care Expenditures Projections generally. For instance, Illinois Medicaid experienced per capita drug spending increases of 12.2 percent in FY02, 8.7 percent in FY03, 12.4 percent in FY04 and estimates an increase of 8.2 percent in FY05. These increases are below those reported or projected by the National Health Care Expenditures for prescription drugs, which were 14.3 percent in 2002, 12.3 percent in 2003, projected at 11.9 percent in 2004 and projected at 11.3 percent in 2005. So for instance $100 of prescription drug spending in Illinois Medicaid in 2003 if inflated using general National Health Care Expenditure increases for prescription drugs equals $139.9 of prescription drug spending in 2005 but using Illinois Medicaid's own growth rate equals $130.8 of prescription drug spending in 2005. States such as Illinois have engaged in aggressive cost containment achieving significant savings through negotiations with manufacturers,

while at the same time maintaining access to a wide array of prescription drugs and avoiding limiting beneficiaries number of prescriptions filled per month. As a testament to Illinois' cost containment abilities, it should be noted that supplemental rebates negotiated from manufacturers increased by 84 percent between FY03 and FY04. The Department should not be penalized for such efficiency.

Using an inflation factor that is higher than our own inflation could result in Illinois paying more for dual eligibles than he Department would if they had not been transferred for prescription drug coverage to the Medicare part D program. While the Congressional Budget Office estimates $17 billion in savings to states due to the transfer of coverage for dual eligibles, CBO admits that these savings will not be evenly distributed across all states.[16] It is possible that large states such as Illinois, which have been involved in extensive cost containment since 2003 will be significantly disadvantaged by "the Clawback" unless CMS utilizes an appropriate growth factor.

The Illinois Department of Public Aid appreciates the opportunity to comment and make recommendations. If there are any questions about these comments, please contact Dr. Anne Marie Murphy, Illinois Medicaid Director at (217)782-2570.

Sincerely,

Anne Marie Murphy, Ph.D.
Illinois Medicaid Director
Illinois Department of Public Aid
201 S. Grand
Springfield, IL 62763

[16] "Savings for individual states may not be proportional to the overall amount" A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit July 2004 found at www.cbo.gov/showdoc.cfm?index=5668&sequence=2&from=0

Submitter : Dr. William Hudson **Date & Time:** 10/04/2004 10:10:09

Organization : HealthSpring, Inc.

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Formulary and P&T Committee 423.120 (b)
The preamble proposed that the P&T committee decisions be binding. Although most P&T decisions are usually adopted by plans, most P&T Committees serve in an advisory role. This approach has worked well for most managed care organizations. HealthSpring recommends against regulatory language requiring that P&T decisions are binding as it would introduce a new and unneeded requirement.

The preamble proposed that the P&T committee be involved designing tiers and programs to encourage use of preferred drug. Certain P&T committees may be involved in this type of activity, however many P&T committee members are not familiar with benefit operations. HealthSpring recommends against regulatory requirement that P&T committees be involved with benefit operations as it could result in unintended consequences.

GENERAL PROVISIONS

Definition of Covered Part D Drug 423.100
We recognized the MMA section 1869-D (e) excludes drugs excluded from Medicaid. This list includes among other things benzodiazepines. We further understand that some of these drugs have been shown to accumulate in elderly patients. However benzodiazepines serve an important role in treatment of anxiety and sleep disorders. The shorter acting agents can be used safely in the elderly population. Exclusion will force prescribers to use less suitable alternatives. Further, the benzodiazepines are all available generically, most alternatives are branded products. A class exclusion is not in the best interest of the population. HealthSpring recommends that CMS pursue a technical correction to remove benzodiazepines from the exclusion.

Definition of Covered Part D Drug 423.100
Both statutory and regulatory intent are to exclude any drug covered under Part B. Part D is to serve as a wrap around benefit. In the case of oral immunosuppressive agents it will be difficult for pharmacies to determine the benefit coverage. Such confusion could delay or result in billing errors. HealthSpring suggests that CMS make very explicate coverage information available for the immunosuppressive agents.

Definition of Dispensing Fee 423.100
CMS has offered three proposed definitions of dispensing fee. HealthSpring proposes that CMS adopt all three definitions. Option 2 and 3 would only be applicable special situations. Adoption of a more narrow Option 1 definition would create coverage gaps in those special situations.

Pharmacy Access Standards 423.120 (a)
CMS has adopted the TRICARE access standards for the Part D benefit. In many urban markets, absolutely every pharmacy would have to be contracted to meet the standard (a pharmacy within 2 miles of 90% of beneficiaries). This access requirement may make it impossible to be competitive in certain markets. CMS has proposed exceptions to the Access requirements for American Indians and Alaskan natives. HealthSpring recommends that CMS consider other exception criteria for network access requirement.

Pharmacies providing services to Special Populations 423.120 (a)
CMS has proposed the options of (1) requiring or (2) encouraging inclusion of long- term pharmacies in the network. In certain markets, the need may not exist or suitable providers may not be available. HealthSpring recommends that CMS adopt option 2 and allow the plans the flexibility to respond to beneficiary needs and provider availability.

Contracting with Pharmacies 423.120 (a)
CMS addressed several contracting issues in the preamble including an intention to not mandate a single set of terms and conditions for participation. CMS solicited comments on use of a standard contract to guarantee any will pharmacy?s participation. HealthSpring would support CMS allowing plans to use their own standard contracts with the flexibility to offer different rates based on market factors.

Preferred and Non-preferred Pharmacies and Cost-sharing Requirements 423.120 (a)
The preamble addresses beneficiaries using preferred pharmacies may have lower cost shares. Given that certain pharmacies will contact at more favorable rates than others, HealthSpring supports this provision as it will allow the plan to encourage beneficiaries to select pharmacies that reduce their out of pocket cost.

Mail order and Extended fills 423.120 (a)
The preamble discusses allowing 90 day fills at retail and the beneficiary being responsible for the difference between the retail and mail order cost. HealthSpring supports this provision as it may drive utilization to the least costly channel. In addition, HealthSpring recommends that the retail transaction inform beneficiaries that they are paying more than would be required in mail order.

Submitter : Dr. Noel Wilkin **Date & Time:** 10/04/2004 10:10:04

Organization : The University of Mississippi

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Access to Covered Part D Drugs (Sections 423.120, 423.124)<o:p></o:p>

CMS should require PDP sponsors and MA organizations to provide a standard contract to all retail pharmacies. A non-standard contract gives the PDPs too much leverage.

Without a standard contract, PDPs will be able to negotiate extremely low rates with large chain pharmacies. The result will give the PDPs extra negotiating power with independent, community, and small chain pharmacies in contracting similar or near-similar low rates. These smaller pharmacies can not afford these extremely low margins in the manner that the larger pharmacies can. The larger pharmacies can disperse losses throughout their multitude of pharmacies and make up profits with additional front end sales due to increased customer count and re-merchandising.

Without a standard contract, PDPs will have some control over patient access to benefits. Pharmacies that contract at lower rates will achieve 'preferred' status. PDPs will persuade customers (patients) to utilize the 'preferred' pharmacies by offering some sort of incentive. Through the process, PDPs will retain a higher profit margin from 'preferred' pharmacies than 'non-preferred' pharmacies even when subtracting incentive costs. The effects are a decreased benefit for patients and a detriment to the economic stability of smaller pharmacies. Patients' access to pharmacies will be narrowed with non-standard contracts. Customers will be drawn away from smaller 'non-preferred' pharmacies and the large pharmacies will, thus, gain a competitive edge.

PDPs will be able to remain profitable with a standard provider contract.

In conclusion, we strongly suggest that CMS include in the regulation a requirement of a standard contract between PDPs and retail pharmacy providers.

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

Quality Improvement Organizations (QIO) Activities (Section 423.162)<o:p></o:p>

We commend CMS on requiring the QIOs to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those pertaining to prescription drugs.

To do this effectively, we encourage CMS to develop a mechanism to evaluate the incidence and prevalence of inappropriate drug use. Currently used mechanisms to abstract data for quality improvement initiatives are resource extensive and do not provide adequate information necessary to guide quality improvement mechanisms for prescription medications.

We encourage CMS to develop a way to analyze electronically available data to develop prescription medication measures and a system to monitor the performance on those developed measures.

To develop such a system, CMS will need to collect data from the pharmacies, MA-PD plans, and PDPs providing the Part D benefit. (We commend CMS for requiring the submission of such data and commend their decision to require the submission using the NCNPDP telecommunications format.) Linking these prescription data to other currently available CMS datasets will be critical to developing and

monitoring prescription quality measures. It is unreasonable to expect each QIO to have the capability to evaluate these prescription claims data for the purpose of improving quality. As a result, it seems appropriate for CMS to develop a system that will support the QIO efforts across the country.

Simply requiring pharmacies, MA-PD plans, and PDPs to report summary statistics will not enable CMS to link these results to health claims data warehoused at CMS.

In conclusion, to effectively develop and monitor quality measures for prescription medications, CMS will need to develop a system that allows for the linking of prescription and medical claims, analysis of performance on quality measures, and reporting of that performance at the local, QIO level.

<b
style='mso-bidi-font-weight:normal'>Medication Therapy Management Programs (Section
423.153)<o:p></o:p>
We 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.

We also appreciate CMS' recognition that pharmacists will likely be the primary providers, but experiences in Mississippi with the Medicaid reimbursement to pharmacists for diabetes care have not indicated a vast willingness to participate in these endeavors by pharmacists.

We encourage CMS to commission a study to determine the willingness of pharmacists to provide these services, the incentives necessary to stimulate the provision of this care, and if and how submitting for this reimbursement may represent a roadblock to service provision.

Pharmacists could be the ideal health care professionals to provide MTM services and determine which services each beneficiary needs, unfortunately more information is needed as to their willingness to participate.

In conclusion, to guide the development of appropriate incentives to encourage effective provision of MTM services we urge CMS to commission a study to determine the willingness of pharmacists to provide these services and to determine the most effective incentives to ensure the success of these services.

CMS-4068-P-1352

Submitter : Dr. Michael Loberg **Date & Time:** 10/04/2004 10:10:25

Organization : NitroMed, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

attached file

CMS-4068-P-1352-Attach-1.doc

October 4, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Re: CMS-4068-P; Medicare Prescription Drug Benefit Comments

Dear Administrator McClellan:

NitroMed, Inc. appreciates the opportunity to comment on the Proposed Rule for implementing the Medicare Prescription Drug Benefit. NitroMed is a pioneer in research and development of nitric oxide enhancing therapies, including a pending application for BiDil®, a product developed for use in African American patients with heart failure. NitroMed is concerned that CMS did not appropriately consider, and the Proposed Rule does not adequately address, certain aspects of the new law with regard to the special needs of minority populations within Medicare and respectfully submits the following comments.

Anti-Discrimination Provision

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides CMS with an important tool to protect Medicare beneficiaries from discrimination by Part D plans. Specifically, the MMA authorizes CMS to reject a prescription drug plan if the plan's design or benefits are "likely to substantially discourage enrollment by certain Part D eligible individuals."[1]

This provision vests CMS with authority to conduct a comprehensive review of plans for potentially discriminatory designs and reject those plans that do not pass muster. Further, the language of this anti-discrimination provision is notably broad in apparent recognition that design and benefits of plans may discriminate against beneficiaries in numerous ways.

Despite the breadth of the anti-discrimination provision of the MMA, the proposed rule implementing Part D indicates that CMS may apply the language narrowly. The preamble language to the proposed rule interprets the anti-discrimination provision to mean that CMS must examine whether a plan discourages beneficiary enrollment "on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic

[1] Social Security Act (SSA) § 1860D-11(e)(2)(D)(i).

information, evidence of insurability, and disability."[2] This will include reviewing a plan's benefit design, such as initial coverage limit, tiered cost-sharing, formulary categories and classes, and the particular drugs included on the formulary in each category, as well as any discriminatory use of prior authorization or other coverage restrictions.[3]

This interpretation of the anti-discrimination provision is exceedingly narrow, because it would permit plans to discriminate against certain groups of Part D enrollees, such as minorities, with particular characteristics that affect how they respond to certain medications. For instance, clinical evidence demonstrates that certain drugs may be more efficacious for minority populations. Such is the case with BiDil®, which is being investigated for its potential to reduce mortality and hospitalization for African-American heart failure patients. The opposite is also true; that is, certain drugs are less effective in minority populations, as is true for enalapril, known commercially as Vasotec, an ACE inhibitor used in treatment of hypertension. According to the enalapril package insert, "it should be noted that in controlled clinical trials ACE inhibitors have an effect on blood pressure that is less in black patients than in non-blacks. In addition, it should be noted that black patients receiving ACE inhibitors have been reported to have a higher incidence of angioedema compared to non-blacks."

Under CMS's interpretation of the anti-discrimination provision, a formulary could discourage enrollment by minorities by excluding a drug that is particularly efficacious for minority enrollees and still be approved by CMS because the formulary would not be discouraging enrollment on the basis of "health status." Accordingly, NitroMed recommends that CMS give the anti-discrimination provision its intended, broad meaning and ensure that all beneficiaries have access to the most efficacious medications available. To that end, when CMS reviews a plan's formulary and benefits design—including utilization management tools such as step therapy, prior authorization, and tiered cost-sharing in their formularies—CMS also should review the extent to which the plan might discourage enrollment of minorities by excluding drugs that are especially efficacious for them or by making such drugs more costly than the less effective alternatives.

Summary

The African American community experiences a disproportionate morbidity and mortality burden associated with cardiovascular disease, including heart failure, relative to the general population. As such, CMS must protect against inequities in patient care in part by ensuring the availability of drugs with demonstrated safety and efficacy in the black population.

NitroMed respectfully requests that CMS review the discriminatory effects possible under the Proposed Rule interpretation of the anti-discrimination provision contained in the MMA, and accordingly include differential racial and ethnic medication

[2] 69 Fed. Reg. at 46,680.
[3] *Id.*

response as prohibited bases of discouraging enrollment in Medicare Part D plans. This is consistent with the congressional intent that all Medicare beneficiaries receive access to effective medications, as well as sound clinical medicine.

Respectfully submitted,

/s/

Michael D. Loberg
President and CEO

CMS-4068-P-1353

Submitter : Dr. Winston Price **Date & Time:** 10/04/2004 10:10:53

Organization : National Medical Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

US DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES

COMMENTS ON PROPOSED REGULATIONS
FILE CODE (CMS-4068-P

Overaching Concerns

The National Medical Association (NMA) 'The Conscience of American Medicine is the nation's oldest membership organization for African American physicians, representing the interests of over 30,000 doctors and the patients they serve. Many of our patients are Medicare beneficiaries, and many of them are also 'dual eligibles,' which makes it imperative in our minds that we comment on a few orarching concers about the proposed implementation regulations for the Medicare Modernization Act (MMA), within the specified public comment period. Our comments at this time are both general and specific and we certainly will comment further as opportunities present.

Another Round of Comments

Due to the sheer volume of the proposed regulations, the NMA is convinced that the opportunity for further comment needs to be made available. Unintended consequences arising from the implementation of the final regulations is a major concern of consumers and as providers who serve the most vulnerable consumers we feel obligated to raise an alarm. We therefore propse that another round of comment be made available before the MMA prescription drug benefit becomes fully operational in January 2006.

Simplification

The complexity of these regulations will present a challenge to America's seniors, who may not have the means of determining which components of MMA will be to their benefit. We are aware of CMS' outreach efforts in this regard, but given the fact that many of the seniors we serve are 'dual eligibles,' and given the substantial health literacy barriers in this population, full access to and utilization of MMA's benefits may not be realized by the seniors the regulations are intended to serve. One of the more implications of this reality is the potentially adverse impact the regulations could have on enrollment in general, and the enrollment of the most vulnerable of seniors in particular, such as those with disabilities, or those with chronic mental illness.

CMS-4068-P-1353-Attach-1.txt

CMS-4068-P-1353-Attach-2.txt

Formularies

The primary focus of the NMA with regard to the Draft Model Guidelines and the proposed regulations is to ensure that Medicare beneficiaries, and in particular those of African descent have access to medicines they need to treat and cure their disease and to maintain their health and quality of life. We are specifically concerned that the special needs and requirements of the African American Medicare community are not currently reflected in the guidelines and ask that these needs are recognized and successfully addressed.

As is well documented, elderly African Americans are at a significant greater risk for hypertension, heart disease, and diabetes. In fact, a new report from the American Heart Association notes that the prevalence of high blood pressure in American Americans in the United States is among the highest in the world. Compared with Caucasians in the United States, African Americans develop high blood pressure earlier in life and their average blood pressures are much higher. As a result, compared to Caucasians, African Americans experience a greater rate of nonfatal stroke (1.3), fatal stroke (1.8), death due to heart disease (1.5) and end-stage kidney disease (4.2). (*Fifth and Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure).* The rationale for lowering blood pressure to a specified goal is to protect target organs from hypertension-related damage and to reduce cardiovascular morbidity and mortality. Given the increased prevalence of co-morbidities, this patient population requires that physicians and patients have access to all available medications and therapies that have demonstrated benefit in treating these conditions.

With regard to cardiovascular medications, the current Draft Model Guidelines could limit access to the full range of high blood pressure medicines that have demonstrated positive health outcomes among the African American Medicare community. Currently, the guidelines fail to provide proper classification for whole classes of drugs, such as angiotensin II receptor blockers (ARBs), angiotensin converting enzyme inhibitors (ACEs), aldosterone antagonists (AAs), beta blockers, or calcium channel blockers.

Specifically, the different mechanisms of action of ACEs and ARBs offer physicians important choices in prescribing medications that best meet the needs of their individual patients. That flexibility is extremely important for elderly patients, whose response to medications vary considerably, either because of their frailty, other illnesses, multiple medications, or as sometimes is the case, because of their ethnic heritage.

Additionally, there is no consideration given in the current Draft Model Guidelines given to fixed-dose combination therapies, which have also proven effective in managing hypertension. It has been well documented that, as monotherapy or in the absence of a diuretic or beta blocker, ACEs and ARBs do not lower blood pressure to the same extent in African American patients that they do in white patients with hypertension. To support the use of fixed-combination therapies, a *Consensus Statement of the Hypertension in African Americans Working Group of the International Society on Hypertension in Blacks* published in the *Archives of Internal Medicine of March 2003*

concluded that to reach appropriate blood pressure goals, most individuals will likely require combination antihypertensive therapy. In fact, large randomized trials among African Americans have demonstrated that 2 to 4 antihypertensive agents are required to achieve DBP and SBP goals in adults with uncomplicated hypertension. Clinical trial data also show that patients with diabetes or renal disease require from of 2.6 to 4.3 different antihypertensive medications to achieve a satisfactory blood pressure goal. Furthermore, fixed-dose combination therapy simplifies treatment and has been shown to improve compliance among African American patients. Thus, it is imperative that proper classification of these medicines is established in the guidelines to accommodate appropriate combinations of drug therapy that ensure access.

Turning our attention to diabetes medications, we believe that the current draft guidelines need to assure that formularies provide access to all forms of insulin—Rapid, Short, Intermediate, and Long—to qualify for safe harbor consideration. Each of these different types of insulin is of particular benefit in helping different patients achieve their blood-sugar goals and are essential for tailoring therapy regimens to meet those individual patients' needs. Currently these four different forms of insulin are listed at the level of Recommended Subdivision in the Therapeutic Category Blood Glucose Regulating Agents, which could result in limited coverage or even exclusion of one or more of these insulin forms should the Model Guidelines go forward unchanged.

Similarly, within the Therapeutic Category Blood Glucose Regulating Agents, the various classes of oral hypoglycemic agents—Alpha Glucosidase Inhibitors, Meglitinides, Biguanides, Sulfonlyureas, and Thiazolidinediones—are designated as Recommended Subdivisions. Each of these classes of drugs has a distinct mechanism of action, which provides different therapeutic applications, side effects, and tolerability. As such, they are all essential tools in designing and providing the most effective and appropriate therapies for individual patients. As currently crafted, the Draft Model Guidelines could result in one or more of these classes of drugs being omitted, even from formularies that are deemed in compliance with safe harbor provisions.

Additionally, given the prevalence of institutional barriers that limit African American's access to quality health care, management of these diseases in African American patients is extremely difficult and complex. The current guidelines would impose restrictive formularies on individuals already disadvantaged by low-income status or disability, the "dual eligibles" whose current ACEIs, ARBs, and AAs or antihypoclycemics are provided by Medicaid but may not be when they are switched over to Medicare. Dual eligibles should be ensured continuity of care either through being granted access to open formularies or through the provision of continuous coverage of a drug that is part of a prescribed therapy until such prescribed therapy is no longer medically necessary for any covered person under such policy.

Not having these vital medicines available on their formularies, African American Medicare beneficiaries' only recourse to obtain their needed medications would be through an appeal to the Centers for Medicare and Medicaid Services, a process that would be costly, time-consuming, and particularly burdensome to non-native English

speakers of African decent or individuals whose culture and customs dissuade confrontation or conflict with governmental authority. At the very least, relying on the appeals process to ensure access to needed medications would present a substantial drain on valuable time and resources at a number of points along the bureaucratic path.

Finally, we recommend that African American physicians and patient advocacy group representatives are well represented on the Plans P&T committees to ensure that African American Medicare beneficiaries' special needs are met within the formulary. As stated earlier, this is a group of the Medicare population that has special health requirements and lack of representation may lead to negative health outcomes.

A comprehensive formulary that includes full ranges of medications will ensure that African Americans will have access to these medicines and will not have to undergo a complicated appeals process that could lead to poor patient compliance of needed medicines and negative health outcomes. As physicians, we are adamant that our patients receive the best possible care, as defined by current best practices, rather than the least costly alternatives.

Transition from Drug Card to Drug Plans

The transition from discount cards to the premium based drug benefits will be a potentially hazardous process for beneficiaries at this time next year. The NMA believes that CMS' outreach efforts in ensuring that beneficiaries understand the differences will be critical to their utilization of the benefits. We foresee a serious impact for continuity and quality of care if this process is not carefully navigated. Explicit information on this transition process should be made available to beneficiaries and providers in multiple formats, and this intent should be clearly specified under the Rule. It would probably be most efficient if these reminders were issued more than once, to ensure that all relevant parties understand the parameters of coverage under a given plan.

Access to Drugs

As physicians seeking to provide the highest quality of care for our patients, we are particularly concerned about access issues. One key access issue, in our view, is how far seniors will have to travel before they find a pharmacy that fits the pharmaceutical profile defined by their particular drug plan. Manufacturers and plan administrators should be required by the Final rule to ensure that seniors are not unnecessarily inconvenienced when they need to fill prescriptions, simply because their local pharmacy cannot accommodate their particular drug card or drug plan. This concern is particularly germane in minority and rural communities, where disparities in health care by race and ethnicity have already reached crisis proportions.

Conclusion

We are hopeful that this implementation phase of MMA is as trouble free as can be expected, and we look forward to the opportunity of collaborating with CMS in the coming months. We thank the Agency and the Department for the openness demonstrated in pursuing this process, specifically we applaud the Administrator and the Secretary for their leadership in moving this process forward.

Submitter : Lee Olson **Date & Time:** 10/04/2004 10:10:19

Organization : Southcentral Foundation

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4068-P-1355

Submitter : Mr. Carmen Catizone **Date & Time:** 10/04/2004 10:10:49

Organization : National Association of Boards of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

The National Association of Boards of Pharmacy is submitting the following information (see 4 attachments)in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the proposed regulations implementing Title I of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). Our response is relevant to pharmacists' provision of services within Medication Therapy Management Programs (MTMPs) and its impact on the public safety and state regulation of the practice of pharmacy.

CMS-4068-P-1356

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

Organization : First Health Services Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

comments attached

CMS-4068-P-1357

Submitter : **Date & Time:** 10/04/2004 10:10:43

Organization :

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the National Association of State Retirement Administrators (NASRA), the National Conference of State Legislatures (NCSL), the National Association of Counties (NACo) the Government Finance Officers Association (GFOA), the National Association of Auditors Comptrollers and Treasurers (NASACT), the National Conference on Public Employee Retirement Systems (NCPERS), and the International Personnel Management Association for Human Resources (IPMA-HR), we submit these comments in response to proposed regulations implementing the Medicare Part D program enacted pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). CMS specifically requested comments from plan sponsors of state and local government group health plans that would be prospective applicants for the retiree drug subsidy available under the MMA. Our national organizations collectively represent state and local governments and their public retirement systems, which provide retiree health care coverage to millions of public employees, retirees, and their beneficiaries.

Public Sector Retiree Plans are an Integral Component of the National Health Care System
Benefits, including retiree health care, continue to be an important factor in the attraction and retention of employees in the public sector. Public sector employees, in many cases, choose the better and more secure benefits typically associated with public sector employment in lieu of the higher compensation that traditionally characterizes the private sector. A recent report issued by AARP found that state and local governments continue to offer their retirees health coverage at a higher rate than any other industry. States alone purchase health care for more than four million employees and retirees, and millions more dependents, according to the JSI Research and Training Institute. These public retiree health care programs are an integral component of our nation?s system of health care insurance for non-working seniors and should receive strong consideration by CMS when finalizing the regulations implementing the new Medicare Part D Program.

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

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

Public Group Health Plans Entitled to MMA Benefits
The proposed regulations recognize two essential facts about governmental plans, which should also be reflected in the final rule. First, governmental group health plans are entitled to t

CMS-4068-P-1357-Attach-1.doc

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

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

Plan Sponsor Definition Should Defer to State and Local Law

The MMA provides that the plan sponsor shall receive the retiree drug subsidy. CMS should not define "plan sponsor" for purposes of the entity that receives the subsidy, but should allow state and local governmental plans to define the sponsor in accordance with applicable state or local law. The proposed rule references the ERISA definition of "plan sponsor" at ERISA Section 3(16). State and local governmental group health plans are excepted from ERISA. Consequently, the ERISA definition of plan sponsor, while a reference point, is not necessarily applicable for state and local governmental health plans.

Governmental group health plans may be established in a variety of methods. In some cases, governmental plans are separate legal entities from the state government. They may have boards of trustees that are responsible for the funding and management of the plan. In other cases, plans may be more closely managed by the state legislature or local government, which sets benefits, eligibility rules, and financing. State and local governmental plans should be free to determine who is the plan sponsor based on applicable state or local law.

Most state and local governmental plans are familiar with the process of determining which entity is the plan sponsor. In particular, state and local plans had to face this issue when implementing the privacy rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Placing guidelines defining "plan sponsor" in the final regulation could impact both state and local law and the interpretation of these laws that was made during the HIPAA implementation process. Consequently, we request that CMS refrain from defining the "plan sponsor" for purposes of state and local governmental plans or, in the alternative if a definition is necessary, simply refer to the "plan sponsor" as defined under applicable state or local law and regulation.

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

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

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

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

Strong Consideration Should be Given to Public Sector Comments

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

If you have any questions or need additional information, please do not hesitate to contact our representatives:

Jeannine Markoe Raymond, NASRA, 202-624-1417, jeannine@nasra.org
Gerri Madrid Davis, NCSL, 202-624-8670, gerri.madrid@ncsl.org
Daria Daniel, NACo, 202- 942-4212, ddaniel@naco.org
Barrie Tabin Berger, GFOA, 202-393-8020, btberger@gfoa.org
Cornelia Chebinou, NASACT, 202-624-5451, cchebinou@nasact.org
Tina Ott Chiapetta, IPMA, (703) 549-7100, cchiapp@ipma-hr.org;
Hank Kim, NCPERS, (202) 624-1458, hank@ncpers.org

CMS-4068-P-1358

Submitter : **Date & Time:** **10/04/2004 10:10:53**

Organization :

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the National Association of State Retirement Administrators (NASRA), the National Conference of State Legislatures (NCSL), the National Association of Counties (NACo) the Government Finance Officers Association (GFOA), the National Association of Auditors Comptrollers and Treasurers (NASACT), the National Conference on Public Employee Retirement Systems (NCPERS), and the International Personnel Management Association for Human Resources (IPMA-HR), we submit these comments in response to proposed regulations implementing the Medicare Part D program enacted pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). CMS specifically requested comments from plan sponsors of state and local government group health plans that would be prospective applicants for the retiree drug subsidy available under the MMA. Our national organizations collectively represent state and local governments and their public retirement systems, which provide retiree health care coverage to millions of public employees, retirees, and their beneficiaries.

CMS-4068-P-1358-Attach-1.doc

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Cornelia Chebinou, NASACT, 202-624-5451, cchebinou@nasact.org
Tina Ott Chiapetta, IPMA, (703) 549-7100, cchiapp@ipma-hr.org;
Hank Kim, NCPERS, (202) 624-1458, hank@ncpers.org

CMS-4068-P-1359

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

Organization :

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

Allowing plans to charge higher prices for an extended supply of medication from a community pharmacy than a mail service pharmacy defeats the purpose of receiving an extended supply of medication from a community pharmacy. A patient should not have to choose on where to get his or her prescription medications based on cost, but rather on the quality of service he or she receives from the pharmacy.

CMS-4068-P-1360

Submitter : Ms. Beth Powers **Date & Time:** 10/04/2004 10:10:21

Organization : Tarzana Treatment Centers, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Dear Friends -

My name is Beth Powers, I live in Pasadena, California and am writing as an individual, although I am currently employed as a program coordinator for Tarzana Treatment Centers, Inc. in the San Fernando Valley.

I am deeply concerned regarding changes suggested to the current HIV/AIDS patients' Medicaid drug coverage. I work with post-incarcerated, dual-diagnosis HIV-positive clients, and see them struggle to make ends meet, take their medications, and strive to be sober and healthy. It's a hard life; many of them have been addicts since they were pre-adolescents, and have been in and out of incarceration since childhood. With a record and health problems, it's hard to find a job. Most don't have partners nor family to fall back on. How are they going to afford their medications, if they become restricted on Medicare? Besides the cost in humanity, is it really cost-effective to deny them coverage of their drugs, then have them go to emergency services and clinics more often? Hospice care is not cheap! Please take the humane, long-term cost approach towards these new drug rules, and address these concerns:

-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 your time and consideration.
Sincerely,
Beth Powers

Submitter : Mr. David Schulke **Date & Time:** 10/04/2004 11:10:58

Organization : American Health Quality Association

Category : Association

Issue Areas/Comments

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Recommendation: CMS should consider using the QIOs to perform expedited independent external appeals related to the drug benefit.

If the plan regions are ultimately mostly confined to individual states, then it will be important for the external appeal entities to have a good understanding of the formularies in use by the plans in the regions. The formularies may vary a fair amount across the regions in response to competition among the plans within the individual regions and the makeup of the beneficiary population. This argues in favor of a contractor with an in-depth knowledge of the plans and the physician practice norms in the region.

CMS-4068-P-1362

Submitter : Ms. Gina Upchurch **Date & Time:** 10/04/2004 11:10:01

Organization : Senior PHARMAssist

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Can TrOOP ("true" out of pocket) expenditures include their "true" medication expenditures? Obviously, just because a medication is not on a particular private PDP formulary does not mean the Medicare beneficiary is not incurring the expense. If the calculation to determine what triggers catastrophic assistance from Medicare is really only what a beneficiairy pays towards "formulary medicines" - then it should be called "adjusted OOP." Consider using the "gross" amount that a beneficiairy pays out of pocket as the "true" OOP. This would not force the PDP to change their formularies - but would acknowledge the actual pressures that beneficiaries face. If this would trigger the catastrophic coverage for too many people given the ever-growing estimates of MMA expenditures, then consider other options that reward thrifty purchasing. For example, generics getting 100% "credit" towards OOP, and brand medicines 50% if - "off formulary." This is again, a means of acknowledging costs that are more "true" for beneficiaries.

Is there any effort from CMS working with the IOM, NIH, AHRQ, etc. to demonstrate the "value" of medications so that data and evidence are more of a force when prescribing? The Vioxx example perfectly illustrates the need for more "data" from FDA and others in informing presribing habits in the U.S. Private PDP formularies will likely be heavily influenced by rebates and or discount prices based on volume/market-share, etc. MTMS that focuses on formularies primarily built on costs and not evidence is not likely to create the outcomes CMS is looking for.

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

This is critical. MTMS should certainly be distinct from usual and customary counseling that is provided when dispensing a product. At Senior PHARMAssist, we have pharmacists who provide one-on-one counseling to seniors with limited incomes and we have had impressive results. This was published in the NC Medical Journal (Catellier DJ, Conlisk EA, Vitt CV, Levin KS, Menon MP, Upchurch G. A Community-Based Pharmaceutical Care Program for the Elderly Reduces Emergency Room and Hospital Use, North Carolina Medical Journal. 2000: 61 (2) ? March/April Issue):
After being enrolled in Senior PHARMAssist for one year, the percentage of participants who had used the emergency department in the past year had decreased by 31%, inpatient stays decreased by 29% and medication knowledge had increased by 30%. Our second evaluation, currently in review at the American Public Health Journal, (which will be presented at their annual meeting in November) demonstrates even more impressive results after community-based seniors have been involved in our medication management and access program for two years.

"Adherence" is more of a surrogate measure - not an outcome. Focusing on adherence primarily, could miss the forest for the trees. In order for "adherence" to be appropriate - the medication has to be prescribed correctly, dispensed correctly, and administered correctly. I hope PDP's are going to be held accountable to support efforts to encourage more prescribing that is based on standards of care that have been individualized to particular patients, qualify of life indicators, functional assessment, unnecessary health utilization, etc.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Currently, many Medicare beneficiaries with incomes primarily at or below 200% access either the drug companies' "free" patient assistance programs, private or now "public" discount cards (some help up to just over 300% FPL), or community- or state-sponsored prescription programs to help obtain their medicines. With the advent of the MMA, and in particular the Rx benefits beginning in 2006,these programs will dramatically change/decrease. In particular, seniors at 151% FPL and above will be left with few "good" options for Rx assistance - unless they can afford to purchase a Part D PDP or want to join a MA plan if one is offered in their area. Many community programs will not be able to survive given that the "poorest of the poor" appear to be taken care of and several states have already noted that they will not provide "wrap around" care for Medicare beneficiaries. Many drug manufacturers will likely consider MMA "coverage" even for folks who will struggle to pay the premiums and deductibles. Have there been any discussions with the manufacturers about continuing to help Medicare beneficiaries who cannot afford the basic Part D benefit? Will CMS work with the manufacturers to allow them to provide "product" that can "count towards" TrOOP for seniors who are able to participate in the Part D PDP during the period of non-coverage (doughnut hole)?

CMS-4068-P-1363

Submitter : Dr. Anne Marie Murphy **Date & Time:** 10/04/2004 11:10:03

Organization : Illinois Department of Public Aid

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please disregard our previous submission. We had technical difficulties using this site and inadvertently submited an older draft of our comments. These attached comments represent our correct submission.

CMS-4068-P-1363-Attach-1.doc

CMS-4068-P-1363-Attach-2.doc

Illinois Department of Public Aid

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October 4, 2004

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

Re: CMS Proposed Rule – 4068-P

Dear Dr. McClellan:

Enclosed please find comments and recommendations regarding 42 CFR Parts 403, 411, 417, and 423, the Medicare Program; Medicare Prescription Drug Benefit; Proposed Rules, which were released for comment on August 3, 2004. These comments reflect the views of the Illinois Department of Public Aid (IDPA), which is the single state Medicaid agency in Illinois and also the administrator of claims for the Illinois State Pharmaceutical Assistance Program, known as Circuit Breaker or Illinois Pharmaceutical Assistance Program (IPAP). These comments first lay out background and the Department's general concerns and later address the Notice of Proposed Rule Making (NPRM) section by section.

Unlike many other states, Illinois currently has a rich array of pharmaceutical assistance programs designed to help our residents with the cost of prescription drugs. Consequently, the implementation of the Medicare drug bill in a manner that in any way impinges upon Illinoisans' current ability to access affordable prescription drugs is of grave concern to the state.

Using Medicaid and the State Children's Health Insurance Program (SCHIP) combined, Illinois provides comprehensive drug coverage to approximately 1.8 million Illinoisans. Of the 1.8 million enrollees, 181,219 are dually eligible for Medicare as of 8/1/04. Children covered by the Illinois Medicaid program have no cost sharing requirements. Children covered by SCHIP have very modest cost sharing. Adults covered by Illinois Medicaid and our HIFA waiver have very modest cost sharing requirements with a $3 copayment for brand name drugs and no copayment for generics.

In addition to the comprehensive Medicaid program outlined above, seniors in Illinois whose incomes are below 200 percent of the federal poverty level (FPL) and who meet the non-financial eligibility standards for Illinois Medicaid may avail themselves of the SeniorCare program. There were, 201,585 seniors enrolled in this program as of 8/1/04. SeniorCare is an 1115 Medicaid Pharmacy Plus waiver, which provides comprehensive prescription drug coverage. Cost sharing is generally minimal with no premiums, no copayments for those whose income is below 100 percent FPL, and for those whose income is above 100 percent FPL $4 co pays for brand name drugs and $1 co pays for generics for the first $1,750 of drug spending. After $1,750 of drug spending has been reached, a senior pays a coinsurance of 20 percent in addition to the co pays. This program is significantly more generous than the program to be enacted in the MMA. The Department estimates that for those beneficiaries whose incomes are above the low-income subsidy level in the Medicare part D program, the difference is on average as follows: for an individual with $1,855 worth of drug spending, the Department estimates the average out-of-pocket costs through Senior Care is $120, whereas the out-of-pocket costs through Medicare would be $1,045; for an individual with $5,100 worth of drug spending, the Department estimates average out-of-pocket costs through SeniorCare are $988 and through Medicare would be $4,020. Therefore, the Department strongly supports CMS' interpretation of the Medicare drug law to allow for the continuation and renewal at state discretion of Pharmacy Plus waivers. In addition, the Department continues to desire to expand the Illinois SeniorCare program to those whose income is up to 250 percent FPL. The Department hopes that there will be flexibility to modify the SeniorCare program to coordinate benefits with Medicare part D when this is in the best interest of beneficiaries and the state and federal government with respect to maximizing coverage and minimizing costs. The Department also suggests that at a minimum state spending on SeniorCare count toward a beneficiary's out-of-pocket costs. The NPRM allows state spending from a State Pharmaceutical Assistance Program (SPAP) to count toward a beneficiary's out-of-pocket costs but precludes equal treatment for Medicaid waivers. This appears discriminatory and will deter SeniorCare enrollees from signing up for Medicare part D.

In addition to these federally funded programs, Illinois also operates an SPAP known as Circuit Breaker or Illinois Pharmaceutical Assistance Program (IPAP). IPAP has been in operation since 1985 and provides coverage of prescription drugs for ten specific health conditions, including heart disease, osteoporosis, and arthritis. IPAP is available to seniors and persons with disabilities whose income is below approximately 240 percent FPL. Therefore, seniors whose incomes are above the SeniorCare limit or whose immigration status precludes them from SeniorCare are eligible for this program. In

addition, persons with disabilities of any age whose income is below the limit are also eligible. Approximately 50,000 individuals are enrolled in IPAP. The Department supports the requirement that the new Medicare Prescription Drug Plans (PDPs) and Medicare Advantage drug plans (MA-PDPs) coordinate with SPAPs. Nonetheless, the Department is concerned about the section of the regulations (Section 423.464(e) 3) that allows PDPs and MA-PDPs to charge SPAPs for coordination as this could unnecessarily strain the finances of IPAP and other SPAPs. SPAP contributions and coordination of benefits enhance Part D benefit packages and such coordination should not carry a financial penalty. The Department is also concerned about CMS' interpretation of the antidiscrimination language in the law at Sec. 1860D-23(b)(2) (proposed regulations Sections 423.4 (SPAP definition (2) and 423.464(e)(1)(ii)), which would preclude the use of a preferred PDP. The Department believes this is not in the best interest of SPAP beneficiaries as it precludes offering them a specific tool that could maximize their benefits. The Department will address this issue in greater detail in our comments on specific sections.

The state of Illinois also operates a prescription drug discount card known as Rx Buying Club. This card is available to seniors and persons with disabilities. Generally, the card costs $25 but this fee is waived for IPAP enrollees and IPAP enrollees are autoenrolled in the program so as to facilitate their receiving discounts on the drugs that are not covered in IPAP. Average savings from this program are 20 percent.

To summarize current prescription drug coverage in Illinois for the 1.6 million Illinoisans enrolled in Medicare, approximately 500,000 Illinoisan have retiree health benefits with prescription drug coverage[1], 181,219 are fully dual eligible Medicaid beneficiaries, 360,000 are eligible for SeniorCare with 201,585 enrolled, 50,000 are enrolled in IPAP. Put another way, Illinois Medicare beneficiaries over the age of 65 with income less than 200 percent FPL, are currently eligible for comprehensive drug coverage through SeniorCare. Illinoisans under the age of 65 who have a disability with an income of less than 100 percent FPL, are eligible for comprehensive drug coverage through Medicaid or if their income is above 100 percent FPL but less than approximately 240 percent FPL, they are eligible for the less comprehensive IPAP program and state drug discount card. This would suggest that the group that will benefit most from enactment of the Medicare drug law will be seniors whose income is above 200 percent FPL who do not have retiree health benefits that cover prescription drugs and persons with disabilities whose incomes are above the eligibility level for Medicaid (100 percent FPL). Our concerns, therefore, are broadly trifold; given the current presence of generous state programs, the Department advocates for implementation of the new Medicare drug law in a manner that will not undermine current coverage, secondly, that Part D benefits for those who have limited current coverage be maximized, and thirdly, those who do not have current coverage receive the most generous coverage possible.

The state of Illinois under Governor Blagojevich's leadership has been improving ease of access for Illinoisans with respect to prescription drug coverage. To do this, the state has

[1] Ken Thorpe "Implications of a Medicare Prescription Drug Benefit for Retiree Health Care Coverage," November 17, 2003

created a single point of entry for SeniorCare, IPAP and RX Buying Club through the Department on Aging (DoA). The state has many years experience with beneficiaries and recognizes that many people prefer to access such coverage through the extensive Aging network. The Department hopes that CMS will recognize states' experience in this area and will allow states flexibility to create the point of entry for access, in particular the low-income subsidy, which works best for each state individually. Our interest here is in providing our residents with an entry point that works for them and that will optimize their ability to receive both the low-income assistance and other benefits for which they are eligible including the Medicare Sharing Program.

The area of greatest concern to the Illinois Medicaid program is the transition of the dual eligibles to coverage by Medicare part D. While the Department supports the concept of autoenrolling those who do not choose a plan with an opt-out mechanism, the Department is particularly concerned about a potential gap in coverage between the time that the Medicare part D goes into effect (January 1, 2006) and the time that autoenrolling would happen (May, 2006). This population does not have current experience in choosing such plans and some may find it particularly difficult to make such choices. This is particularly true for certain nursing home residents or those who have impaired cognitive function. According to MedPAC, 39 percent of dual eligible individuals suffer mental illness.[2] There are two potential solutions to this problem. Either CMS could allow for temporary Medicaid coverage until autoenrollment is effective or CMS could do autoenrollment prior to the start of the program so as to ensure that a safety net was provided to these beneficiaries who are the most vulnerable and unable to afford prescription drugs without such a safety net. The Department realizes that the Medicare law may preclude the first option. However, the Department believes that consideration should be given to modifying the law in this area in particular for the group mentioned above.

Full benefit Medicaid, SeniorCare and SCHIP enrollees currently enjoy access to all prescription drugs for which the Department of Health and Human Services (DHHS) has a rebate agreement. Illinois Medicaid coverage goes beyond the coverage mandated by federal statute, covering drugs such as smoking cessation agents, certain barbiturates and benzodiazepines, which under Sec. 1927(d)(2) of the Social Security Act could be restricted. While IDPA does employ the use of a Preferred Drug List (PDL), drugs that are not on the PDL are available to enrollees when medically necessary through the use of a prior authorization system consistent with Sec. 1927 (d)(4) and (5) of the Social Security Act.

As the Department describes in more detail in our comments on Subpart P, we are very concerned that the NPRM does not address ongoing eligibility for full subsidies for dual eligible individuals. It appears that CMS has focused its attention primarily, and we admit understandably, on program implementation. The Department urges CMS to consider that maintaining full subsidies for dual eligible persons will be critical to preserving their health.

[2] MedPAC "A Databook: Healthcare spending and the Medicare Program," June 2004

Illinois Medicaid and SCHIP provide comprehensive drug coverage at a total cost of $1.8 billion in FY04. Per capita prescription drug expenditures have been rising rapidly over the last several years in the United States. While Illinois Medicaid has also seen increases, IDPA has engaged in aggressive cost containment in order to achieve reduction in the growth of prescription drug costs. So while the per capita increase in prescription drug expenditures nationally was 14.3 percent in 2002, 12.3 percent in 2003 and is projected to be 11.9 percent in 2004 and 11.3 percent in 2005, here in Illinois Medicaid's increases were 12.2 percent in FY2002, 8.7 percent in FY2003, and are projected to be 12.4 percent in FY2004 and 8.2 percent in FY2005. The Department is particularly concerned that the "phase down state contribution" (423.908 and 423.910 of the NPRM) may not fully take into account these recent cost containment measures and so the amount charged to Illinois for the cost of dual eligibles may be inflated. In fact, while congressional intent was to phase down state contributions, usage of a growth factor that overstates cost increases in the Medicaid program may actually result in states paying more rather than less for prescription drug coverage for dual eligibles under Medicare part D compared to Medicaid. While it is true that states did seek to transfer responsibility of providing dual eligibles with prescription drug coverage to the federal Medicare program, this was not advocated with the idea of states retaining financial responsibility for such a program. The Department would suggest that the Medicare Part D law in this area is particularly unfair to states, which will no longer have any control over spending in this area and yet will be financially responsible for the costs of a fragmented and potentially less competitively priced program. The Department urges Congress to revisit this provision and further suggests that CMS utilize the most appropriate growth factor that actually is representative of Medicaid program prescription drug cost increases.

Additionally, while the Department supports enrolling those individuals eligible for Medicare cost sharing, the Department anticipates an increase of up to 20,000 new Illinois beneficiaries in the Medicare cost sharing programs and is concerned about the likelihood of Illinois Medicaid costs rising by between $10-20 million annually as a result.

The Department is concerned about the structure of the Part D law, which fragments drug coverage among many PDP sponsors. The Department knows from its own experience that successful acquisition of competitively priced prescriptions drugs requires a large purchasing pool. This is consistent with CMS' recent initiatives to promote multi-state purchasing pools. Therefore, the Department suggests that creating the largest regions possible across which PDPs may operate is likely to be in the best interest of both states and the federal government, which are financially liable for this new program. The Department also suggests that CMS consider contracting with some of the largest states as either PDP or fallback plans, due to the extensive experience that states have operating cost-effective, comprehensive drug programs and the leverage that such states have due to the large size of their purchasing pool.

While the Department understands that promoting choices for beneficiaries is also an important goal, the Department suggests that the experience with the Medicare discount

card has been instructive in the area of beneficiary choice. It is clear from that program that when individuals are confronted with a wide array of choices, it is often very difficult to compare them all and that this promotes confusion and inaction. Furthermore, there are some beneficiaries who spend time in different geographic areas, including different states, during the course of a year. The Medicare program is a national program and currently, those beneficiaries enjoy their Medicare benefits throughout the entire United States. Consideration should be given to making some Part D plans available that can be accessed in all parts of the United States. Such portable coverage is consistent with the overall Medicare national program.

Detailed comments on the sections of the proposed rules

Subpart A – General Provisions

Section 423.4 - Definitions
PDP sponsor
The NPRM limits PDP sponsors to nongovernmental entities. The Department does not believe that CMS has legal authority to so limit choice of sponsors. The MMA does not include a provision to so limit the choice of PDP sponsors.

It is curious that CMS would choose to limit PDP sponsors to nongovernmental entities, given the enormous experience that states have in providing prescription drug coverage. Private sector companies do not currently provide stand-alone prescription drug coverage as an insurance option. Instead, drug coverage is generally integrated within other insurance coverage. In contrast, the states have created stand-alone drug coverage programs both in the form of SPAPs and 1115 Pharmacy Plus waivers. The stability of the state run programs is in marked contrast to the instability of many private sector insurance products including the Medicare + Choice insurance products. The Department suggests that CMS reconsider this definition. In some areas of the United States, it may be difficult to contract with an appropriate PDP sponsor. However, a governmental entity may be willing to provide such a benefit. This is particularly true in states where a large SPAP or 1115 waiver program currently exists. There may be significant benefits to both the federal government, the state government and to beneficiaries from the utilization of a structure that has been in operation for several years and that is well known to beneficiaries.

In addition, states are required to continue to contribute to the cost of prescription drug coverage for the dual eligibles. However, states will have no control over the costs of such coverage. Furthermore, states will be giving up a certain proportion of their population and may lose some bargaining power, which will also negatively affect a state's ability to control prescription drug costs for the rest of its Medicaid program. Therefore, some states may be eager partners with the federal government to provide such coverage to Medicare enrollees, especially to the dual eligibles. This option may prove to be a much more stable and reliable option for the federal government compared to other options.

Subpart B – Eligibility and Enrollment

The Department recognizes that the task of educating Medicare beneficiaries about how to enroll in this new benefit will be enormous. The structure of the part D benefit itself is in many ways designed to be fragmented by its use of many PDPs and MA-PDPs as opposed to a uniform national program with single point of entry. This new design will be very different for beneficiaries compared to the traditional Medicare part A and B enrollment process. The Department is consequently concerned that sufficient attention be directed to outreach to the many different populations served by the Medicare program. In particular, the Department is concerned about outreach to persons with disabilities and those who reside in nursing homes or institutions for mental disease (IMDs).

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. These organizations are staffed primarily by volunteers who are already overburdened. Moreover, SHIPs are primarily focused on assisting seniors and generally do not have the capacity to address the special needs of individuals with disabilities.

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 most appropriate plan available. The conference report for the Medicare Modernization Act, 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.] States have had significant experience in enrolling individuals suffering from mental illness in to state mental health programs and their experience 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.

Additionally, experience with the Medicare discount card is clearly instructive. While many low-income individuals are eligible for transitional assistance, very few have signed up by themselves. Seventy five percent of enrollment has been via autoenrollment.[3]

The Department suggests that CMS partner with and finance 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. Here in Illinois, the Department has great experience in this

[3] Kaiser Family Foundation report "Medicare discount cards: A work in progress," July 2004 and found at www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

area. The Department has partnered with community-based organizations to enroll children and families in our KidCare and FamilyCare program. The Department has over 1100 KidCare Application agents (KCAA). IDPA provides KCAAs with $50 for every complete application they submit that is approved. Similar groups or even some of the same organizations are likely to be known and trusted by Medicare beneficiaries with disabilities.

CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (Preamble discussion of 423.48 at pages 46642-46644). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources and training. Here in Illinois, the Department provides our KCAAs with on-going training so that they are familiar and up to date on our programs.

While information on the Internet may be useful to some beneficiaries, in general such a mode of communication will not be suitable for the majority of the Medicare population. The Kaiser Family Foundation has done some surveying in this area and finds that 70 percent of those over 65 report never using the Internet. Of those who do go on line, just 2 percent have visited CMS' Medicare.gov site. In addition, use of the Internet is stratified by income. For those with incomes below $20,000 per year, only 15 percent have ever visited the Internet.[4]

The Department suggests that CMS develop very specific plans for facilitating enrollment of beneficiaries with disabilities and other particularly vulnerable populations such as those residing in institutions in each region that incorporates collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. CMS should also consider providing additional grants to SHIPs, Departments on Aging, Area Agencies on Aging, state agencies providing assistance to persons with disabilities and Medicaid agencies for the purpose of providing public education and information on this new program. In addition, in their bids, PDPs and MA-PDs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness.

423.30 - Eligibility to enroll

Consistent with the MMA at 1860D-1(a)(1)(B), the NPRM restricts Medicare Advantage enrollees to MA-PD plans. However, as pointed out in the preamble, this could under certain circumstances present CMS with a quandary with respect to low-income individuals, if the Medicare Advantage plan does not offer a plan at or below the low-income benchmark premium. This would be contrary to the clear intent expressed by

[4] Kaiser Family Foundation report "Medicare discount cards: A work in progress," July 2004 and found at www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

Congress at 1860D-14(b)(3), to avoid a situation where there are no plans available to those people qualifying for a low cost plan. The Department recommends that CMS require all MAs to offer an MA-PD at or below the low-income benchmark premium.

In addition, due to the restriction of choices for enrollees of Medicare Advantage plans, the Department suggests that CMS notify all such enrollees of such restriction and give them the opportunity to return to Medicare Fee for Service if they desire to enroll in a PDP plan.

423.34 (b) - Enrollment.
The final rule should clearly provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual. This is most appropriate for those Medicare enrollees who will find it hard to enroll by themselves.

423.34(c) – Denied Enrollment Notice Requirement.
The notice should be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

423.34(d) - Enrollment requirement for full benefit duals
As mentioned earlier, the Department supports the provision in the law to allow for autoenrollment of full benefit duals in a PDP or MA-PDP if they fail to choose a plan. However, the Department is concerned about the timing of this autoenrollment, which may leave this very vulnerable population without coverage for several months. In the absence of a law change to provide transitional Medicaid coverage, the Department suggests that CMS take the precautionary approach of pre-autoenrolling them in a plan as a fallback. Beneficiaries can then move to the plan of their choice at any time due to the availability of "special enrollment periods" for the dual eligibles under 423.36 (c) (4). However, enrollees would have the guarantee of a safety net plan under such a proposal.

In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. The Preamble suggested that states have more experience with auto-assigning beneficiaries. This may be true in states that operate mandatory managed care programs. However, in states such as Illinois this is not the case. While it is true that states have more readily available data identifying the dual eligibles in their state and they will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment, they are currently suffering significant budgetary and staffing challenges and MMA only provides a limited match for administrative costs imposed on the states by this law. Additionally, the states have no relationship with the new PDP sponsors and their only involvement for enrollment will be enrollment in the subsidy rather than enrollment with a specific PDP sponsor. CMS is in fact in the best entity to do autoenrolling because it has contractual relationships with the PDP sponsors and is funded to administer the program. Furthermore, if CMS chooses to insist on the states performing this task, then 50 different entities (states) will have to find solutions for this task. This has the potential for far more disruption. Each state has a different computer system and significant system

changes would be necessary in a relatively short time period to effectuate this autoenrollment. It is highly likely that many states would be unable to perform this function within the time period needed. Medicare is a national program and this issue is most efficiently dealt with once by the federal government.

If CMS does, however, decide to impose this new mandate on the states, the administrative match should be 100 percent and CMS should provide the states with technical staff to assist in this implementation including staff for necessary system changes.

423.36(c) - Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the provisions for involuntary disenrollment (see comments under section 423.44). CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties.

The special enrollment provisions should be clarified to ensure that dual eligibles would not be subject to a late enrollment fee if the complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

423.38 (c) - Effective dates for special enrollment periods
The Department supports the principle of determining effective dates for coverage in a manner consistent with protecting the continuity of health benefits coverage.

423.42 (e) – Maintenance of enrollment
The Department supports the principles contained in this section. CMS should develop a methodology for ensuring that no beneficiary loses coverage if a PDP is discontinued, including perhaps temporary autoenrollment into another plan until such time as a beneficiary chooses a new PDP.

Certain beneficiaries may lack the ability to address future changes due to instability or discontinuance of coverage. While they may receive assistance with initial enrollment due to the large amount of public awareness surrounding the initiation of the program, in the future when only a portion of enrollees are affected by a change, their need for assistance may go unnoticed. It is therefore, incumbent upon CMS to ensure that if there are changes in PDP sponsors, that enrolled beneficiaries do not fall through the cracks and therefore lose coverage.

423.44(b)(2)(i) - Required involuntary disenrollment by the PDP.
CMS stated that it was "particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area."

The disenrollment requirement in this section raises the issue of "snowbirds"—the large number of Medicare beneficiaries who move for large parts of the year. The churning—the enrolling and disenrolling—that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination (as described in the June, 2004 MedPAC report to Congress), the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

The Department suggests several ways that CMS can better address this issue:

- **Create certain PDP options that are available throughout the United States**.

- **Require traveler benefits policies and require plans to provide information on their traveler benefits.** Unlike Medicaid, Medicare is a completely federally funded and administered program. Medicare beneficiaries are currently able to access their benefits in all parts of the United States. Therefore, the Department believes that CMS should require as a condition of participation that plans have a system of visitor or traveler benefits. In addition to requiring traveler benefit policies, CMS should require plans to provide prospective enrollees with specific information on traveler benefits and "out-of-plan service policies." In many cases, 90-day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. Beneficiaries who are traveling and need emergency pharmaceutical services need to know how their plan will (or will not) reimburse for those services.

- **Allow PDP exceptions.** Consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement. At a minimum, beneficiaries must have a clear understanding of how a plan will serve people temporarily out of the service area.

- **Define time period.** The regulations should also clearly define the time period that a plan could consider an enrollee as "no longer reside(ing) in the PDP's service area." This should be defined to accommodate seasonal travelers who maintain a residence in the service area.

423.44(d)(2) - Disenrollment for disruptive or threatening behavior.

The Department is particularly concerned about beneficiaries who currently receive their prescription drug coverage through Medicaid. There are no provisions in the Medicaid statute to allow a state to disenroll an individual due to disruptive or threatening behavior. Therefore, dual eligible individuals could experience less protection under this section compared to their current coverage.

The NPRM allows Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44). CMS' authority to allow such disenrollment is questionable. The MMA does not include

any mention of disenrollment of beneficiaries for disruptive behavior who are enrolled in PDPs. While the MMA does under Sec 1860D-1(b)(1)(B) allow for the establishment by the Secretary of rules for enrollment for MA-PDs similar to those in effect for current MAs, this provision is limited to MA-PDs. Section 1851(g) of the Social Security Act allows Medicare + Choice plans to terminate enrollment for individuals who have engaged in disruptive behavior. However such termination allows the individual to return to traditional Medicare. MMA does not include a provision to extend such disenrollment to traditional Medicare or PDPs.

CMS' inclusion of these provisions creates 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.

Further, the NPRM does not allow a process by which a beneficiary can appeal an involuntary disenrollment due to disruptive or threatening behavior. This lack of an appeal right opens the door for abuses resulting in a PDP eliminating beneficiaries with above-average costs from its program. Further, this lack of an appeal right may result in the denial of due process.

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.

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 would appear 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.

As the provider of other health care services for dually eligible population, the Department is particularly concerned about the effect this may have on our beneficiaries who may be hospitalized due to the deterioration of their health due to the denial of drug coverage.

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. The term "threatening" is not defined. The Department is concerned about how such an undefined term might be interpreted.

Reenrollment. In the preamble, CMS asks 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. Individuals who are subject to involuntary disenrollment may have no resources to pay for their medications. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify one 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 MMA requires fallback plans be available in areas where there are not at least two private drug plans.

The continuing stigma surrounding mental illness and other cognitive impairments, which 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 minimized. 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 or dementia, 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. The Department questions 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 the Department urges 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.

Protections to include. While the Department believes that CMS lacks authority to allow for disenrollment of beneficiaries from PDPs due to disruptive behavior, if CMS insists on maintaining these provisions, 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, the Department strongly recommends 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":

- CMS is strongly encouraged to prohibit PDPs and MA-PDPs from disenrolling any low-income subsidy eligible individuals unless the beneficiary is enrolling in another PDP or MA-PDP. It is essential that PDPs and MA-PDPs be prohibited from disenrolling any dual eligible individuals unless the beneficiary is enrolling in another plan. These individuals will not have means available to purchase drugs out-of-pocket and they should never experience gaps in pharmacy coverage. Beyond the personal suffering that will result, if dual eligibles lose pharmacy benefits, it can be expected that they will become more acutely ill and require other, probably more expensive, Medicare or Medicaid covered acute care services.

- 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 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.

- Enrollees should have the opportunity to appeal such disenrollment;

- If, upon establishment of the appropriate process, an enrollee appeals this involuntary disenrollment, the disenrollment should not be effective until the appeal has been decided.

Section 423.46 - Late enrollment penalty.

The Department urges CMS to delay implementation of this section for all enrollees for at least one year. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or will not understand that they must choose a plan and enroll. This is particularly true for non-deemed low-income beneficiaries who will have to know to apply through two separate processes, one with the PDP sponsor and one for the low-income subsidy.

IDPA has observed from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them. The Department also sees from our own experience providing prescription drug coverage to Illinoisans that many people who desperately need prescription drug coverage and who are eligible for prescription drug coverage do not necessarily know how to access it. For instance, the Department estimates that close to 360,000 Illinois seniors are eligible for SeniorCare, a comprehensive drug program without a premium or deductible. Yet only approximately 200,000 are enrolled. The state has engaged in extensive outreach to make the public aware of this program, which unlike the Medicare part D benefit has a no cost for enrollment.

The Department understands CMS' concern that healthy beneficiaries will not apply and will instead wait until they need prescription drug coverage to apply. This would result in adverse selection in the program and has the potential for driving up the cost of the program. However, the Department believes that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness. The Medicare Part D program is new and confusing. The Department knows from the experience with the Medicare endorsed discount card that people delay enrollment in a drug card because they do not understand the program and find the choices overwhelming. Many Medicare

beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

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

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complexity. CMS should recognize that persons who have previously received Medicaid drug benefits may not realize the relevance of the MMA to them. It will take extra effort to assure they know that the Medicaid benefit is ending.

Omissions in this section.
Beyond that general comment, The Department have several more specific concerns regarding omissions in this section.

- **Add appeals opportunity.** There should be an opportunity for enrollees to appeal late enrollment penalties. This should be noted in this section and should be incorporated as part of the general system for appeals outlined in Subpart M.

- **Coordinate with "special enrollment periods."** Late enrollment penalties should be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties. The exemption of time during special enrollment periods from late penalties should be stated in this section.

- **Exemption for individuals involuntarily disenrolled.** Unless CMS adds special enrollment opportunities for individuals who are involuntarily disenrolled—as strongly recommended under our comments on section 423.36(c)—those who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period. At that point, they may be subject to a late penalty and increased premiums. For those disenrolled due to "disruptive behavior," this may have resulted from denial of access to needed medications. Where disenrollment was not related to failure to pay premiums, the Department suggests that the late enrollment penalty be waived.

- **Late enrollment penalties and people with disabilities**. CMS should incorporate an enrollment "grace period" for individuals with disabilities. The rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to beneficiaries with disabilities, and these beneficiaries might well require additional time to make a selection and complete the enrollment process. Therefore, CMS should incorporate a late enrollment "grace period" for this

population.

Section 423.48 - Information about Part D.
Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references the role of SHIPs in relation to this section (as well as section 423.30). As noted in our introductory comments to our discussion of Subpart B, the reference is inadequate and, in general, insufficient attention is being given to what will be the very difficult task of adequately disseminating information on this program to ensure that, at the least, those with coverage—particularly dual eligibles—do not experience a gap in coverage or late enrollment penalties.

An extensive network of local, face-to-face counseling services will be needed. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate. SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. The Department believes that the SHIPs and Area Agencies on Aging, and related local counseling services are significantly under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, is about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. The Department urges a further increase in funding for SHIP/AAA/Departments on Aging/Medicaid agencies.

Information plans must provide. This section states that "each PDP and MA-PDP plan must provide…information necessary" to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient.

Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance.

In addition, CMS needs to require plans to make information available in alternative formats for people with disabilities and in languages other than English to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. The Department suggests that CMS develop a comparative brochure that can be provided to each beneficiary so that beneficiaries can compare options. The Department realizes that a different brochure would be necessary for each region. However, without independent, unbiased

comparative information, beneficiaries are likely to be unable to make informed choices. CMS should continue to make information available upon written request and through 1-800-Medicare but the Department believes an additional annual mailing by CMS is also necessary. The Department also asks CMS to continue to work to improve information sources, as they sometimes are difficult for consumers.

Minimal information plans should be required to provide. While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on the benefit itself that potential enrollees will need in order to make a choice among plans. This minimum set of information should be specified in this section. Specifically, beneficiaries will need to understand:

- Premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay;

- The benefits structure and comparative value of the plans available to them;

- The coinsurance or copayment they will need to pay for each covered Part D drug on the formulary;

- The specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage;

- Formulary structure, the actual drugs on the formulary, and information on whether the formulary can change during the plan year and if such changes are allowed on how this will be take place;

- Participating pharmacies, mail order options, out-of-service options;

- Appeals and grievance processes;

- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans. Plans should also be required to provide this information to potential enrollees (see comments on section 423.50, below). Therefore, the Department urges CMS to specify the minimal information that plans will need to provide. As noted, guidance is insufficient.

Specifically, the Department urges CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees,

who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. The Department urges CMS to require plans to publish, as part of their marketing materials, price information. This could be provided in a manageable format.

For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish in a standardized format, and post on the Internet, their negotiated price for each of those drugs. Such a list would be easy to prepare and take only about one page in marketing materials.

Information and outreach for dual eligibles. In the Preamble, CMS states that "prior to [this] automatic enrollment process, a widespread education and information campaign (described later in this subpart at Section 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled" (Federal Register, Vol. 69, No. 148, Tuesday, August 3, 2004, Proposed Rules, page 46638). Such an education and information campaign targeted to dual eligible individuals and that does equip them to select among plans and enroll prior to automatic enrollment is critical. However, the proposed regulations may be insufficient.

In the Preamble, CMS discusses education and information materials that it will provide to beneficiaries. This discussion focuses on support through the Internet sources and the 1-800-Medicare number. Both are necessary but, as noted above, insufficient to meet the needs of the Medicare population and particularly insufficient to meet the education and information needs of dual eligibles. This is a difficult to reach population with limited Internet access and, in many cases, limited telephone access.

The Department recommends that CMS involve community-based organizations and providers who serve and work with dual eligibles in this enrollment process. In addition, CMS should devote resources to helping these organizations and providers inform dual eligibles that Medicaid drug benefits are ending, of their choices and what they need to do to sign up. These organizations can help duals find the best plan available to them and let them know that they can switch plans through the special enrollment provision in § 423.36 of the regulations if they have been automatically enrolled in a plan that is not the best for them. The Department further recommends that CMS develop brochures or guidebooks for each region, which are mailed to each beneficiary and are also made available to community-based organizations. This material should provide comparative information on the available plans in each region. This compilation of information is critical to the success of this program.

423.50 - Approval of marketing material and enrollment forms

Experience in this area in both Medicare and Medicaid is extensive and development of the marketing rules for the PDPs and MA-PDPs should be based on that experience. Most recently, Illinois has seen fraudulent marketing with respect to the Medicare drug

discount card.[5,6] The Department urges CMS to be vigilant and to identify and prohibit these problematic areas and practices as it develops final regulations.

423.50(c) - Guidelines for CMS review.
This section vaguely states benefit information that plans must provide in their marketing materials in subparts (i), (ii), and (iii). The Department urges CMS to include more specific requirements. It will be important that beneficiaries have comprehensive information on plan benefits and drug prices, since the drug co-pays, coinsurance and donut hole costs they might have to pay could be substantial. The Department recommends that CMS add to this list the requirement that plans make available the following information on benefits and benefits structure, in written format and on the Internet:

- **Information on the formulary**: What the formulary is; information on the fact that the formulary might change; notice that will be provided if there is a formulary change; and, at the least, formulary and cost-share tier information for 25 to 50 drugs frequently prescribed to Medicare beneficiaries (see section 423.48 above).

- **Information on drug prices.** A description of the "negotiated price," and a list of the negotiated price for 25 to 50 frequently prescribed drugs (again, see section 423.48 above).

- **Premium information**. Information on plan benefits and the premium (for the basic benefit and any other benefits offered). If a plan offers multiple benefits, marketing material should include a side-by-side comparison of those benefits. For each benefit offered, plans should be required to note, clearly and conspicuously whether individuals qualifying for the low-income subsidy will have to pay a premium and, if so, the amount that will have to be paid.

This information will be critical if beneficiaries are to make informed choices among plans. It should be part of standard marketing materials; potential enrollees should not have to request this basic information.

423.50 (e) - Standards for PDP marketing.

Prohibit telemarketing. Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. There have been numerous reports of telemarketing fraud under the Medicare Drug Discount Program.[7] The Part D benefit is susceptible to even more fraudulent business practices. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential

[5] "Medicare Drug Cards: Illinois accuses 2 firms of fraud" Chicago Tribune, September 19,2004
[6] "Medicare Drug Cards may trigger headaches, consumer groups warn" Chicago Tribune, March 8, 2004
[7] "Medicare Scams Prey on Seniors," Chicago Sun-Times, News Special Edition at 8, May 24, 2004

enrollee requests contact through such means in response to a direct mail or other advertisement.

Prohibit marketing of other services. In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS seems to believe that this would encourage entities such as financial services firms to participate as prescription drug plans. The Department finds such a proposal alarming. The MMA clearly lays out the purposes for which a PDP sponsor may market. The law is silent on additional purposes and The Department believes that such silence was intentional. Congress did not envision allowing PDP sponsors to use the information they receive on Medicare enrollees to market other products. PDP sponsors should be participating in this program based on their ability to provide covered benefits not on their desire to tap into this market for other non-Medicare related activities. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. This would be inadvisable for several reasons:

- Having plans offer added services would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved card"; the difficult task of comparing plans would become even more complex for potential enrollees; beneficiaries might mistakenly believe that they need to take an entire package of offered services when they sign up for the drug plan. This section prohibits marketing activities that could "mislead or confuse." Allowing plan sponsors to market added services is so apt to create situations that confuse and mislead beneficiaries that it is in direct conflict with the provisions of this section.

The Act intends the use of beneficiary information to be solely for facilitation of marketing of plans and enrollment of beneficiaries, and the Preamble notes the disclosure of this information is permissible under the HIPAA Privacy Rule. However, permitting PDP sponsors to use detailed health information to market other products to beneficiaries violates the intention of the Act. PDP sponsors that seek to market other products would be subject to the marketing restrictions of the HIPAA Privacy Rule, including being required to obtain a beneficiary's prior authorization to market those products to that beneficiary. However, there is enormous potential for marketing abuses by a PDP sponsor when the PDP sponsor attempts to obtain that prior authorization, in the same way door-to-door and telemarketing may open the door to deceptive marketing practices. In soliciting authorizations to market other products, PDP sponsors may bundle those products with plan information creating confusion about what the beneficiary is authorizing the PDP sponsor to do.

Prohibit single-contract pharmacies from marketing.
CMS asked for comment on the applicability of MMA marketing requirements for PDP marketing. The Department recommends that PDP marketing be much more severely constrained. There is the potential for pharmacies to market certain

PDPs more aggressively, regardless of whether or not that PDP is the best for the beneficiary. The Department can easily foresee this occurring if a pharmacy has a contract with only one PDP or has more favorable contract terms with a specific PDP. Providers with relationships with a PDP plan might market that plan more heavily. The Department urges CMS to consider the potential for provider and pharmacy-based marketing to steer beneficiaries into inappropriate PDPs and to make marketing requirements more limited than those for the Medicare Discount Card and also to specify marketing limits in the regulations.

At the very least, pharmacies with only one PDP contract should not be allowed to market the program; other pharmacies (those with multiple contracts) should be required to provide equal space to materials from all PDPs with which they contract.

Do not allow plans to use Medicare discount card enrollee and applicant information. The regulations should prohibit prescription drug plans from obtaining and using Medicare Drug Discount Card enrollee and applicant information, and information collected from any other card programs the company might sponsor.

It is foreseeable that many Discount Card sponsors will apply to be prescription drug plans. As Discount Card plans, these entities will have beneficiary-level information on drug use, creating the potential for prescription drug plans to use Discount Card information to target marketing to low-cost beneficiaries, either directly or through marketing firms.

Section 423.50(e)(2) prohibits drug plans from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." The regulations should:

- Specifically prohibit prescription drug plans from obtaining or using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor.

- Prohibit others from using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor to market on behalf of a prescription drug plan sponsor.

Specify whether and how the Secretary can provide information to prescription drug plans. The MMA added section 1860D-1(b)(4)(A) to the Social Security Act. This permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may

only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."[8]

The proposed rule does not contain any provision governing whether and how this information will be provided and in the Preamble, CMS seeks comments on a number of operational issues as well as on the provision in general.

The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair information practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. The Department recognizes that there may be some benefit in the Secretary's providing information to prescription drug plans if the plans send information to eligible individuals information that would actually be useful in determining which plan to select. The Department recommends the following in the disclosure of identifiable information:

- If the Secretary provides information to prescription drug plans, the information provided should be limited to the minimal amount necessary: the potential enrollee's name and address. No health or financial information should be disclosed.

- The Secretary should disclose identifiable information to prescription drug plans to facilitate marketing or enrollment only if the plan's marketing materials contain formulary and drug pricing information or are accompanied by an application form. This approach could help balance privacy concerns with the need for beneficiaries to obtain important plan information.

- The Secretary should not disclose telephone numbers. Telemarketing should be prohibited; there is no need for plans to have beneficiary phone numbers unless provided by the beneficiary.

- Beneficiaries should be given the choice of whether they want this information disclosed. The Department suggests that an opt-out approach be used to ensure that beneficiaries have the ability to limit their exposure to such marketing. Ordinarily, the Department would suggest an opt-in rather than opt-out approach. However, from our own experience with asking beneficiaries for responses, the Department realizes that many will not read the opt-in/out notice and therefore, will not make any choice. Setting the default to opting-out (ie a beneficiary is considered to have opted-out unless they affirmatively opt-in) will result in many beneficiaries not receiving information on the plans when in fact they had not chosen to opt-out, rather they had not acted at all. The opt-out notice should be clear; written with the Medicare population in mind; state what will be shared; and clearly state that even if a beneficiary elects to opt-out, they can still enroll in the benefit, they will still receive

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

information about the benefit from CMS, and they can still request information directly from plans.

423.56 - Creditable coverage
The Department supports inclusion of Medicaid coverage under Title XIX of the Act or under a waiver under section 1115 of the Act.

Given the long history of fraudulent sales of insurance products billed as meeting certain federal standards, the Department strongly supports the provision in Sec. 423.56(f) allowing an individual to apply to CMS to have coverage treated as creditable coverage for the purposes of applying 423.46 when the individual can show that they were not adequately informed that coverage was not creditable.

Subpart C – Benefits and Beneficiary Protections

423.100 - Definitions
Long Term Care Facility
Definition of "long-term care facility" to explicitly include Supportive Living Facilities, Assisted Living Facilities, ICF/MRs and ICF/DDs, the State of Illinois operates a home and community based waiver for supportive living facilities. This innovative program provides Medicaid services to individuals in an assisted living like setting. Due to federal law that precludes receipt of food stamps in a licensed facility, these facilities are certified as supportive living facilities rather than licensed as assisted living facilities so that the beneficiaries may receive nutritional support in the form of food stamps. The Department recommends that the final rule include a definition of "long-term care facility" that explicitly includes such facilities and their counterpart assisted living facilities along with inclusion of intermediate care facilities for persons with mental retardation or developmental disabilities (ICF/MRs and ICF/DDs). The Department believes that many mid to large size ICF/MRs, ICF/DDs, supportive living facilities and some assisted living facilities operate exclusive contracts with long-term care pharmacies. Other states may have other types of facilities that are similar in nature but that contract with long-term care pharmacies and so a broad definition that can encompass the widest variety of settings that utilize such long-term care pharmacies, the Department believes would be advantageous to beneficiaries.

Incurred Costs
The Department support the inclusion of payments made by SPAPs as counting toward a beneficiary's incurred costs.

A state's contribution to a Pharmacy Plus waiver authorized under an 1115 Medicaid waiver should also count toward incurred costs. It does not make sense to allow certain state contributions for drug coverage to count toward incurred costs but to exclude other state contributions. States that were in the forefront of maximizing prescription drug coverage for seniors prior to a Medicare benefit should not be penalized. Illinois raised this issue in its negotiations with CMS over its SeniorCare waiver, the first Pharmacy Plus program in the nation. This is also true of other state programs such as state

contributions to ADAP programs for people with HIV. If Pharmacy Plus waiver expenses are not included in incurred costs, then enrollees in these plans will never reach catastrophic coverage and there will be no reason for them to enroll in the Medicare part D program.

423.104(e)(2)(ii) - Establishing limits on tiered co-payments.
The MMA is a law whose goal is to provide voluntary prescription drug coverage to Medicare beneficiaries. The provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit" is counter to that goal. Allowing a plan to subject a beneficiary to 100 percent cost sharing runs counter to the concept of drug coverage. While the Department understands that describing a prescription drug as covered even when it has 100 percent cost sharing allows the cost to be counted toward the beneficiaries true out-of-pocket costs, which is advantageous to the beneficiary reaching the full catastrophic benefit, it is difficult to justify such a practice as consistent with coverage.

Section 1860D-2(b)(2)(B) of the MMA permits tiered cost sharing provided it is consistent with 1860D-2(b)(2)(A)(ii), which requires actuarial equivalence to a 25 percent coinsurance. This allows Part D plans to incentivize the use of preferred drugs within a class, when it is clinically appropriate. However, 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 and the 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.

The absence of reasonable limits on cost-sharing tiers combined with a difficult to navigate exceptions process could result in certain Medicare Part D enrollees in effect being uncovered. 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. 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. Therefore, the Department suggests that allowing such unlimited cost sharing is inconsistent with Sec.1860D-11(e)(2)(D)(i) of the MMA.

It should also be noted that this practice would be outside the mainstream of current private sector practice. In 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers.[9]

[9] *Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004

The Department recommends that the final rule 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. A limit on the highest tier of cost sharing is also necessary to ensure that coverage is meaningful. This would bring the proposed regulations into closer alignment with Sec.1860D-11(e)(2)(D)(i) of the MMA.

423.104 (h)(3)(i) – Negotiated prices – Disclosure
The NPRM states that a PDP sponsor or an MA organization offering a qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals, or in the form of lower monthly beneficiary premiums and lower covered Part D drug prices at the point of sale as specified in 423.336 (c)(1) and 423.343.(c)(1). It is in the best interest of the program to require PDP and MA-PDP sponsors to disclose ALL negotiated price concessions not those passed on to the beneficiaries and CMS in the form of lower prices. This is essential if CMS is to really address the true costs of the program and its actuarial value in the long run.

423.112 – Establishment of prescription drug plan service areas.
As mentioned earlier, it is in the best interest of the financial integrity of the Medicare part D program to create as large regions as possible, while maintaining beneficiary choices. In addition, CMS should look at contracting with certain PDPs that are available to enrollees all across the United States.

423.120 (b) 5 – Notice regarding formulary changes
The proposed time for notifying beneficiaries of changes in a formulary are too short. Many beneficiaries will not have sufficient time to make an appointment with his or her doctor so as to discuss alternative medications or to seek an exception.

The Department recommends a 90-day notification period with receipt of notification acting as a coverage determination that may then be appealed.

423. 124 (a) – Special rules for access to covered Part D drugs at out-of-network pharmacies
When a beneficiary cannot reasonably be expected to obtain drugs at an in-network pharmacy, then the out-of-network cost should be the same for the beneficiary as the in-network costs.

<u>Subpart J – Coordination Under Part D with Other Prescription Drug Coverage</u>

423.464(a) – Coordination of Benefits with Other Providers of Prescription drug coverage
The Department supports the requirement that PDP sponsors must permit SPAPs to coordinate benefits with the prescription drug plan or MA-PD plan.

423.464 (f)(3) – Imposition of fees
The Department strongly objects to the provision in the NPRM that allows PDP sponsors to charge SPAPs with coordination fees.

423.578 (a) and (b) Exceptions Process for a PDP's tiered cost-sharing structure
These sections differentiate between exceptions from tiered cost sharing and exceptions involving non-formulary drugs. The Department would suggest that in light of the current proposed rules to "apply tiered co-payments without limit" (see discussion under 423.104(e)(2)(ii)) this is a distinction without a practical difference for beneficiaries. If tiers are going to be allowed to be so high as to confer no real benefit, the criteria or threshold for approving a tiered copayment exception should be no different than for approving a non-formulary drug. In either case, the issue at stake is financial access to the drug. This is particularly true for beneficiaries of more modest means.

The Department recommends that criteria or the threshold for approving a copayment exception should be no different from that used for approving a non-formulary drug. In fact the law at Sec 1860D-4(g)(2) clearly states that "denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h)" of that section.

Subpart M—Grievances, Coverage Determinations and Appeals

As the current provider of prescription drug coverage to Medicaid enrollees including dual eligibles and the claims administrator of the Illinois SPAP program, the Department is particularly concerned about this section of the proposed regulation. The Department recognizes that the law as written is difficult to navigate. However, the Department believes that CMS has some scope to improve this section and to create a more consumer friendly system that does not rely on two separate tracks depending on whether a person personally pays for a drug and files an appeal or instead does not obtain the drug and then files an appeal.

The timeframes laid out in this section are far too long. Gaps in coverage are guaranteed under the NPRM as it stands. For certain types of patients, such gaps in coverage can be life threatening or at the very least hazardous to the enrollee's health.

Pursuant to federal Medicaid law (Section 1927(d)(5) of the Social Security Act), a 72-hour supply of medications is available to beneficiaries while they await a decision on a prior approval request. Beneficiaries are also entitled to a fair hearing and administrative review of an adverse hearing decision when a prior approval is denied.

Sections 1860D-4 (f), (g) and (h) require PDPs and MA-PDs to establish a grievance, coverage determination and reconsideration, and appeals process in accordance with Sections 1852 (f) and (g) of the Social Security Act. Section 1852 (f) and (g) of the Social Security Act are the sections that deal with grievances and coverage determination appeals in the Medicare + Choice program. So it would appear that Congress intended the existing Medicare + Choice grievance and appeals system to be used as a model for this new benefit.

Case law provides some guidance as to how the system should operate. In the case of Grijalva v. Shalala[10], the court dealt with the issue of notice for denials of coverage. The court originally found that HMOs failed to provide adequate notice of coverage denials, that the notices were at times illegible and failed to specify the reason for the denial, and failed to inform the beneficiary that he or she had the right to present additional evidence to the HMO. Further, the court found that the Secretary of DHHS was under an obligation to insure that appropriate notice was given. The court suggested that to be considered legible, notice should be at least 12-point type. The notice should state clearly the reason for denial, inform the enrollee of all appeal rights, explain hearing rights and procedures, and provide instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician. The Department recommends that greater specificity be given in the NPRM as to the requirements for grievance and appeals. Beneficiaries are in danger of being denied their rights because the system as currently described by CMS is excessively cumbersome and confusing.

423.560 - Definitions
This section defines an authorized representative as someone authorized by the enrollee to deal with appeals. Given the fact that SPAPs will likely be at risk for coverage in the absence of Medicare coverage, this definition should be modified to clearly include SPAPs in this definition.

423.562 – General Provisions
This section states that "if an enrollee has no further obligation to pay…a determination regarding these services is not subject to appeal." CMS has verbally indicated that this could prohibit SPAPs from appealing if they pay for a drug. The Department believes that such a proposal would be unfair to states and to beneficiaries.

SPAPS have the mission of assuring that their enrollees have uninterrupted access to needed medications. As the party responsible for payment, the SPAP should have the right to appeal. The enrollee who has coverage whether Medicare pays or not, will have no incentive to appeal if the SPAP is picking up the tab. Such a situation could lead PDP sponsors to deny SPAP enrollees full coverage with impunity, while SPAPs are left defenseless. If SPAPs were to change their policies so as to no longer pay until after an appeal is filed by the beneficiary, this would result in considerable delays for many low-income beneficiaries.

The Department, therefore, recommends that this language be revised to exempt payments from SPAPs from resulting in any abridgement of appeal rights.

Section 423.562 (c)(2) precludes an enrollee from challenging a denial of coverage for a drug when it is accessed from a non-network provider, except in those situations where a PDP sponsor is required to provide such coverage. This section lacks clarity and could lead to a PDP sponsor denying an enrollee their appeal rights when there is a dispute as to whether the PDP sponsor is required to provide such coverage. In the interest of

[10] Grijalva et al v. Shalala 946 F. Supp. 747 (D. Ariz. 1996)

simplifying these rules, CMS should delete this section. While doing so may increase the number of appeals, it will be easier to administer and explain to enrollees. Simplification should be a goal for CMS in this section.

423.566 – Coverage determination
Greater clarity as to what constitutes a coverage determination is needed. CMS should consider how this system will be implemented. When a pharmacist first submits an electronic claim and receives an electronic admittance advice, this should be treated as a request for coverage. If such a request is denied, it should trigger the appeals process.

Section 1860 D-4 (g)(1) states that "a PDP sponsor shall meet the requirements of paragraphs 1-3 of section 1852 (g) of the Social Security Act… in the same manner as… an MA organization." Under such a system for other non-drug benefits, the initial claim denial is the coverage determination and it results in a written notice of appeal rights. Re-determination follows. Medicare + Choice rules for plans that include drugs do not vary between drugs and non-drug benefits on this matter. Therefore, CMS' construction of an alternative system under Medicare Part D, whereby after a pharmacy submission is denied the beneficiary must request a coverage determination appears on its face to run counter to the MMA statutory language. It also exacerbates the complexity of this system.

The Department recommends that an initial claim denial at the pharmacy be considered a coverage determination and the exceptions process should be considered the redetermination.

423.568 – Standard timeframe and notice requirements for coverage determinations
This entire section is again premised on the notion that the initial submission of a claim by the pharmacy is not a coverage determination. As mentioned above, this must be remedied by CMS for this system to work for enrollees.

In the absence of remedy, when a claim is denied at a pharmacy, the PDP is not required to send a notice of such denial to the beneficiary. It is in the best interest of the enrollees to receive such notice in a timely fashion at point of sale. PDPs should be required through their contracts with participating pharmacies to provide enrollees with such notice upon initial claim denial. These notices should include the remedies available to the enrollee, including the enrollees right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or is on too high a tier.

One might argue that this is a burden on the pharmacy. However, the pharmacies and the PDP sponsors must be in close contact so as to keep up-to-date with formularies, coinsurance and calculations of an enrollee's out-of-pocket expenses.

Denials of drug claims can be just as detrimental to the health of an enrollee as other denials of benefits and can result in large out-of-pocket expenses. It does not make much sense to treat such drug claims in a manner that differs from other health services claims.

In addition to providing enrollees with notice of such a coverage determination, The Department also suggest that if the enrollee is also in a SPAP, that notice be provided to the SPAP so the SPAP can also appeal a coverage denial on behalf of the beneficiary.

423.568 (a)(1) – Timeframe for requests for drug benefits
Fourteen days is far too long for exception requests.. Normally these requests are completed in 2-3 days for commercial plans and 24 hours for Medicaid. Most drugs for Medicare enrollees will be for chronic illness, which may deteriorate if there are lapses in coverage. As the provider of medical benefits for dual eligibles, the Department is particularly concerned about lapses in coverage for this group, who often suffer from multiple chronic illnesses. For certain groups such as those with HIV/AIDs or mental illness, gaps in coverage can be particularly dangerous.

Similar to the Medicaid program, in cases of acute illness or urgency, the pharmacist should be authorized to issue a 72-hour supply of a denied medication to enable the patient time to return to their physician to discuss options.

Without this safety measure, dual eligibles will see their protections eroded with implementation of the Medicare drug law.

The Department recommends that the timeline for PDP sponsors to make a decision on a request for an exception be no more than 3 days, unless the beneficiary or physician failed to supply needed information. Dual eligibles or those covered by SPAPs or other low-income beneficiaries should be able to receive a 72-hour emergency supply of denied medications, if the pharmacist determines that they are necessary for the health of the patient.

Additionally, low-income beneficiaries who will be unable to pay out-of-pocket as a stopgap measure during an appeal, should receive a temporary supply while the appeal is being decided. Again, this would be consistent with Medicaid policy.

Finally, those who are currently on a particular medication when a formulary or other change in coverage policy occurs, should receive a 90 day supply of the drug until they can see their physician to discuss their medical options or can pursue an appeal. The NAIC model act on prescription drug benefits provides a workable template with respect to this issue.

423.568 (c) – Notice of denials
In the interest of promoting an easier to navigate system, the Department suggests that CMS eliminate the differential treatment in the NPRM for drug benefit denials versus drug payment denials. However, in the absence of such a change, both situations need denial notices for enrollees.

423.570 and 423.590 – Expediting Certain Coverage Determinations

The Department understands the concept behind differentiating between appeals where a prescription drug has not been provided versus where the beneficiary has paid for the drug and is now appealing non-payment. One could argue that in the first instance, access to health care is being denied and so urgency may be necessary but in the second instance the care has been provided and so urgency is not necessary. In reality, this may be a distinction without a difference for enrollees of modest means. In many cases, the need for the prescription drug is ongoing. In others, while the beneficiary may have paid, they may be in urgent need of reimbursement so that they can pay for rent, food or other necessities.

If one is to penalize an enrollee who pays out-of-pocket because they believe their health is at risk, then the system is promoting the prolonging of denial of care. This is not good public policy and is not in the best interest of Medicare beneficiaries.

CMS should revise these sections to eliminate the differential treatment accorded beneficiaries who pay for their prescription drugs out-of-pocket and then seek to recoup those costs through the appeals process. Neither commercial PBMs nor Medicaid make a distinction in a person's right to a speedy appeal of a prescription drug denial based upon whether they paid out-of-pocket for a stopgap supply.

423.578 and 423.584 – Exceptions Process and Expediting Certain Redeterminations
SPAPs should be entitled to act on behalf of their enrollees to pursue all levels of exceptions. Likewise an authorized representative or a prescribing physician should be able to seek a standard redetermination and any other appeal that is in the best interest of the patient. Many older patients will look to their doctor for assistance with the appeals process. It is likely that the overall system will be confusing and intimidating to many enrollees who have no current experience with managed care.

523.578 – Exceptions process
The preamble considers requiring PDP sponsors to provide "continued access" to a drug at the old copayment rate if the copayment is increased midyear. The Department supports this concept because it will deter "bait and switch" tactics by PDP sponsors. The Department does, however, support allowing pricing changes in the event a generic alternative becomes available. Generic drugs are approved by the Food and Drug Administration and are required to be fully substitutable for their brand name counterpart. The promotion of the use of generics is essential to maintain cost controls on the Medicare part D program.

The Texas insurance code (Art 21.52J) provides useful model language for this purpose: "A (PDP) shall make a prescription drug that was approved or covered for a medical condition or mental illness available to each enrollee at the contracted benefit level until the enrollee's plan renewal date, regardless of whether the prescribed drug has been removed from the (PDP's) formulary or moved to a higher copayment tier.

423.578 (a) Exceptions for tiered copayments

CMS should develop rules to more formally lay out the rules for tiered copayments. If there are no limits on the way that tiers can operate, there is great potential here for massive confusion. If tiers can vary based on a drug being preferred versus non-preferred and also between whether the pharmacy is preferred, mail order, or non-preferred, there may be too many variables for enrollees to comprehend. Such confusion will deter beneficiaries and SPAPs from appealing the high cost tiered products.

The Department recommends that CMS work with NCPDP to establish a standard claims processing field that all payors and pharmacies would be required to use for purposes of communicating which tier is applied. This information can then be shared at the point of services with the beneficiary, as well as on written explanations of benefits (EOBs).

423.578 (C)(2) Untimely exceptions decisions
If an exception decision on a formulary deletion case is not made in 14 days, then the PDP must cover a 1-month supply. If the PDP still fails to act, then a continued supply must be covered until the PDP makes a decision. Even with this continued supply, the beneficiary will have been 14 days without coverage. No similar provision appears to be available for enrollees when a beneficiary is denied access to a drug due to a closed formulary. Yet such an enrollee has exactly the same access problems as those described in the first example. This is particularly worrisome for low-income beneficiaries who are unable to purchase prescription drugs due to lack of income.

The Department recommends that dual eligibles and other low-income beneficiaries including SPAP enrollees have access to at a minimum a 72-hour emergency supply of denied medications, if their doctor or pharmacist determines that they are necessary for their health. This will give the enrollee time to file an exception request. Additionally, low-income beneficiaries should be able to access a supply of medication until the exception or appeal is resolved. As mentioned earlier, for certain types of patients gaps in coverage can be particularly dangerous and CMS should do everything in its power to avoid such gaps.

423.578 (c)(3) –Approved exceptions request
The restriction on applying a special tier for drugs approved on exceptions should be broadened to include drugs approved through redetermination, IRE, ALJ, or MAC. Additionally, a stipulation should be included that the preferred drug formulary drug copayment be the operative copayment when exceptions are approved.

423.600 – Reconsideration by an Independent Review Entity (IRE)
This section provides that if the redetermination is denied, the enrollee may submit a written request for reconsideration by the IRE. The preamble distinguishes this process from the process available for non-drug benefits, wherein a referral to the IRE is automatically made by the MA plan.

The Department suggests that this differential treatment is unwarranted. The preamble suggests that interruption in this referral is necessary so as to get information from the physician regarding medical necessity. However, in practice, drug plans require the

prescribing physician to submit their justification for denied drugs during the exception process. Therefore, this argument appears without merit.

The preamble indicates that many drug appeals will involve small monetary amounts. However, no data is provided to back such an assertion up. In many instances, the drugs are likely to be for a chronic disease and will over time add up to significant amounts of money.

The Department recommends that requests for redetermination, which are denied by the PDP, be automatically forwarded to the IRE by the PDP. The IRE should be authorized to review the cases de novo and to use its own clinical judgment. This is particularly important given the MMA's rather weak provisions with respect to conflicts of interest. CMS should not require that all requests to the IRE be in writing as this will restrict some beneficiaries' access.

423.610 –Right to an ALJ hearing

To determine whether the threshold for accessing the ALJ has been met, CMS should require that the calculation of drug costs include the costs of the drug over the period for which the drug is needed during the contract year. Thus, if the drug is a maintenance drug, then the cost might be the annual cost of the drug. To arbitrarily limit the calculation to a 30 or 60 day supply of the drug would limit beneficiaries' rights under this section.

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

The family size, income and resource definitions established in this Subpart vary significantly from those Illinois uses for its Medicaid program. Forcing the state to establish separate processes to make determinations of eligibility for low-income subsidies is a burden the Department is not in a position to afford. The Department strongly supports efforts to enable states to assist applicants to efficiently use SSA's application processes. If, however, CMS determines that states must independently determine eligibility, the Secretary must exercise the discretion established in 1860D-14(3)(E)(iv) of the Act to permit them to use the same resource methodologies as are used for Medicare cost-sharing even though this will result in variable determinations of eligibility among the states. Barring that, Subpart S should be amended to reimburse states for 100 percent of costs associated with establishing and operating eligibility determinations under the MMA.

Illinois is particularly interested in preserving the benefits of SeniorCare, our existing Pharmacy Plus waiver, for our residents. CMS is urged to modify the proposed rule to clarify that Medicaid FFP will continue to be available to states for the operation of Pharmacy Plus waivers.

423.772 - Definitions

Family Size. This definition is vague as to whether relatives of the spouse of an applicant can count toward family size. This should be made explicit.

This definition of family size will greatly complicate the actual determination of eligibility by states. This is a point that argues strongly for states to be permitted to support applicants in using or applying to SSA but not operating an independent eligibility determination process. Operating its own system will cost Illinois in both systems development and ongoing time spent in application processing – it will add further workload to already strapped eligibility workers.

There is no guidance in the rules as to how a state would determine that a relative was dependent on the applicant or spouse for half of their financial support. For example, could a state rely upon the declaration of the applicant or alternately require documentation that the dependent was claimed on the applicant's or spouse's tax return? This will be a difficult determination to document in other ways and the Department urges CMS to allow states flexibility in this area.

Full Benefit Dual Eligible Individual. Illinois interprets this definition to include persons participating in the state's Medicaid Buy-In under the provisions of the Ticket to Work and Work Incentives Improvement Act and persons eligible pursuant to the state's decision to disregard certain income through section 1902(r)(2). If this is not CMS's intention, the rule must be clarified.

This definition does not take into account the fluctuating nature of Medicaid eligibility. CMS should state clearly in the rule that a person who qualifies as a full benefit dual eligible in the month of application stays in this category for a full 12 months regardless of changes in Medicaid status. This is essential to avoiding confusion and to carry out the simplification mandate of the MMA. Current state and federal systems supporting Part B premium payments by states to SSA on behalf of individuals are not sufficiently efficient and information can lag for months. This is at best a nuisance for dual eligibles receiving Part B subsidies but it will have far more dire consequences if it causes delays in access to essential medications for persons who need Part D subsidies. The fluid nature of Medicaid eligibility is common, especially for persons who spend down to become Medicaid eligible and for persons in Group-Care. CMS must clarify the rules to ensure that eligibility for Part D low-income subsidies will not be similarly erratic.

The rules also fail to account for the retroactive eligibility required for Medicaid. The rules must make clear that persons who were dually eligible during a retroactive period are deemed eligible for the low-income subsidy as well even if the subsidy does not become effective until the month in which they apply for it.

Notwithstanding these changes, for purposes of calculating state participation under Subpart S, only the actual periods of Medicaid eligibility should be counted toward the state's contribution to the program.

Subpart P is silent concerning how or when states must notify CMS or CMS must notify states that an individual qualifies as a full benefit dual eligible individual. Expectations for these transmissions should be made explicit.

Institutionalized Individual. Regarding institutionalized persons, the rules make no provision for persons who may move from institutional to community settings. These transitions are difficult and will be complicated by the imposition of cost sharing once a person is back at home. The rules should provide for phasing out of subsidies for persons who will lose them as a result of leaving an institution. (Many persons are eligible for Medicaid through spend down because of the high cost of institutional care. Often such persons would not be Medicaid eligible in the community.)

It would be appropriate to apply the same cost sharing requirements that are available to institutionalized individuals to those who are enrolled in Home and Community-based Services waivers, including the Illinois Supportive Living Program. In recent years, there has been a move to assist seniors and persons with disabilities in their desire to remain or return to their home or other community setting. This concept is embodied in the President's new Freedom Initiative. However, for those who have significant prescription drug needs, the application of copayments for prescription drugs may act as a barrier for such community living.

Resources. Defining resources for the purposes of the MMA to mean only liquid assets provides another argument in favor of CMS permitting states to support subsidy applicants through assistance to apply to SSA but not requiring states to operate independent eligibility determination processes. This definition of countable assets does not match Illinois' existing Medicaid rules and operationalizing the difference will require extensive system changes as well as unfunded additional staffing resources. Such extra work will materially degrade service to other Medicaid eligible persons.

Other Subsidy Eligible Individuals. Similarly to the dual eligible population, persons who are not dually eligible for Part D and Medicaid but who otherwise are eligible for full subsidies as well as other low-income subsidy individuals, should be made eligible for a full 12 months, regardless of change in status, or income or resources during that period.

423.774 - Eligibility determinations, redeterminations, and applications
General Comments
As noted previously, Illinois strongly urges CMS to extend flexibility to states to fulfill their obligations to make determinations of eligibility through assisting individuals to use SSA application process.

Application Requirements. The rules are vague on the timing within which individuals applying for subsidies must supply all required information. Reasonable time periods for response and notice of missing information should be specified. Also, no standards are established for the amount of time SSA or a state has to complete a determination of eligibility for subsidy.

423.780 - Premium subsidy
The structure of the premium subsidy virtually assures that in regions with larger numbers of PDPs and MA-PDs, persons receiving subsidies will have fewer choices of plans.

Sliding Scale Premium. Illinois has employed a stepped premium structure for its Medicaid Buy-In program rather than a scale based on strict percentage of income. The state's experience has been positive with regard to this approach and The Department recommends that CMS adopt it for Part D. Using a finite set of established premiums is easier to display in a table and consequently makes it easier for beneficiaries to understand what their contributions will be.

Premium Subsidy for Late Enrollment Penalty. The premium subsidy for late enrollment should by 100 percent for at least the first year of the program

Recognizing the complexity of enrolling in and applying for the Part D benefit and subsidy, CMS must acknowledge that large numbers of subsidy eligible persons will fail to apply for the benefit in a timely manner. They must not be penalized for late enrollment. Similarly, the rules must provide that persons who were initially deemed eligible for the subsidy but subsequently lose dual eligibility may not be penalized for late enrollment. These are the poorest and sickest among us and successful negotiation of the complexity of Medicaid compounded by the complexity of Part D subsidy eligibility will require resources and sophistication that CMS cannot reasonably expect them to possess. They should not be penalized for having difficult lives.

423.800 - Administration of Subsidy Program
The rules are silent concerning how quickly PDPs and MA-PDs must act to extend subsidies once notified by CMS of an enrollee's eligibility. Illinois urges CMS to set standards for such action because failure to act promptly will materially affect the health and well being of beneficiaries.

Similarly, the rules are silent as to how quickly reimbursement for prior periods of subsidy eligibility must be made by the PDPs and MA-PDs. The Department urges CMS to set explicit time limits.

Subpart S – Special Rules for States

423.904 - Eligibility determinations for low-income subsidies
CMS should state clearly that states could satisfy their obligations to make determinations and redeterminations through taking applications and submitting them on behalf of applicants to SSA. Furthermore, the rules should offer states the flexibility to take or process subsidy applications through state agencies or other entities that are not the single state Medicaid agency, so long as such other agency or entity are operating under the terms of an interagency agreement with the single state agency. For example,

in Illinois, DoA is widely regarded by seniors as the agency that serves them and DoA is currently conducting outreach and enrollment for both the state's Pharmacy Plus and SPAP. It is essential for the success of Medicare Part D in Illinois that DoA be permitted to play a key role in educating seniors, assisting them to complete applications and perhaps in making determinations of eligibility for low income subsidies.

423.904 (c) - Screening for Medicare Cost Sharing
The rules are vague as to states' obligation to screen individuals for eligibility for Medicare cost sharing when those individuals apply to SSA for low income subsidies. States have no ability to screen persons unless they apply to the states. Illinois gladly accepts responsibility to consider persons eligible for any Medicaid program when that person contacts the state for information or to apply. The rule should be clarified to assure states are not called to account for something they cannot reasonably accomplish.

Illinois anticipates increased costs due to increased enrollment in Medicare cost-sharing programs. The Department anticipates up to 20,000 new enrollees at a cost of between $10-20 million for the state. While the Department fully supports enrollment of eligible Illinoisans in to these programs, the Department wishes to point out that it will put a significant financial strain on the entire Medicaid program. The Department suggests that Congress should consider providing states with either an enhanced match or full federal subsidy for this expanded enrollment.

423.904 (d) - Application Process
In instances where states do make determinations of eligibility for low-income subsidies, the rules should clearly provide state flexibility to accept all information from applicants or their representatives on the basis of the applicant's declaration of the validity of the information. That is, states should be permitted great flexibility in defining the documentation necessary for the information in the application.

423.906 - General Payment Provisions
Regular Federal Matching
As mentioned previously in our comments on Subpart P, the Department strongly supports efforts to enable states to assist applicants to efficiently use SSA's application processes. If, however, CMS determines that states must independently determine eligibility using family size, income and resource definitions established in Subpart P, CMS must amend Subpart S to reimburse states for 100 percent of costs associated with establishing and operating eligibility determinations under the MMA.

423.908, 423.910 – Phased-down State contribution ("the Clawback") to drug benefit costs assumed by Medicare
Enactment of this section of the MMA represents an alarming new way of doing business with respect to the Federal government's imposition upon states. In what the Department believes is an unprecedented move, the U.S. Congress will create a federal benefit and will require states to provide significant financing without allowing states to control in any way the program's costs. In fact, under the NPRM states are excluded as potential

PDP sponsors and yet the law requires states to pay for coverage of a large portion of the enrollees of this program.

The Congressional Budget Office estimates that states will pay $88 billion toward Part D coverage between 2006 and 2013.[11] These payments will likely be the largest single flow of funds from state to federal government in the years after program initiation. Neither the House or Senate passed versions of the MMA contained "the clawback."[12] However, "the clawback" was inserted during conference negotiations as a way of off-setting the expense of this new federal benefit. In fact, "the clawback" represents 25 percent of the offsets contained in the bill over the time period of 2006 to 2010.[13]

It may be suggested that states advocated for the transfer of responsibility for prescription drug coverage of dual eligibles to Medicare and that is true. However, states did not advocate transferring control with state retention of financial responsibility. While state contributions are phased-down in the MMA, they are far from eliminated. At full phase-down, states are still responsible for 75 percent of their share of current funding for dual eligibles. This state contribution, unlike previous proposed House of Representative's legislation, is permanent.[14]

While it is true that states contribute to the cost of certain Medicare cost-sharing programs, in those instances there is a clear benefit to states from such a contribution as Medicaid is the payor of last resort and enrolling beneficiaries in Medicare reduces states' overall health care costs throughout the Medicaid program. In contrast, Medicare beneficiaries enrollment in part D has no overall effect on Medicaid beneficiary's enrollment in Medicare generally. Furthermore, the portion of Medicare part B that the states subsidize is limited to only 25 percent of the part B cost. In the case of part D, the only entity that benefits from state contributions is the federal government.

Additionally, enrollment of dual eligibles into part D will hurt states' ability to negotiate competitive drug prices for their entire Medicaid program. Currently, 80 percent of prescribed Medicaid drugs are for enrollees over the age of 65 and persons with disabilities. Fifty two percent of Medicaid drug spending is attributable to dual eligibles nationally.[15] For states to loose such a large amount of purchase and with it the ability to negotiate better prices, without their being relieved of the responsibility of paying for the dual eligibles is to the detriment of state's fiscal health.

There are a variety of other aspects of "the clawback" that are particularly unfair to certain states, including Illinois. First "the clawback" is based on the number of fully dual eligibles that a state has. So states that have more generous coverage for dual

[11] see www.cbo.gov/showdoc.cfm?index=5668&sequence=2&from=0
[12] Health Policy Alternatives "Prescription Drug Coverage for Medicare Beneficiaries: A Side-by-Side Comparison of S.1 and H.R. 1 and the Conference Agreement (H.R.1)," November 26, 2003
[13] Kaiser Family Foundation ""The Clawback:" State Financing of Medicare Drug Coverage" by Andy Schneider, June 2004.
[14] H.R. 4954 "Medicare Modernization and Prescription Drug Act of 2002."
[15] Kaiser Family Foundation "Medicaid Prescription Drug Spending and Use," by Brian Bruen and Arunabh Ghosh, June 2004

eligibles are penalized with increased costs. Illinois expanded coverage through the Assistance to Aged, Blind and Disabled program (AABD) over the last several years. Whereas coverage was previously limited to those with incomes below 40 percent FPL, current coverage extends to those with incomes up to 100 percent FPL. Today, 87,000 Illinoisans covered under AABD have incomes above the federal minimum coverage level.

Second, "the clawback" is calculated based on a state's Per Capita Expenditures(PCE) on prescription drugs in 2003 for full dual eligibles. States that provided the most generous coverage are, therefore, again penalized. In 2002, Illinois spent $1,237 per dual eligible. This was the 8th highest level of spending per person nationally. Unlike many other states, Illinois does not limit Medicaid beneficiaries' access to prescription drugs by limiting the number of prescriptions they may have each month. Some states limit the number of prescriptions a beneficiary may fill to as few as 3 per month. However, "the clawback" does not differentiate between states that have comprehensive benefits and those that have a far more limited benefit. In fact, "the clawback" rewards states with the most limited coverage.

The Department recognizes that the points listed above require congressional action and The Department urges Congress to revisit this issue. Our first preference would be a full elimination of "the clawback." Failing such a revision, The Department suggests that "the clawback" be revised to only count federally mandated dual eligibles and the 2003 figure be adjusted to reflect coverage levels comparable to the Medicare part D benefit.

Our third area of concern is one that CMS has authority to address under the NPRM and it relates to the applicable growth factor used to inflate PCE in 2003 to 2006. Section 103(b) of the MMA specifies that the applicable growth factor for 2004, 2005, and 2006 will be based on the most recent National Health Expenditure projections for the years involved with respect to increases in the per capita amount of prescription drug expenditures. The Department suggests that CMS consider whether the per capita increases in National Health Expenditures for Medicaid prescription drugs are in fact lower than the general per capita increases in National Health Expenditures. CMS has verbally indicated that they might be willing to consider this option. Illinois' per capita drug spending in Medicaid as a whole over the last several years has been lower than the National Health Care Expenditures Projections generally. For instance, Illinois Medicaid experienced per capita drug spending increases of 12.2 percent in FY02, 8.7 percent in FY03, 12.4 percent in FY04 and estimates an increase of 8.2 percent in FY05. These increases are below those reported or projected by the National Health Care Expenditures for prescription drugs, which were 14.3 percent in 2002, 12.3 percent in 2003, projected at 11.9 percent in 2004 and projected at 11.3 percent in 2005. So for instance $100 of prescription drug spending in Illinois Medicaid in 2003 if inflated using general National Health Care Expenditure increases for prescription drugs equals $139.9 of prescription drug spending in 2005 but using Illinois Medicaid's own growth rate equals $130.8 of prescription drug spending in 2005. States such as Illinois have engaged in aggressive cost containment achieving significant savings through negotiations with manufacturers, while at the same time maintaining access to a wide array of prescription drugs and

avoiding limiting beneficiaries' number of prescriptions filled per month. As a testament to Illinois' cost containment abilities, it should be noted that supplemental rebates negotiated from manufacturers increased by 84 percent between FY03 and FY04. The Department should not be penalized for such efficiency.

Using an inflation factor that is higher than our own inflation could result in Illinois paying more for dual eligibles than he Department would if they had not been transferred for prescription drug coverage to the Medicare part D program. While the Congressional Budget Office estimates $17 billion in savings to states due to the transfer of coverage for dual eligibles, CBO admits that these savings will not be evenly distributed across all states.[16] It is possible that large states such as Illinois, which have been involved in extensive cost containment since 2003 will be significantly disadvantaged by "the Clawback" unless CMS utilizes an appropriate growth factor.

The Illinois Department of Public Aid appreciates the opportunity to comment and make recommendations. If there are any questions about these comments, please contact Dr. Anne Marie Murphy, Illinois Medicaid Director at (217)782-2570.

Sincerely,

Anne Marie Murphy, Ph.D.
Illinois Medicaid Director
Illinois Department of Public Aid
201 S. Grand
Springfield, IL 62763

[16] "Savings for individual states may not be proportional to the overall amount" A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit July 2004 found at www.cbo.gov/showdoc.cfm?index=5668&sequence=2&from=0

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October 4, 2004

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

Re: CMS Proposed Rule – 4068-P

Dear Dr. McClellan:

Enclosed please find comments and recommendations regarding 42 CFR Parts 403, 411, 417, and 423, the Medicare Program; Medicare Prescription Drug Benefit; Proposed Rules, which were released for comment on August 3, 2004. These comments reflect the views of the Illinois Department of Public Aid (IDPA), which is the single state Medicaid agency in Illinois and also the administrator of claims for the Illinois State Pharmaceutical Assistance Program, known as Circuit Breaker or Illinois Pharmaceutical Assistance Program (IPAP). These comments first lay out background and the Department's general concerns and later address the Notice of Proposed Rule Making (NPRM) section by section.

Unlike many other states, Illinois currently has a rich array of pharmaceutical assistance programs designed to help our residents with the cost of prescription drugs. Consequently, the implementation of the Medicare drug bill in a manner that in any way impinges upon Illinoisans' current ability to access affordable prescription drugs is of grave concern to the state.

Using Medicaid and the State Children's Health Insurance Program (SCHIP) combined, Illinois provides comprehensive drug coverage to approximately 1.8 million Illinoisans. Of the 1.8 million enrollees, 181,219 are dually eligible for Medicare as of 8/1/04. Children covered by the Illinois Medicaid program have no cost sharing requirements. Children covered by SCHIP have very modest cost sharing. Adults covered by Illinois Medicaid and our HIFA waiver have very modest cost sharing requirements with a $3 copayment for brand name drugs and no copayment for generics.

In addition to the comprehensive Medicaid program outlined above, seniors in Illinois whose incomes are below 200 percent of the federal poverty level (FPL) and who meet the non-financial eligibility standards for Illinois Medicaid may avail themselves of the SeniorCare program. There were, 201,585 seniors enrolled in this program as of 8/1/04. SeniorCare is an 1115 Medicaid Pharmacy Plus waiver, which provides comprehensive prescription drug coverage. Cost sharing is generally minimal with no premiums, no copayments for those whose income is below 100 percent FPL, and for those whose income is above 100 percent FPL $4 co pays for brand name drugs and $1 co pays for generics for the first $1,750 of drug spending. After $1,750 of drug spending has been reached, a senior pays a coinsurance of 20 percent in addition to the co pays. This program is significantly more generous than the program to be enacted in the MMA. The Department estimates that for those beneficiaries whose incomes are above the low-income subsidy level in the Medicare part D program, the difference is on average as follows: for an individual with $1,855 worth of drug spending, the Department estimates the average out-of-pocket costs through Senior Care is $120, whereas the out-of-pocket costs through Medicare would be $1,045; for an individual with $5,100 worth of drug spending, the Department estimates average out-of-pocket costs through SeniorCare are $988 and through Medicare would be $4,020. Therefore, the Department strongly supports CMS' interpretation of the Medicare drug law to allow for the continuation and renewal at state discretion of Pharmacy Plus waivers. In addition, the Department continues to desire to expand the Illinois SeniorCare program to those whose income is up to 250 percent FPL. The Department hopes that there will be flexibility to modify the SeniorCare program to coordinate benefits with Medicare part D when this is in the best interest of beneficiaries and the state and federal government with respect to maximizing coverage and minimizing costs. The Department also suggests that at a minimum state spending on SeniorCare count toward a beneficiary's out-of-pocket costs. The NPRM allows state spending from a State Pharmaceutical Assistance Program (SPAP) to count toward a beneficiary's out-of-pocket costs but precludes equal treatment for Medicaid waivers. This appears discriminatory and will deter SeniorCare enrollees from signing up for Medicare part D.

In addition to these federally funded programs, Illinois also operates an SPAP known as Circuit Breaker or Illinois Pharmaceutical Assistance Program (IPAP). IPAP has been in operation since 1985 and provides coverage of prescription drugs for ten specific health conditions, including heart disease, osteoporosis, and arthritis. IPAP is available to seniors and persons with disabilities whose income is below approximately 240 percent FPL. Therefore, seniors whose incomes are above the SeniorCare limit or whose immigration status precludes them from SeniorCare are eligible for this program. In

addition, persons with disabilities of any age whose income is below the limit are also eligible. Approximately 50,000 individuals are enrolled in IPAP. The Department supports the requirement that the new Medicare Prescription Drug Plans (PDPs) and Medicare Advantage drug plans (MA-PDPs) coordinate with SPAPs. Nonetheless, the Department is concerned about the section of the regulations (Section 423.464(e) 3) that allows PDPs and MA-PDPs to charge SPAPs for coordination as this could unnecessarily strain the finances of IPAP and other SPAPs. SPAP contributions and coordination of benefits enhance Part D benefit packages and such coordination should not carry a financial penalty. The Department is also concerned about CMS' interpretation of the antidiscrimination language in the law at Sec. 1860D-23(b)(2) (proposed regulations Sections 423.4 (SPAP definition (2) and 423.464(e)(1)(ii)), which would preclude the use of a preferred PDP. The Department believes this is not in the best interest of SPAP beneficiaries as it precludes offering them a specific tool that could maximize their benefits. The Department will address this issue in greater detail in our comments on specific sections.

The state of Illinois also operates a prescription drug discount card known as Rx Buying Club. This card is available to seniors and persons with disabilities. Generally, the card costs $25 but this fee is waived for IPAP enrollees and IPAP enrollees are autoenrolled in the program so as to facilitate their receiving discounts on the drugs that are not covered in IPAP. Average savings from this program are 20 percent.

To summarize current prescription drug coverage in Illinois for the 1.6 million Illinoisans enrolled in Medicare, approximately 500,000 Illinoisan have retiree health benefits with prescription drug coverage[1], 181,219 are fully dual eligible Medicaid beneficiaries, 360,000 are eligible for SeniorCare with 201,585 enrolled, 50,000 are enrolled in IPAP. Put another way, Illinois Medicare beneficiaries over the age of 65 with income less than 200 percent FPL, are currently eligible for comprehensive drug coverage through SeniorCare. Illinoisans under the age of 65 who have a disability with an income of less than 100 percent FPL, are eligible for comprehensive drug coverage through Medicaid or if their income is above 100 percent FPL but less than approximately 240 percent FPL, they are eligible for the less comprehensive IPAP program and state drug discount card. This would suggest that the group that will benefit most from enactment of the Medicare drug law will be seniors whose income is above 200 percent FPL who do not have retiree health benefits that cover prescription drugs and persons with disabilities whose incomes are above the eligibility level for Medicaid (100 percent FPL). Our concerns, therefore, are broadly trifold; given the current presence of generous state programs, the Department advocates for implementation of the new Medicare drug law in a manner that will not undermine current coverage, secondly, that Part D benefits for those who have limited current coverage be maximized, and thirdly, those who do not have current coverage receive the most generous coverage possible.

The state of Illinois under Governor Blagojevich's leadership has been improving ease of access for Illinoisans with respect to prescription drug coverage. To do this, the state has

[1] Ken Thorpe "Implications of a Medicare Prescription Drug Benefit for Retiree Health Care Coverage," November 17, 2003

created a single point of entry for SeniorCare, IPAP and RX Buying Club through the Department on Aging (DoA). The state has many years experience with beneficiaries and recognizes that many people prefer to access such coverage through the extensive Aging network. The Department hopes that CMS will recognize states' experience in this area and will allow states flexibility to create the point of entry for access, in particular the low-income subsidy, which works best for each state individually. Our interest here is in providing our residents with an entry point that works for them and that will optimize their ability to receive both the low-income assistance and other benefits for which they are eligible including the Medicare Sharing Program.

The area of greatest concern to the Illinois Medicaid program is the transition of the dual eligibles to coverage by Medicare part D. While the Department supports the concept of autoenrolling those who do not choose a plan with an opt-out mechanism, the Department is particularly concerned about a potential gap in coverage between the time that the Medicare part D goes into effect (January 1, 2006) and the time that autoenrolling would happen (May, 2006). This population does not have current experience in choosing such plans and some may find it particularly difficult to make such choices. This is particularly true for certain nursing home residents or those who have impaired cognitive function. According to MedPAC, 39 percent of dual eligible individuals suffer mental illness.[2] There are two potential solutions to this problem. Either CMS could allow for temporary Medicaid coverage until autoenrollment is effective or CMS could do autoenrollment prior to the start of the program so as to ensure that a safety net was provided to these beneficiaries who are the most vulnerable and unable to afford prescription drugs without such a safety net. The Department realizes that the Medicare law may preclude the first option. However, the Department believes that consideration should be given to modifying the law in this area in particular for the group mentioned above.

Full benefit Medicaid, SeniorCare and SCHIP enrollees currently enjoy access to all prescription drugs for which the Department of Health and Human Services (DHHS) has a rebate agreement. Illinois Medicaid coverage goes beyond the coverage mandated by federal statute, covering drugs such as smoking cessation agents, certain barbiturates and benzodiazepines, which under Sec. 1927(d)(2) of the Social Security Act could be restricted. While IDPA does employ the use of a Preferred Drug List (PDL), drugs that are not on the PDL are available to enrollees when medically necessary through the use of a prior authorization system consistent with Sec. 1927 (d)(4) and (5) of the Social Security Act.

As the Department describes in more detail in our comments on Subpart P, we are very concerned that the NPRM does not address ongoing eligibility for full subsidies for dual eligible individuals. It appears that CMS has focused its attention primarily, and we admit understandably, on program implementation. The Department urges CMS to consider that maintaining full subsidies for dual eligible persons will be critical to preserving their health.

[2] MedPAC "A Databook: Healthcare spending and the Medicare Program," June 2004

Illinois Medicaid and SCHIP provide comprehensive drug coverage at a total cost of $1.8 billion in FY04. Per capita prescription drug expenditures have been rising rapidly over the last several years in the United States. While Illinois Medicaid has also seen increases, IDPA has engaged in aggressive cost containment in order to achieve reduction in the growth of prescription drug costs. So while the per capita increase in prescription drug expenditures nationally was 14.3 percent in 2002, 12.3 percent in 2003 and is projected to be 11.9 percent in 2004 and 11.3 percent in 2005, here in Illinois Medicaid's increases were 12.2 percent in FY2002, 8.7 percent in FY2003, and are projected to be 12.4 percent in FY2004 and 8.2 percent in FY2005. The Department is particularly concerned that the "phase down state contribution" (423.908 and 423.910 of the NPRM) may not fully take into account these recent cost containment measures and so the amount charged to Illinois for the cost of dual eligibles may be inflated. In fact, while congressional intent was to phase down state contributions, usage of a growth factor that overstates cost increases in the Medicaid program may actually result in states paying more rather than less for prescription drug coverage for dual eligibles under Medicare part D compared to Medicaid. While it is true that states did seek to transfer responsibility of providing dual eligibles with prescription drug coverage to the federal Medicare program, this was not advocated with the idea of states retaining financial responsibility for such a program. The Department would suggest that the Medicare Part D law in this area is particularly unfair to states, which will no longer have any control over spending in this area and yet will be financially responsible for the costs of a fragmented and potentially less competitively priced program. The Department urges Congress to revisit this provision and further suggests that CMS utilize the most appropriate growth factor that actually is representative of Medicaid program prescription drug cost increases.

Additionally, while the Department supports enrolling those individuals eligible for Medicare cost sharing, the Department anticipates an increase of up to 20,000 new Illinois beneficiaries in the Medicare cost sharing programs and is concerned about the likelihood of Illinois Medicaid costs rising by between $10-20 million annually as a result.

The Department is concerned about the structure of the Part D law, which fragments drug coverage among many PDP sponsors. The Department knows from its own experience that successful acquisition of competitively priced prescriptions drugs requires a large purchasing pool. This is consistent with CMS' recent initiatives to promote multi-state purchasing pools. Therefore, the Department suggests that creating the largest regions possible across which PDPs may operate is likely to be in the best interest of both states and the federal government, which are financially liable for this new program. The Department also suggests that CMS consider contracting with some of the largest states as either PDP or fallback plans, due to the extensive experience that states have operating cost-effective, comprehensive drug programs and the leverage that such states have due to the large size of their purchasing pool.

While the Department understands that promoting choices for beneficiaries is also an important goal, the Department suggests that the experience with the Medicare discount

card has been instructive in the area of beneficiary choice. It is clear from that program that when individuals are confronted with a wide array of choices, it is often very difficult to compare them all and that this promotes confusion and inaction. Furthermore, there are some beneficiaries who spend time in different geographic areas, including different states, during the course of a year. The Medicare program is a national program and currently, those beneficiaries enjoy their Medicare benefits throughout the entire United States. Consideration should be given to making some Part D plans available that can be accessed in all parts of the United States. Such portable coverage is consistent with the overall Medicare national program.

Detailed comments on the sections of the proposed rules

Subpart A – General Provisions

Section 423.4 - Definitions
PDP sponsor
The NPRM limits PDP sponsors to nongovernmental entities. The Department does not believe that CMS has legal authority to so limit choice of sponsors. The MMA does not include a provision to so limit the choice of PDP sponsors.

It is curious that CMS would choose to limit PDP sponsors to nongovernmental entities, given the enormous experience that states have in providing prescription drug coverage. Private sector companies do not currently provide stand-alone prescription drug coverage as an insurance option. Instead, drug coverage is generally integrated within other insurance coverage. In contrast, the states have created stand-alone drug coverage programs both in the form of SPAPs and 1115 Pharmacy Plus waivers. The stability of the state run programs is in marked contrast to the instability of many private sector insurance products including the Medicare + Choice insurance products. The Department suggests that CMS reconsider this definition. In some areas of the United States, it may be difficult to contract with an appropriate PDP sponsor. However, a governmental entity may be willing to provide such a benefit. This is particularly true in states where a large SPAP or 1115 waiver program currently exists. There may be significant benefits to both the federal government, the state government and to beneficiaries from the utilization of a structure that has been in operation for several years and that is well known to beneficiaries.

In addition, states are required to continue to contribute to the cost of prescription drug coverage for the dual eligibles. However, states will have no control over the costs of such coverage. Furthermore, states will be giving up a certain proportion of their population and may lose some bargaining power, which will also negatively affect a state's ability to control prescription drug costs for the rest of its Medicaid program. Therefore, some states may be eager partners with the federal government to provide such coverage to Medicare enrollees, especially to the dual eligibles. This option may prove to be a much more stable and reliable option for the federal government compared to other options.

Subpart B – Eligibility and Enrollment

The Department recognizes that the task of educating Medicare beneficiaries about how to enroll in this new benefit will be enormous. The structure of the part D benefit itself is in many ways designed to be fragmented by its use of many PDPs and MA-PDPs as opposed to a uniform national program with single point of entry. This new design will be very different for beneficiaries compared to the traditional Medicare part A and B enrollment process. The Department is consequently concerned that sufficient attention be directed to outreach to the many different populations served by the Medicare program. In particular, the Department is concerned about outreach to persons with disabilities and those who reside in nursing homes or institutions for mental disease (IMDs).

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. These organizations are staffed primarily by volunteers who are already overburdened. Moreover, SHIPs are primarily focused on assisting seniors and generally do not have the capacity to address the special needs of individuals with disabilities.

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 most appropriate plan available. The conference report for the Medicare Modernization Act, 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.] States have had significant experience in enrolling individuals suffering from mental illness in to state mental health programs and their experience 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.

Additionally, experience with the Medicare discount card is clearly instructive. While many low-income individuals are eligible for transitional assistance, very few have signed up by themselves. Seventy five percent of enrollment has been via autoenrollment.[3]

The Department suggests that CMS partner with and finance 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. Here in Illinois, the Department has great experience in this

[3] Kaiser Family Foundation report "Medicare discount cards: A work in progress," July 2004 and found at www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

area. The Department has partnered with community-based organizations to enroll children and families in our KidCare and FamilyCare program. The Department has over 1100 KidCare Application agents (KCAA). IDPA provides KCAAs with $50 for every complete application they submit that is approved. Similar groups or even some of the same organizations are likely to be known and trusted by Medicare beneficiaries with disabilities.

CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (Preamble discussion of 423.48 at pages 46642-46644). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources and training. Here in Illinois, the Department provides our KCAAs with on-going training so that they are familiar and up to date on our programs.

While information on the Internet may be useful to some beneficiaries, in general such a mode of communication will not be suitable for the majority of the Medicare population. The Kaiser Family Foundation has done some surveying in this area and finds that 70 percent of those over 65 report never using the Internet. Of those who do go on line, just 2 percent have visited CMS' Medicare.gov site. In addition, use of the Internet is stratified by income. For those with incomes below $20,000 per year, only 15 percent have ever visited the Internet.[4]

The Department suggests that CMS develop very specific plans for facilitating enrollment of beneficiaries with disabilities and other particularly vulnerable populations such as those residing in institutions in each region that incorporates collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. CMS should also consider providing additional grants to SHIPs, Departments on Aging, Area Agencies on Aging, state agencies providing assistance to persons with disabilities and Medicaid agencies for the purpose of providing public education and information on this new program. In addition, in their bids, PDPs and MA-PDs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness.

423.30 - Eligibility to enroll

Consistent with the MMA at 1860D-1(a)(1)(B), the NPRM restricts Medicare Advantage enrollees to MA-PD plans. However, as pointed out in the preamble, this could under certain circumstances present CMS with a quandary with respect to low-income individuals, if the Medicare Advantage plan does not offer a plan at or below the low-income benchmark premium. This would be contrary to the clear intent expressed by

[4] Kaiser Family Foundation report "Medicare discount cards: A work in progress," July 2004 and found at www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

Congress at 1860D-14(b)(3), to avoid a situation where there are no plans available to those people qualifying for a low cost plan. The Department recommends that CMS require all MAs to offer an MA-PD at or below the low-income benchmark premium.

In addition, due to the restriction of choices for enrollees of Medicare Advantage plans, the Department suggests that CMS notify all such enrollees of such restriction and give them the opportunity to return to Medicare Fee for Service if they desire to enroll in a PDP plan.

423.34 (b) - Enrollment.
The final rule should clearly provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual. This is most appropriate for those Medicare enrollees who will find it hard to enroll by themselves.

423.34(c) – Denied Enrollment Notice Requirement.
The notice should be in writing and inform an individual who is denied enrollment of his or her appeal rights, including the right to appeal the imposition of a penalty for late enrollment.

423.34(d) - Enrollment requirement for full benefit duals
As mentioned earlier, the Department supports the provision in the law to allow for autoenrollment of full benefit duals in a PDP or MA-PDP if they fail to choose a plan. However, the Department is concerned about the timing of this autoenrollment, which may leave this very vulnerable population without coverage for several months. In the absence of a law change to provide transitional Medicaid coverage, the Department suggests that CMS take the precautionary approach of pre-autoenrolling them in a plan as a fallback. Beneficiaries can then move to the plan of their choice at any time due to the availability of "special enrollment periods" for the dual eligibles under 423.36 (c) (4). However, enrollees would have the guarantee of a safety net plan under such a proposal.

In the Preamble, CMS requested comments on whether CMS or the states should perform automatic enrollment of dual eligibles. The Preamble suggested that states have more experience with auto-assigning beneficiaries. This may be true in states that operate mandatory managed care programs. However, in states such as Illinois this is not the case. While it is true that states have more readily available data identifying the dual eligibles in their state and they will be involved in the enrollment process because they are already required to perform low-income subsidy enrollment, they are currently suffering significant budgetary and staffing challenges and MMA only provides a limited match for administrative costs imposed on the states by this law. Additionally, the states have no relationship with the new PDP sponsors and their only involvement for enrollment will be enrollment in the subsidy rather than enrollment with a specific PDP sponsor. CMS is in fact in the best entity to do autoenrolling because it has contractual relationships with the PDP sponsors and is funded to administer the program. Furthermore, if CMS chooses to insist on the states performing this task, then 50 different entities (states) will have to find solutions for this task. This has the potential for far more disruption. Each state has a different computer system and significant system

changes would be necessary in a relatively short time period to effectuate this autoenrollment. It is highly likely that many states would be unable to perform this function within the time period needed. Medicare is a national program and this issue is most efficiently dealt with once by the federal government.

If CMS does, however, decide to impose this new mandate on the states, the administrative match should be 100 percent and CMS should provide the states with technical staff to assist in this implementation including staff for necessary system changes.

423.36(c) - Special Enrollment Periods.
This section should be expanded to provide "special enrollment exceptions" for individuals disenrolled by a PDP (such as for disruptive behavior) so that the individual will have an opportunity to join another PDP and continue with necessary medications. These "special enrollment exceptions" are necessary given the high risk of discrimination presented by the provisions for involuntary disenrollment (see comments under section 423.44). CMS should provide a special enrollment period for these beneficiaries. It should include a reasonable time period for plan selection and be exempt from late enrollment penalties.

The special enrollment provisions should be clarified to ensure that dual eligibles would not be subject to a late enrollment fee if the complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

423.38 (c) - Effective dates for special enrollment periods
The Department supports the principle of determining effective dates for coverage in a manner consistent with protecting the continuity of health benefits coverage.

423.42 (e) – Maintenance of enrollment
The Department supports the principles contained in this section. CMS should develop a methodology for ensuring that no beneficiary loses coverage if a PDP is discontinued, including perhaps temporary autoenrollment into another plan until such time as a beneficiary chooses a new PDP.

Certain beneficiaries may lack the ability to address future changes due to instability or discontinuance of coverage. While they may receive assistance with initial enrollment due to the large amount of public awareness surrounding the initiation of the program, in the future when only a portion of enrollees are affected by a change, their need for assistance may go unnoticed. It is therefore, incumbent upon CMS to ensure that if there are changes in PDP sponsors, that enrolled beneficiaries do not fall through the cracks and therefore lose coverage.

423.44(b)(2)(i) - Required involuntary disenrollment by the PDP.
CMS stated that it was "particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area."

The disenrollment requirement in this section raises the issue of "snowbirds"—the large number of Medicare beneficiaries who move for large parts of the year. The churning—the enrolling and disenrolling—that plans serving this population will face as they apply this section will be enormous. Because of different formularies between plans and problems of coordination (as described in the June, 2004 MedPAC report to Congress), the regulations should seek to minimize plan changes and maintain continuity of care. This section, as written, could result in a significant number of plan changes, disrupting continuity of care.

The Department suggests several ways that CMS can better address this issue:

- **Create certain PDP options that are available throughout the United States**.

- **Require traveler benefits policies and require plans to provide information on their traveler benefits.** Unlike Medicaid, Medicare is a completely federally funded and administered program. Medicare beneficiaries are currently able to access their benefits in all parts of the United States. Therefore, the Department believes that CMS should require as a condition of participation that plans have a system of visitor or traveler benefits. In addition to requiring traveler benefit policies, CMS should require plans to provide prospective enrollees with specific information on traveler benefits and "out-of-plan service policies." In many cases, 90-day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. Beneficiaries who are traveling and need emergency pharmaceutical services need to know how their plan will (or will not) reimburse for those services.

- **Allow PDP exceptions.** Consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement. At a minimum, beneficiaries must have a clear understanding of how a plan will serve people temporarily out of the service area.

- **Define time period.** The regulations should also clearly define the time period that a plan could consider an enrollee as "no longer reside(ing) in the PDP's service area." This should be defined to accommodate seasonal travelers who maintain a residence in the service area.

423.44(d)(2) - Disenrollment for disruptive or threatening behavior.

The Department is particularly concerned about beneficiaries who currently receive their prescription drug coverage through Medicaid. There are no provisions in the Medicaid statute to allow a state to disenroll an individual due to disruptive or threatening behavior. Therefore, dual eligible individuals could experience less protection under this section compared to their current coverage.

The NPRM allows Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44). CMS' authority to allow such disenrollment is questionable. The MMA does not include

any mention of disenrollment of beneficiaries for disruptive behavior who are enrolled in PDPs. While the MMA does under Sec 1860D-1(b)(1)(B) allow for the establishment by the Secretary of rules for enrollment for MA-PDs similar to those in effect for current MAs, this provision is limited to MA-PDs. Section 1851(g) of the Social Security Act allows Medicare + Choice plans to terminate enrollment for individuals who have engaged in disruptive behavior. However such termination allows the individual to return to traditional Medicare. MMA does not include a provision to extend such disenrollment to traditional Medicare or PDPs.

CMS' inclusion of these provisions creates 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.

Further, the NPRM does not allow a process by which a beneficiary can appeal an involuntary disenrollment due to disruptive or threatening behavior. This lack of an appeal right opens the door for abuses resulting in a PDP eliminating beneficiaries with above-average costs from its program. Further, this lack of an appeal right may result in the denial of due process.

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.

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 would appear 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.

As the provider of other health care services for dually eligible population, the Department is particularly concerned about the effect this may have on our beneficiaries who may be hospitalized due to the deterioration of their health due to the denial of drug coverage.

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. The term "threatening" is not defined. The Department is concerned about how such an undefined term might be interpreted.

Reenrollment. In the preamble, CMS asks 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. Individuals who are subject to involuntary disenrollment may have no resources to pay for their medications. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify one 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 MMA requires fallback plans be available in areas where there are not at least two private drug plans.

The continuing stigma surrounding mental illness and other cognitive impairments, which 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 minimized. 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 or dementia, 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. The Department questions 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 the Department urges 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.

Protections to include. While the Department believes that CMS lacks authority to allow for disenrollment of beneficiaries from PDPs due to disruptive behavior, if CMS insists on maintaining these provisions, 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, the Department strongly recommends 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":

- CMS is strongly encouraged to prohibit PDPs and MA-PDPs from disenrolling any low-income subsidy eligible individuals unless the beneficiary is enrolling in another PDP or MA-PDP. It is essential that PDPs and MA-PDPs be prohibited from disenrolling any dual eligible individuals unless the beneficiary is enrolling in another plan. These individuals will not have means available to purchase drugs out-of-pocket and they should never experience gaps in pharmacy coverage. Beyond the personal suffering that will result, if dual eligibles lose pharmacy benefits, it can be expected that they will become more acutely ill and require other, probably more expensive, Medicare or Medicaid covered acute care services.

- 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 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.

- Enrollees should have the opportunity to appeal such disenrollment;

- If, upon establishment of the appropriate process, an enrollee appeals this involuntary disenrollment, the disenrollment should not be effective until the appeal has been decided.

Section 423.46 - Late enrollment penalty.

The Department urges CMS to delay implementation of this section for all enrollees for at least one year. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or will not understand that they must choose a plan and enroll. This is particularly true for non-deemed low-income beneficiaries who will have to know to apply through two separate processes, one with the PDP sponsor and one for the low-income subsidy.

IDPA has observed from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them. The Department also sees from our own experience providing prescription drug coverage to Illinoisans that many people who desperately need prescription drug coverage and who are eligible for prescription drug coverage do not necessarily know how to access it. For instance, the Department estimates that close to 360,000 Illinois seniors are eligible for SeniorCare, a comprehensive drug program without a premium or deductible. Yet only approximately 200,000 are enrolled. The state has engaged in extensive outreach to make the public aware of this program, which unlike the Medicare part D benefit has a no cost for enrollment.

The Department understands CMS' concern that healthy beneficiaries will not apply and will instead wait until they need prescription drug coverage to apply. This would result in adverse selection in the program and has the potential for driving up the cost of the program. However, the Department believes that the people most at risk of not applying are the most vulnerable beneficiaries, including people with mental illness. The Medicare Part D program is new and confusing. The Department knows from the experience with the Medicare endorsed discount card that people delay enrollment in a drug card because they do not understand the program and find the choices overwhelming. Many Medicare

beneficiaries will need more than 6 months to understand the program, understand how Part D coordinates with other drug coverage they may have, and then to choose the drug plan that is right for them. During the initial implementation process, people should not be penalized because of the complexity of the program.

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

Until such time as beneficiaries become familiar with the program, they should not be penalized because of its complexity. CMS should recognize that persons who have previously received Medicaid drug benefits may not realize the relevance of the MMA to them. It will take extra effort to assure they know that the Medicaid benefit is ending.

Omissions in this section.
Beyond that general comment, The Department have several more specific concerns regarding omissions in this section.

- **Add appeals opportunity.** There should be an opportunity for enrollees to appeal late enrollment penalties. This should be noted in this section and should be incorporated as part of the general system for appeals outlined in Subpart M.

- **Coordinate with "special enrollment periods."** Late enrollment penalties should be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties. The exemption of time during special enrollment periods from late penalties should be stated in this section.

- **Exemption for individuals involuntarily disenrolled.** Unless CMS adds special enrollment opportunities for individuals who are involuntarily disenrolled—as strongly recommended under our comments on section 423.36(c)—those who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period. At that point, they may be subject to a late penalty and increased premiums. For those disenrolled due to "disruptive behavior," this may have resulted from denial of access to needed medications. Where disenrollment was not related to failure to pay premiums, the Department suggests that the late enrollment penalty be waived.

- **Late enrollment penalties and people with disabilities**. CMS should incorporate an enrollment "grace period" for individuals with disabilities. The rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to beneficiaries with disabilities, and these beneficiaries might well require additional time to make a selection and complete the enrollment process. Therefore, CMS should incorporate a late enrollment "grace period" for this

population.

Section 423.48 - Information about Part D.
Outreach and funding the State Health Insurance Assistance Programs (SHIPs). The preamble references the role of SHIPs in relation to this section (as well as section 423.30). As noted in our introductory comments to our discussion of Subpart B, the reference is inadequate and, in general, insufficient attention is being given to what will be the very difficult task of adequately disseminating information on this program to ensure that, at the least, those with coverage—particularly dual eligibles—do not experience a gap in coverage or late enrollment penalties.

An extensive network of local, face-to-face counseling services will be needed. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate. SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. The Department believes that the SHIPs and Area Agencies on Aging, and related local counseling services are significantly under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, is about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. The Department urges a further increase in funding for SHIP/AAA/Departments on Aging/Medicaid agencies.

Information plans must provide. This section states that "each PDP and MA-PDP plan must provide…information necessary" to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient.

Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance.

In addition, CMS needs to require plans to make information available in alternative formats for people with disabilities and in languages other than English to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. The Department suggests that CMS develop a comparative brochure that can be provided to each beneficiary so that beneficiaries can compare options. The Department realizes that a different brochure would be necessary for each region. However, without independent, unbiased

comparative information, beneficiaries are likely to be unable to make informed choices. CMS should continue to make information available upon written request and through 1-800-Medicare but the Department believes an additional annual mailing by CMS is also necessary. The Department also asks CMS to continue to work to improve information sources, as they sometimes are difficult for consumers.

Minimal information plans should be required to provide. While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on the benefit itself that potential enrollees will need in order to make a choice among plans. This minimum set of information should be specified in this section. Specifically, beneficiaries will need to understand:

- Premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay;

- The benefits structure and comparative value of the plans available to them;

- The coinsurance or copayment they will need to pay for each covered Part D drug on the formulary;

- The specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage;

- Formulary structure, the actual drugs on the formulary, and information on whether the formulary can change during the plan year and if such changes are allowed on how this will be take place;

- Participating pharmacies, mail order options, out-of-service options;

- Appeals and grievance processes;

- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans. Plans should also be required to provide this information to potential enrollees (see comments on section 423.50, below). Therefore, the Department urges CMS to specify the minimal information that plans will need to provide. As noted, guidance is insufficient.

Specifically, the Department urges CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees,

who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. The Department urges CMS to require plans to publish, as part of their marketing materials, price information. This could be provided in a manageable format.

For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish in a standardized format, and post on the Internet, their negotiated price for each of those drugs. Such a list would be easy to prepare and take only about one page in marketing materials.

Information and outreach for dual eligibles. In the Preamble, CMS states that "prior to [this] automatic enrollment process, a widespread education and information campaign (described later in this subpart at Section 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled" (Federal Register, Vol. 69, No. 148, Tuesday, August 3, 2004, Proposed Rules, page 46638). Such an education and information campaign targeted to dual eligible individuals and that does equip them to select among plans and enroll prior to automatic enrollment is critical. However, the proposed regulations may be insufficient.

In the Preamble, CMS discusses education and information materials that it will provide to beneficiaries. This discussion focuses on support through the Internet sources and the 1-800-Medicare number. Both are necessary but, as noted above, insufficient to meet the needs of the Medicare population and particularly insufficient to meet the education and information needs of dual eligibles. This is a difficult to reach population with limited Internet access and, in many cases, limited telephone access.

The Department recommends that CMS involve community-based organizations and providers who serve and work with dual eligibles in this enrollment process. In addition, CMS should devote resources to helping these organizations and providers inform dual eligibles that Medicaid drug benefits are ending, of their choices and what they need to do to sign up. These organizations can help duals find the best plan available to them and let them know that they can switch plans through the special enrollment provision in § 423.36 of the regulations if they have been automatically enrolled in a plan that is not the best for them. The Department further recommends that CMS develop brochures or guidebooks for each region, which are mailed to each beneficiary and are also made available to community-based organizations. This material should provide comparative information on the available plans in each region. This compilation of information is critical to the success of this program.

423.50 - Approval of marketing material and enrollment forms

Experience in this area in both Medicare and Medicaid is extensive and development of the marketing rules for the PDPs and MA-PDPs should be based on that experience. Most recently, Illinois has seen fraudulent marketing with respect to the Medicare drug

discount card.[5,6] The Department urges CMS to be vigilant and to identify and prohibit these problematic areas and practices as it develops final regulations.

423.50(c) - Guidelines for CMS review.
This section vaguely states benefit information that plans must provide in their marketing materials in subparts (i), (ii), and (iii). The Department urges CMS to include more specific requirements. It will be important that beneficiaries have comprehensive information on plan benefits and drug prices, since the drug co-pays, coinsurance and donut hole costs they might have to pay could be substantial. The Department recommends that CMS add to this list the requirement that plans make available the following information on benefits and benefits structure, in written format and on the Internet:

- **Information on the formulary**: What the formulary is; information on the fact that the formulary might change; notice that will be provided if there is a formulary change; and, at the least, formulary and cost-share tier information for 25 to 50 drugs frequently prescribed to Medicare beneficiaries (see section 423.48 above).

- **Information on drug prices.** A description of the "negotiated price," and a list of the negotiated price for 25 to 50 frequently prescribed drugs (again, see section 423.48 above).

- **Premium information**. Information on plan benefits and the premium (for the basic benefit and any other benefits offered). If a plan offers multiple benefits, marketing material should include a side-by-side comparison of those benefits. For each benefit offered, plans should be required to note, clearly and conspicuously whether individuals qualifying for the low-income subsidy will have to pay a premium and, if so, the amount that will have to be paid.

This information will be critical if beneficiaries are to make informed choices among plans. It should be part of standard marketing materials; potential enrollees should not have to request this basic information.

423.50 (e) - Standards for PDP marketing.

Prohibit telemarketing. Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. There have been numerous reports of telemarketing fraud under the Medicare Drug Discount Program.[7] The Part D benefit is susceptible to even more fraudulent business practices. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential

[5] "Medicare Drug Cards: Illinois accuses 2 firms of fraud" Chicago Tribune, September 19,2004
[6] "Medicare Drug Cards may trigger headaches, consumer groups warn" Chicago Tribune, March 8, 2004
[7] "Medicare Scams Prey on Seniors," Chicago Sun-Times, News Special Edition at 8, May 24, 2004

enrollee requests contact through such means in response to a direct mail or other advertisement.

Prohibit marketing of other services. In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS seems to believe that this would encourage entities such as financial services firms to participate as prescription drug plans. The Department finds such a proposal alarming. The MMA clearly lays out the purposes for which a PDP sponsor may market. The law is silent on additional purposes and The Department believes that such silence was intentional. Congress did not envision allowing PDP sponsors to use the information they receive on Medicare enrollees to market other products. PDP sponsors should be participating in this program based on their ability to provide covered benefits not on their desire to tap into this market for other non-Medicare related activities. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. This would be inadvisable for several reasons:

- Having plans offer added services would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved card"; the difficult task of comparing plans would become even more complex for potential enrollees; beneficiaries might mistakenly believe that they need to take an entire package of offered services when they sign up for the drug plan. This section prohibits marketing activities that could "mislead or confuse." Allowing plan sponsors to market added services is so apt to create situations that confuse and mislead beneficiaries that it is in direct conflict with the provisions of this section.

The Act intends the use of beneficiary information to be solely for facilitation of marketing of plans and enrollment of beneficiaries, and the Preamble notes the disclosure of this information is permissible under the HIPAA Privacy Rule. However, permitting PDP sponsors to use detailed health information to market other products to beneficiaries violates the intention of the Act. PDP sponsors that seek to market other products would be subject to the marketing restrictions of the HIPAA Privacy Rule, including being required to obtain a beneficiary's prior authorization to market those products to that beneficiary. However, there is enormous potential for marketing abuses by a PDP sponsor when the PDP sponsor attempts to obtain that prior authorization, in the same way door-to-door and telemarketing may open the door to deceptive marketing practices. In soliciting authorizations to market other products, PDP sponsors may bundle those products with plan information creating confusion about what the beneficiary is authorizing the PDP sponsor to do.

Prohibit single-contract pharmacies from marketing.
CMS asked for comment on the applicability of MMA marketing requirements for PDP marketing. The Department recommends that PDP marketing be much more severely constrained. There is the potential for pharmacies to market certain

PDPs more aggressively, regardless of whether or not that PDP is the best for the beneficiary. The Department can easily foresee this occurring if a pharmacy has a contract with only one PDP or has more favorable contract terms with a specific PDP. Providers with relationships with a PDP plan might market that plan more heavily. The Department urges CMS to consider the potential for provider and pharmacy-based marketing to steer beneficiaries into inappropriate PDPs and to make marketing requirements more limited than those for the Medicare Discount Card and also to specify marketing limits in the regulations.

At the very least, pharmacies with only one PDP contract should not be allowed to market the program; other pharmacies (those with multiple contracts) should be required to provide equal space to materials from all PDPs with which they contract.

Do not allow plans to use Medicare discount card enrollee and applicant information. The regulations should prohibit prescription drug plans from obtaining and using Medicare Drug Discount Card enrollee and applicant information, and information collected from any other card programs the company might sponsor.

It is foreseeable that many Discount Card sponsors will apply to be prescription drug plans. As Discount Card plans, these entities will have beneficiary-level information on drug use, creating the potential for prescription drug plans to use Discount Card information to target marketing to low-cost beneficiaries, either directly or through marketing firms.

Section 423.50(e)(2) prohibits drug plans from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." The regulations should:

- Specifically prohibit prescription drug plans from obtaining or using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor.

- Prohibit others from using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor to market on behalf of a prescription drug plan sponsor.

Specify whether and how the Secretary can provide information to prescription drug plans. The MMA added section 1860D-1(b)(4)(A) to the Social Security Act. This permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may

only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."[8]

The proposed rule does not contain any provision governing whether and how this information will be provided and in the Preamble, CMS seeks comments on a number of operational issues as well as on the provision in general.

The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair information practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. The Department recognizes that there may be some benefit in the Secretary's providing information to prescription drug plans if the plans send information to eligible individuals information that would actually be useful in determining which plan to select. The Department recommends the following in the disclosure of identifiable information:

- If the Secretary provides information to prescription drug plans, the information provided should be limited to the minimal amount necessary: the potential enrollee's name and address. No health or financial information should be disclosed.

- The Secretary should disclose identifiable information to prescription drug plans to facilitate marketing or enrollment only if the plan's marketing materials contain formulary and drug pricing information or are accompanied by an application form. This approach could help balance privacy concerns with the need for beneficiaries to obtain important plan information.

- The Secretary should not disclose telephone numbers. Telemarketing should be prohibited; there is no need for plans to have beneficiary phone numbers unless provided by the beneficiary.

- Beneficiaries should be given the choice of whether they want this information disclosed. The Department suggests that an opt-out approach be used to ensure that beneficiaries have the ability to limit their exposure to such marketing. Ordinarily, the Department would suggest an opt-in rather than opt-out approach. However, from our own experience with asking beneficiaries for responses, the Department realizes that many will not read the opt-in/out notice and therefore, will not make any choice. Setting the default to opting-out (ie a beneficiary is considered to have opted-out unless they affirmatively opt-in) will result in many beneficiaries not receiving information on the plans when in fact they had not chosen to opt-out, rather they had not acted at all. The opt-out notice should be clear; written with the Medicare population in mind; state what will be shared; and clearly state that even if a beneficiary elects to opt-out, they can still enroll in the benefit, they will still receive

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

information about the benefit from CMS, and they can still request information directly from plans.

423.56 - Creditable coverage
The Department supports inclusion of Medicaid coverage under Title XIX of the Act or under a waiver under section 1115 of the Act.

Given the long history of fraudulent sales of insurance products billed as meeting certain federal standards, the Department strongly supports the provision in Sec. 423.56(f) allowing an individual to apply to CMS to have coverage treated as creditable coverage for the purposes of applying 423.46 when the individual can show that they were not adequately informed that coverage was not creditable.

Subpart C – Benefits and Beneficiary Protections

423.100 - Definitions
Long Term Care Facility
Definition of "long-term care facility" to explicitly include Supportive Living Facilities, Assisted Living Facilities, ICF/MRs and ICF/DDs, the State of Illinois operates a home and community based waiver for supportive living facilities. This innovative program provides Medicaid services to individuals in an assisted living like setting. Due to federal law that precludes receipt of food stamps in a licensed facility, these facilities are certified as supportive living facilities rather than licensed as assisted living facilities so that the beneficiaries may receive nutritional support in the form of food stamps. The Department recommends that the final rule include a definition of "long-term care facility" that explicitly includes such facilities and their counterpart assisted living facilities along with inclusion of intermediate care facilities for persons with mental retardation or developmental disabilities (ICF/MRs and ICF/DDs). The Department believes that many mid to large size ICF/MRs, ICF/DDs, supportive living facilities and some assisted living facilities operate exclusive contracts with long-term care pharmacies. Other states may have other types of facilities that are similar in nature but that contract with long-term care pharmacies and so a broad definition that can encompass the widest variety of settings that utilize such long-term care pharmacies, the Department believes would be advantageous to beneficiaries.

Incurred Costs
The Department support the inclusion of payments made by SPAPs as counting toward a beneficiary's incurred costs.

A state's contribution to a Pharmacy Plus waiver authorized under an 1115 Medicaid waiver should also count toward incurred costs. It does not make sense to allow certain state contributions for drug coverage to count toward incurred costs but to exclude other state contributions. States that were in the forefront of maximizing prescription drug coverage for seniors prior to a Medicare benefit should not be penalized. Illinois raised this issue in its negotiations with CMS over its SeniorCare waiver, the first Pharmacy Plus program in the nation. This is also true of other state programs such as state

contributions to ADAP programs for people with HIV. If Pharmacy Plus waiver expenses are not included in incurred costs, then enrollees in these plans will never reach catastrophic coverage and there will be no reason for them to enroll in the Medicare part D program.

423.104(e)(2)(ii) - Establishing limits on tiered co-payments.
The MMA is a law whose goal is to provide voluntary prescription drug coverage to Medicare beneficiaries. The provision in the proposed rule that permits Part D plans to "apply tiered co-payments without limit" is counter to that goal. Allowing a plan to subject a beneficiary to 100 percent cost sharing runs counter to the concept of drug coverage. While the Department understands that describing a prescription drug as covered even when it has 100 percent cost sharing allows the cost to be counted toward the beneficiaries true out-of-pocket costs, which is advantageous to the beneficiary reaching the full catastrophic benefit, it is difficult to justify such a practice as consistent with coverage.

Section 1860D-2(b)(2)(B) of the MMA permits tiered cost sharing provided it is consistent with 1860D-2(b)(2)(A)(ii), which requires actuarial equivalence to a 25 percent coinsurance. This allows Part D plans to incentivize the use of preferred drugs within a class, when it is clinically appropriate. However, 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 and the 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.

The absence of reasonable limits on cost-sharing tiers combined with a difficult to navigate exceptions process could result in certain Medicare Part D enrollees in effect being uncovered. 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. 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. Therefore, the Department suggests that allowing such unlimited cost sharing is inconsistent with Sec.1860D-11(e)(2)(D)(i) of the MMA.

It should also be noted that this practice would be outside the mainstream of current private sector practice. In 2004, 85 percent of private sector plans that use tiered cost sharing had only two or three tiers.[9]

[9] *Employer Health Benefits, 2004, Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004

The Department recommends that the final rule 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. A limit on the highest tier of cost sharing is also necessary to ensure that coverage is meaningful. This would bring the proposed regulations into closer alignment with Sec.1860D-11(e)(2)(D)(i) of the MMA.

423.104 (h)(3)(i) – Negotiated prices – Disclosure
The NPRM states that a PDP sponsor or an MA organization offering a qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals, or in the form of lower monthly beneficiary premiums and lower covered Part D drug prices at the point of sale as specified in 423.336 (c)(1) and 423.343.(c)(1). It is in the best interest of the program to require PDP and MA-PDP sponsors to disclose ALL negotiated price concessions not those passed on to the beneficiaries and CMS in the form of lower prices. This is essential if CMS is to really address the true costs of the program and its actuarial value in the long run.

423.112 – Establishment of prescription drug plan service areas.
As mentioned earlier, it is in the best interest of the financial integrity of the Medicare part D program to create as large regions as possible, while maintaining beneficiary choices. In addition, CMS should look at contracting with certain PDPs that are available to enrollees all across the United States.

423.120 (b) 5 – Notice regarding formulary changes
The proposed time for notifying beneficiaries of changes in a formulary are too short. Many beneficiaries will not have sufficient time to make an appointment with his or her doctor so as to discuss alternative medications or to seek an exception.

The Department recommends a 90-day notification period with receipt of notification acting as a coverage determination that may then be appealed.

423. 124 (a) – Special rules for access to covered Part D drugs at out-of-network pharmacies
When a beneficiary cannot reasonably be expected to obtain drugs at an in-network pharmacy, then the out-of-network cost should be the same for the beneficiary as the in-network costs.

<u>Subpart J – Coordination Under Part D with Other Prescription Drug Coverage</u>

423.464(a) – Coordination of Benefits with Other Providers of Prescription drug coverage
The Department supports the requirement that PDP sponsors must permit SPAPs to coordinate benefits with the prescription drug plan or MA-PD plan.

423.464 (f)(3) – Imposition of fees
The Department strongly objects to the provision in the NPRM that allows PDP sponsors to charge SPAPs with coordination fees.

423.578 (a) and (b) Exceptions Process for a PDP's tiered cost-sharing structure
These sections differentiate between exceptions from tiered cost sharing and exceptions involving non-formulary drugs. The Department would suggest that in light of the current proposed rules to "apply tiered co-payments without limit" (see discussion under 423.104(e)(2)(ii)) this is a distinction without a practical difference for beneficiaries. If tiers are going to be allowed to be so high as to confer no real benefit, the criteria or threshold for approving a tiered copayment exception should be no different than for approving a non-formulary drug. In either case, the issue at stake is financial access to the drug. This is particularly true for beneficiaries of more modest means.

The Department recommends that criteria or the threshold for approving a copayment exception should be no different from that used for approving a non-formulary drug. In fact the law at Sec 1860D-4(g)(2) clearly states that "denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h)" of that section.

Subpart M—Grievances, Coverage Determinations and Appeals

As the current provider of prescription drug coverage to Medicaid enrollees including dual eligibles and the claims administrator of the Illinois SPAP program, the Department is particularly concerned about this section of the proposed regulation. The Department recognizes that the law as written is difficult to navigate. However, the Department believes that CMS has some scope to improve this section and to create a more consumer friendly system that does not rely on two separate tracks depending on whether a person personally pays for a drug and files an appeal or instead does not obtain the drug and then files an appeal.

The timeframes laid out in this section are far too long. Gaps in coverage are guaranteed under the NPRM as it stands. For certain types of patients, such gaps in coverage can be life threatening or at the very least hazardous to the enrollee's health.

Pursuant to federal Medicaid law (Section 1927(d)(5) of the Social Security Act), a 72-hour supply of medications is available to beneficiaries while they await a decision on a prior approval request. Beneficiaries are also entitled to a fair hearing and administrative review of an adverse hearing decision when a prior approval is denied.

Sections 1860D-4 (f), (g) and (h) require PDPs and MA-PDs to establish a grievance, coverage determination and reconsideration, and appeals process in accordance with Sections 1852 (f) and (g) of the Social Security Act. Section 1852 (f) and (g) of the Social Security Act are the sections that deal with grievances and coverage determination appeals in the Medicare + Choice program. So it would appear that Congress intended the existing Medicare + Choice grievance and appeals system to be used as a model for this new benefit.

Case law provides some guidance as to how the system should operate. In the case of Grijalva v. Shalala[10], the court dealt with the issue of notice for denials of coverage. The court originally found that HMOs failed to provide adequate notice of coverage denials, that the notices were at times illegible and failed to specify the reason for the denial, and failed to inform the beneficiary that he or she had the right to present additional evidence to the HMO. Further, the court found that the Secretary of DHHS was under an obligation to insure that appropriate notice was given. The court suggested that to be considered legible, notice should be at least 12-point type. The notice should state clearly the reason for denial, inform the enrollee of all appeal rights, explain hearing rights and procedures, and provide instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician. The Department recommends that greater specificity be given in the NPRM as to the requirements for grievance and appeals. Beneficiaries are in danger of being denied their rights because the system as currently described by CMS is excessively cumbersome and confusing.

423.560 - Definitions
This section defines an authorized representative as someone authorized by the enrollee to deal with appeals. Given the fact that SPAPs will likely be at risk for coverage in the absence of Medicare coverage, this definition should be modified to clearly include SPAPs in this definition.

423.562 – General Provisions
This section states that "if an enrollee has no further obligation to pay…a determination regarding these services is not subject to appeal." CMS has verbally indicated that this could prohibit SPAPs from appealing if they pay for a drug. The Department believes that such a proposal would be unfair to states and to beneficiaries.

SPAPS have the mission of assuring that their enrollees have uninterrupted access to needed medications. As the party responsible for payment, the SPAP should have the right to appeal. The enrollee who has coverage whether Medicare pays or not, will have no incentive to appeal if the SPAP is picking up the tab. Such a situation could lead PDP sponsors to deny SPAP enrollees full coverage with impunity, while SPAPs are left defenseless. If SPAPs were to change their policies so as to no longer pay until after an appeal is filed by the beneficiary, this would result in considerable delays for many low-income beneficiaries.

The Department, therefore, recommends that this language be revised to exempt payments from SPAPs from resulting in any abridgement of appeal rights.

Section 423.562 (c)(2) precludes an enrollee from challenging a denial of coverage for a drug when it is accessed from a non-network provider, except in those situations where a PDP sponsor is required to provide such coverage. This section lacks clarity and could lead to a PDP sponsor denying an enrollee their appeal rights when there is a dispute as to whether the PDP sponsor is required to provide such coverage. In the interest of

[10] Grijalva et al v. Shalala 946 F. Supp. 747 (D. Ariz. 1996)

simplifying these rules, CMS should delete this section. While doing so may increase the number of appeals, it will be easier to administer and explain to enrollees. Simplification should be a goal for CMS in this section.

423.566 – Coverage determination
Greater clarity as to what constitutes a coverage determination is needed. CMS should consider how this system will be implemented. When a pharmacist first submits an electronic claim and receives an electronic admittance advice, this should be treated as a request for coverage. If such a request is denied, it should trigger the appeals process.

Section 1860 D-4 (g)(1) states that "a PDP sponsor shall meet the requirements of paragraphs 1-3 of section 1852 (g) of the Social Security Act… in the same manner as… an MA organization." Under such a system for other non-drug benefits, the initial claim denial is the coverage determination and it results in a written notice of appeal rights. Re-determination follows. Medicare + Choice rules for plans that include drugs do not vary between drugs and non-drug benefits on this matter. Therefore, CMS' construction of an alternative system under Medicare Part D, whereby after a pharmacy submission is denied the beneficiary must request a coverage determination appears on its face to run counter to the MMA statutory language. It also exacerbates the complexity of this system.

The Department recommends that an initial claim denial at the pharmacy be considered a coverage determination and the exceptions process should be considered the redetermination.

423.568 – Standard timeframe and notice requirements for coverage determinations
This entire section is again premised on the notion that the initial submission of a claim by the pharmacy is not a coverage determination. As mentioned above, this must be remedied by CMS for this system to work for enrollees.

In the absence of remedy, when a claim is denied at a pharmacy, the PDP is not required to send a notice of such denial to the beneficiary. It is in the best interest of the enrollees to receive such notice in a timely fashion at point of sale. PDPs should be required through their contracts with participating pharmacies to provide enrollees with such notice upon initial claim denial. These notices should include the remedies available to the enrollee, including the enrollees right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or is on too high a tier.

One might argue that this is a burden on the pharmacy. However, the pharmacies and the PDP sponsors must be in close contact so as to keep up-to-date with formularies, coinsurance and calculations of an enrollee's out-of-pocket expenses.

Denials of drug claims can be just as detrimental to the health of an enrollee as other denials of benefits and can result in large out-of-pocket expenses. It does not make much sense to treat such drug claims in a manner that differs from other health services claims.

In addition to providing enrollees with notice of such a coverage determination, The Department also suggest that if the enrollee is also in a SPAP, that notice be provided to the SPAP so the SPAP can also appeal a coverage denial on behalf of the beneficiary.

423.568 (a)(1) – Timeframe for requests for drug benefits
Fourteen days is far too long for exception requests.. Normally these requests are completed in 2-3 days for commercial plans and 24 hours for Medicaid. Most drugs for Medicare enrollees will be for chronic illness, which may deteriorate if there are lapses in coverage. As the provider of medical benefits for dual eligibles, the Department is particularly concerned about lapses in coverage for this group, who often suffer from multiple chronic illnesses. For certain groups such as those with HIV/AIDs or mental illness, gaps in coverage can be particularly dangerous.

Similar to the Medicaid program, in cases of acute illness or urgency, the pharmacist should be authorized to issue a 72-hour supply of a denied medication to enable the patient time to return to their physician to discuss options.

Without this safety measure, dual eligibles will see their protections eroded with implementation of the Medicare drug law.

The Department recommends that the timeline for PDP sponsors to make a decision on a request for an exception be no more than 3 days, unless the beneficiary or physician failed to supply needed information. Dual eligibles or those covered by SPAPs or other low-income beneficiaries should be able to receive a 72-hour emergency supply of denied medications, if the pharmacist determines that they are necessary for the health of the patient.

Additionally, low-income beneficiaries who will be unable to pay out-of-pocket as a stopgap measure during an appeal, should receive a temporary supply while the appeal is being decided. Again, this would be consistent with Medicaid policy.

Finally, those who are currently on a particular medication when a formulary or other change in coverage policy occurs, should receive a 90 day supply of the drug until they can see their physician to discuss their medical options or can pursue an appeal. The NAIC model act on prescription drug benefits provides a workable template with respect to this issue.

423.568 (c) – Notice of denials
In the interest of promoting an easier to navigate system, the Department suggests that CMS eliminate the differential treatment in the NPRM for drug benefit denials versus drug payment denials. However, in the absence of such a change, both situations need denial notices for enrollees.

423.570 and 423.590 – Expediting Certain Coverage Determinations

The Department understands the concept behind differentiating between appeals where a prescription drug has not been provided versus where the beneficiary has paid for the drug and is now appealing non-payment. One could argue that in the first instance, access to health care is being denied and so urgency may be necessary but in the second instance the care has been provided and so urgency is not necessary. In reality, this may be a distinction without a difference for enrollees of modest means. In many cases, the need for the prescription drug is ongoing. In others, while the beneficiary may have paid, they may be in urgent need of reimbursement so that they can pay for rent, food or other necessities.

If one is to penalize an enrollee who pays out-of-pocket because they believe their health is at risk, then the system is promoting the prolonging of denial of care. This is not good public policy and is not in the best interest of Medicare beneficiaries.

CMS should revise these sections to eliminate the differential treatment accorded beneficiaries who pay for their prescription drugs out-of-pocket and then seek to recoup those costs through the appeals process. Neither commercial PBMs nor Medicaid make a distinction in a person's right to a speedy appeal of a prescription drug denial based upon whether they paid out-of-pocket for a stopgap supply.

423.578 and 423.584 – Exceptions Process and Expediting Certain Redeterminations
SPAPs should be entitled to act on behalf of their enrollees to pursue all levels of exceptions. Likewise an authorized representative or a prescribing physician should be able to seek a standard redetermination and any other appeal that is in the best interest of the patient. Many older patients will look to their doctor for assistance with the appeals process. It is likely that the overall system will be confusing and intimidating to many enrollees who have no current experience with managed care.

523.578 – Exceptions process
The preamble considers requiring PDP sponsors to provide "continued access" to a drug at the old copayment rate if the copayment is increased midyear. The Department supports this concept because it will deter "bait and switch" tactics by PDP sponsors. The Department does, however, support allowing pricing changes in the event a generic alternative becomes available. Generic drugs are approved by the Food and Drug Administration and are required to be fully substitutable for their brand name counterpart. The promotion of the use of generics is essential to maintain cost controls on the Medicare part D program.

The Texas insurance code (Art 21.52J) provides useful model language for this purpose: "A (PDP) shall make a prescription drug that was approved or covered for a medical condition or mental illness available to each enrollee at the contracted benefit level until the enrollee's plan renewal date, regardless of whether the prescribed drug has been removed from the (PDP's) formulary or moved to a higher copayment tier.

423.578 (a) Exceptions for tiered copayments

CMS should develop rules to more formally lay out the rules for tiered copayments. If there are no limits on the way that tiers can operate, there is great potential here for massive confusion. If tiers can vary based on a drug being preferred versus non-preferred and also between whether the pharmacy is preferred, mail order, or non-preferred, there may be too many variables for enrollees to comprehend. Such confusion will deter beneficiaries and SPAPs from appealing the high cost tiered products.

The Department recommends that CMS work with NCPDP to establish a standard claims processing field that all payors and pharmacies would be required to use for purposes of communicating which tier is applied. This information can then be shared at the point of services with the beneficiary, as well as on written explanations of benefits (EOBs).

423.578 (C)(2) Untimely exceptions decisions
If an exception decision on a formulary deletion case is not made in 14 days, then the PDP must cover a 1-month supply. If the PDP still fails to act, then a continued supply must be covered until the PDP makes a decision. Even with this continued supply, the beneficiary will have been 14 days without coverage. No similar provision appears to be available for enrollees when a beneficiary is denied access to a drug due to a closed formulary. Yet such an enrollee has exactly the same access problems as those described in the first example. This is particularly worrisome for low-income beneficiaries who are unable to purchase prescription drugs due to lack of income.

The Department recommends that dual eligibles and other low-income beneficiaries including SPAP enrollees have access to at a minimum a 72-hour emergency supply of denied medications, if their doctor or pharmacist determines that they are necessary for their health. This will give the enrollee time to file an exception request. Additionally, low-income beneficiaries should be able to access a supply of medication until the exception or appeal is resolved. As mentioned earlier, for certain types of patients gaps in coverage can be particularly dangerous and CMS should do everything in its power to avoid such gaps.

423.578 (c)(3) –Approved exceptions request
The restriction on applying a special tier for drugs approved on exceptions should be broadened to include drugs approved through redetermination, IRE, ALJ, or MAC. Additionally, a stipulation should be included that the preferred drug formulary drug copayment be the operative copayment when exceptions are approved.

423.600 – Reconsideration by an Independent Review Entity (IRE)
This section provides that if the redetermination is denied, the enrollee may submit a written request for reconsideration by the IRE. The preamble distinguishes this process from the process available for non-drug benefits, wherein a referral to the IRE is automatically made by the MA plan.

The Department suggests that this differential treatment is unwarranted. The preamble suggests that interruption in this referral is necessary so as to get information from the physician regarding medical necessity. However, in practice, drug plans require the

prescribing physician to submit their justification for denied drugs during the exception process. Therefore, this argument appears without merit.

The preamble indicates that many drug appeals will involve small monetary amounts. However, no data is provided to back such an assertion up. In many instances, the drugs are likely to be for a chronic disease and will over time add up to significant amounts of money.

The Department recommends that requests for redetermination, which are denied by the PDP, be automatically forwarded to the IRE by the PDP. The IRE should be authorized to review the cases de novo and to use its own clinical judgment. This is particularly important given the MMA's rather weak provisions with respect to conflicts of interest. CMS should not require that all requests to the IRE be in writing as this will restrict some beneficiaries' access.

423.610 –Right to an ALJ hearing

To determine whether the threshold for accessing the ALJ has been met, CMS should require that the calculation of drug costs include the costs of the drug over the period for which the drug is needed during the contract year. Thus, if the drug is a maintenance drug, then the cost might be the annual cost of the drug. To arbitrarily limit the calculation to a 30 or 60 day supply of the drug would limit beneficiaries' rights under this section.

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

The family size, income and resource definitions established in this Subpart vary significantly from those Illinois uses for its Medicaid program. Forcing the state to establish separate processes to make determinations of eligibility for low-income subsidies is a burden the Department is not in a position to afford. The Department strongly supports efforts to enable states to assist applicants to efficiently use SSA's application processes. If, however, CMS determines that states must independently determine eligibility, the Secretary must exercise the discretion established in 1860D-14(3)(E)(iv) of the Act to permit them to use the same resource methodologies as are used for Medicare cost-sharing even though this will result in variable determinations of eligibility among the states. Barring that, Subpart S should be amended to reimburse states for 100 percent of costs associated with establishing and operating eligibility determinations under the MMA.

Illinois is particularly interested in preserving the benefits of SeniorCare, our existing Pharmacy Plus waiver, for our residents. CMS is urged to modify the proposed rule to clarify that Medicaid FFP will continue to be available to states for the operation of Pharmacy Plus waivers.

423.772 - Definitions

Family Size. This definition is vague as to whether relatives of the spouse of an applicant can count toward family size. This should be made explicit.

This definition of family size will greatly complicate the actual determination of eligibility by states. This is a point that argues strongly for states to be permitted to support applicants in using or applying to SSA but not operating an independent eligibility determination process. Operating its own system will cost Illinois in both systems development and ongoing time spent in application processing – it will add further workload to already strapped eligibility workers.

There is no guidance in the rules as to how a state would determine that a relative was dependent on the applicant or spouse for half of their financial support. For example, could a state rely upon the declaration of the applicant or alternately require documentation that the dependent was claimed on the applicant's or spouse's tax return? This will be a difficult determination to document in other ways and the Department urges CMS to allow states flexibility in this area.

Full Benefit Dual Eligible Individual. Illinois interprets this definition to include persons participating in the state's Medicaid Buy-In under the provisions of the Ticket to Work and Work Incentives Improvement Act and persons eligible pursuant to the state's decision to disregard certain income through section 1902(r)(2). If this is not CMS's intention, the rule must be clarified.

This definition does not take into account the fluctuating nature of Medicaid eligibility. CMS should state clearly in the rule that a person who qualifies as a full benefit dual eligible in the month of application stays in this category for a full 12 months regardless of changes in Medicaid status. This is essential to avoiding confusion and to carry out the simplification mandate of the MMA. Current state and federal systems supporting Part B premium payments by states to SSA on behalf of individuals are not sufficiently efficient and information can lag for months. This is at best a nuisance for dual eligibles receiving Part B subsidies but it will have far more dire consequences if it causes delays in access to essential medications for persons who need Part D subsidies. The fluid nature of Medicaid eligibility is common, especially for persons who spend down to become Medicaid eligible and for persons in Group-Care. CMS must clarify the rules to ensure that eligibility for Part D low-income subsidies will not be similarly erratic.

The rules also fail to account for the retroactive eligibility required for Medicaid. The rules must make clear that persons who were dually eligible during a retroactive period are deemed eligible for the low-income subsidy as well even if the subsidy does not become effective until the month in which they apply for it.

Notwithstanding these changes, for purposes of calculating state participation under Subpart S, only the actual periods of Medicaid eligibility should be counted toward the state's contribution to the program.

Subpart P is silent concerning how or when states must notify CMS or CMS must notify states that an individual qualifies as a full benefit dual eligible individual. Expectations for these transmissions should be made explicit.

Institutionalized Individual. Regarding institutionalized persons, the rules make no provision for persons who may move from institutional to community settings. These transitions are difficult and will be complicated by the imposition of cost sharing once a person is back at home. The rules should provide for phasing out of subsidies for persons who will lose them as a result of leaving an institution. (Many persons are eligible for Medicaid through spend down because of the high cost of institutional care. Often such persons would not be Medicaid eligible in the community.)

It would be appropriate to apply the same cost sharing requirements that are available to institutionalized individuals to those who are enrolled in Home and Community-based Services waivers, including the Illinois Supportive Living Program. In recent years, there has been a move to assist seniors and persons with disabilities in their desire to remain or return to their home or other community setting. This concept is embodied in the President's new Freedom Initiative. However, for those who have significant prescription drug needs, the application of copayments for prescription drugs may act as a barrier for such community living.

Resources. Defining resources for the purposes of the MMA to mean only liquid assets provides another argument in favor of CMS permitting states to support subsidy applicants through assistance to apply to SSA but not requiring states to operate independent eligibility determination processes. This definition of countable assets does not match Illinois' existing Medicaid rules and operationalizing the difference will require extensive system changes as well as unfunded additional staffing resources. Such extra work will materially degrade service to other Medicaid eligible persons.

Other Subsidy Eligible Individuals. Similarly to the dual eligible population, persons who are not dually eligible for Part D and Medicaid but who otherwise are eligible for full subsidies as well as other low-income subsidy individuals, should be made eligible for a full 12 months, regardless of change in status, or income or resources during that period.

423.774 - Eligibility determinations, redeterminations, and applications
General Comments
As noted previously, Illinois strongly urges CMS to extend flexibility to states to fulfill their obligations to make determinations of eligibility through assisting individuals to use SSA application process.

Application Requirements. The rules are vague on the timing within which individuals applying for subsidies must supply all required information. Reasonable time periods for response and notice of missing information should be specified. Also, no standards are established for the amount of time SSA or a state has to complete a determination of eligibility for subsidy.

423.780 - Premium subsidy
The structure of the premium subsidy virtually assures that in regions with larger numbers of PDPs and MA-PDs, persons receiving subsidies will have fewer choices of plans.

Sliding Scale Premium. Illinois has employed a stepped premium structure for its Medicaid Buy-In program rather than a scale based on strict percentage of income. The state's experience has been positive with regard to this approach and The Department recommends that CMS adopt it for Part D. Using a finite set of established premiums is easier to display in a table and consequently makes it easier for beneficiaries to understand what their contributions will be.

Premium Subsidy for Late Enrollment Penalty. The premium subsidy for late enrollment should by 100 percent for at least the first year of the program

Recognizing the complexity of enrolling in and applying for the Part D benefit and subsidy, CMS must acknowledge that large numbers of subsidy eligible persons will fail to apply for the benefit in a timely manner. They must not be penalized for late enrollment. Similarly, the rules must provide that persons who were initially deemed eligible for the subsidy but subsequently lose dual eligibility may not be penalized for late enrollment. These are the poorest and sickest among us and successful negotiation of the complexity of Medicaid compounded by the complexity of Part D subsidy eligibility will require resources and sophistication that CMS cannot reasonably expect them to possess. They should not be penalized for having difficult lives.

423.800 - Administration of Subsidy Program
The rules are silent concerning how quickly PDPs and MA-PDs must act to extend subsidies once notified by CMS of an enrollee's eligibility. Illinois urges CMS to set standards for such action because failure to act promptly will materially affect the health and well being of beneficiaries.

Similarly, the rules are silent as to how quickly reimbursement for prior periods of subsidy eligibility must be made by the PDPs and MA-PDs. The Department urges CMS to set explicit time limits.

Subpart S – Special Rules for States

423.904 - Eligibility determinations for low-income subsidies
CMS should state clearly that states could satisfy their obligations to make determinations and redeterminations through taking applications and submitting them on behalf of applicants to SSA. Furthermore, the rules should offer states the flexibility to take or process subsidy applications through state agencies or other entities that are not the single state Medicaid agency, so long as such other agency or entity are operating under the terms of an interagency agreement with the single state agency. For example,

in Illinois, DoA is widely regarded by seniors as the agency that serves them and DoA is currently conducting outreach and enrollment for both the state's Pharmacy Plus and SPAP. It is essential for the success of Medicare Part D in Illinois that DoA be permitted to play a key role in educating seniors, assisting them to complete applications and perhaps in making determinations of eligibility for low income subsidies.

423.904 (c) - Screening for Medicare Cost Sharing
The rules are vague as to states' obligation to screen individuals for eligibility for Medicare cost sharing when those individuals apply to SSA for low income subsidies. States have no ability to screen persons unless they apply to the states. Illinois gladly accepts responsibility to consider persons eligible for any Medicaid program when that person contacts the state for information or to apply. The rule should be clarified to assure states are not called to account for something they cannot reasonably accomplish.

Illinois anticipates increased costs due to increased enrollment in Medicare cost-sharing programs. The Department anticipates up to 20,000 new enrollees at a cost of between $10-20 million for the state. While the Department fully supports enrollment of eligible Illinoisans in to these programs, the Department wishes to point out that it will put a significant financial strain on the entire Medicaid program. The Department suggests that Congress should consider providing states with either an enhanced match or full federal subsidy for this expanded enrollment.

423.904 (d) - Application Process
In instances where states do make determinations of eligibility for low-income subsidies, the rules should clearly provide state flexibility to accept all information from applicants or their representatives on the basis of the applicant's declaration of the validity of the information. That is, states should be permitted great flexibility in defining the documentation necessary for the information in the application.

423.906 - General Payment Provisions
Regular Federal Matching
As mentioned previously in our comments on Subpart P, the Department strongly supports efforts to enable states to assist applicants to efficiently use SSA's application processes. If, however, CMS determines that states must independently determine eligibility using family size, income and resource definitions established in Subpart P, CMS must amend Subpart S to reimburse states for 100 percent of costs associated with establishing and operating eligibility determinations under the MMA.

423.908, 423.910 – Phased-down State contribution ("the Clawback") to drug benefit costs assumed by Medicare
Enactment of this section of the MMA represents an alarming new way of doing business with respect to the Federal government's imposition upon states. In what the Department believes is an unprecedented move, the U.S. Congress will create a federal benefit and will require states to provide significant financing without allowing states to control in any way the program's costs. In fact, under the NPRM states are excluded as potential

PDP sponsors and yet the law requires states to pay for coverage of a large portion of the enrollees of this program.

The Congressional Budget Office estimates that states will pay $88 billion toward Part D coverage between 2006 and 2013.[11] These payments will likely be the largest single flow of funds from state to federal government in the years after program initiation. Neither the House or Senate passed versions of the MMA contained "the clawback."[12] However, "the clawback" was inserted during conference negotiations as a way of off-setting the expense of this new federal benefit. In fact, "the clawback" represents 25 percent of the offsets contained in the bill over the time period of 2006 to 2010.[13]

It may be suggested that states advocated for the transfer of responsibility for prescription drug coverage of dual eligibles to Medicare and that is true. However, states did not advocate transferring control with state retention of financial responsibility. While state contributions are phased-down in the MMA, they are far from eliminated. At full phase-down, states are still responsible for 75 percent of their share of current funding for dual eligibles. This state contribution, unlike previous proposed House of Representative's legislation, is permanent.[14]

While it is true that states contribute to the cost of certain Medicare cost-sharing programs, in those instances there is a clear benefit to states from such a contribution as Medicaid is the payor of last resort and enrolling beneficiaries in Medicare reduces states' overall health care costs throughout the Medicaid program. In contrast, Medicare beneficiaries enrollment in part D has no overall effect on Medicaid beneficiary's enrollment in Medicare generally. Furthermore, the portion of Medicare part B that the states subsidize is limited to only 25 percent of the part B cost. In the case of part D, the only entity that benefits from state contributions is the federal government.

Additionally, enrollment of dual eligibles into part D will hurt states' ability to negotiate competitive drug prices for their entire Medicaid program. Currently, 80 percent of prescribed Medicaid drugs are for enrollees over the age of 65 and persons with disabilities. Fifty two percent of Medicaid drug spending is attributable to dual eligibles nationally.[15] For states to loose such a large amount of purchase and with it the ability to negotiate better prices, without their being relieved of the responsibility of paying for the dual eligibles is to the detriment of state's fiscal health.

There are a variety of other aspects of "the clawback" that are particularly unfair to certain states, including Illinois. First "the clawback" is based on the number of fully dual eligibles that a state has. So states that have more generous coverage for dual

[11] see www.cbo.gov/showdoc.cfm?index=5668&sequence=2&from=0
[12] Health Policy Alternatives "Prescription Drug Coverage for Medicare Beneficiaries: A Side-by-Side Comparison of S.1 and H.R. 1 and the Conference Agreement (H.R.1)," November 26, 2003
[13] Kaiser Family Foundation ""The Clawback:" State Financing of Medicare Drug Coverage" by Andy Schneider, June 2004.
[14] H.R. 4954 "Medicare Modernization and Prescription Drug Act of 2002."
[15] Kaiser Family Foundation "Medicaid Prescription Drug Spending and Use," by Brian Bruen and Arunabh Ghosh, June 2004

eligibles are penalized with increased costs. Illinois expanded coverage through the Assistance to Aged, Blind and Disabled program (AABD) over the last several years. Whereas coverage was previously limited to those with incomes below 40 percent FPL, current coverage extends to those with incomes up to 100 percent FPL. Today, 87,000 Illinoisans covered under AABD have incomes above the federal minimum coverage level.

Second, "the clawback" is calculated based on a state's Per Capita Expenditures(PCE) on prescription drugs in 2003 for full dual eligibles. States that provided the most generous coverage are, therefore, again penalized. In 2002, Illinois spent $1,237 per dual eligible. This was the 8th highest level of spending per person nationally. Unlike many other states, Illinois does not limit Medicaid beneficiaries' access to prescription drugs by limiting the number of prescriptions they may have each month. Some states limit the number of prescriptions a beneficiary may fill to as few as 3 per month. However, "the clawback" does not differentiate between states that have comprehensive benefits and those that have a far more limited benefit. In fact, "the clawback" rewards states with the most limited coverage.

The Department recognizes that the points listed above require congressional action and The Department urges Congress to revisit this issue. Our first preference would be a full elimination of "the clawback." Failing such a revision, The Department suggests that "the clawback" be revised to only count federally mandated dual eligibles and the 2003 figure be adjusted to reflect coverage levels comparable to the Medicare part D benefit.

Our third area of concern is one that CMS has authority to address under the NPRM and it relates to the applicable growth factor used to inflate PCE in 2003 to 2006. Section 103(b) of the MMA specifies that the applicable growth factor for 2004, 2005, and 2006 will be based on the most recent National Health Expenditure projections for the years involved with respect to increases in the per capita amount of prescription drug expenditures. The Department suggests that CMS consider whether the per capita increases in National Health Expenditures for Medicaid prescription drugs are in fact lower than the general per capita increases in National Health Expenditures. CMS has verbally indicated that they might be willing to consider this option. Illinois' per capita drug spending in Medicaid as a whole over the last several years has been lower than the National Health Care Expenditures Projections generally. For instance, Illinois Medicaid experienced per capita drug spending increases of 12.2 percent in FY02, 8.7 percent in FY03, 12.4 percent in FY04 and estimates an increase of 8.2 percent in FY05. These increases are below those reported or projected by the National Health Care Expenditures for prescription drugs, which were 14.3 percent in 2002, 12.3 percent in 2003, projected at 11.9 percent in 2004 and projected at 11.3 percent in 2005. So for instance $100 of prescription drug spending in Illinois Medicaid in 2003 if inflated using general National Health Care Expenditure increases for prescription drugs equals $139.9 of prescription drug spending in 2005 but using Illinois Medicaid's own growth rate equals $130.8 of prescription drug spending in 2005. States such as Illinois have engaged in aggressive cost containment achieving significant savings through negotiations with manufacturers, while at the same time maintaining access to a wide array of prescription drugs and

avoiding limiting beneficiaries' number of prescriptions filled per month. As a testament to Illinois' cost containment abilities, it should be noted that supplemental rebates negotiated from manufacturers increased by 84 percent between FY03 and FY04. The Department should not be penalized for such efficiency.

Using an inflation factor that is higher than our own inflation could result in Illinois paying more for dual eligibles than he Department would if they had not been transferred for prescription drug coverage to the Medicare part D program. While the Congressional Budget Office estimates $17 billion in savings to states due to the transfer of coverage for dual eligibles, CBO admits that these savings will not be evenly distributed across all states.[16] It is possible that large states such as Illinois, which have been involved in extensive cost containment since 2003 will be significantly disadvantaged by "the Clawback" unless CMS utilizes an appropriate growth factor.

The Illinois Department of Public Aid appreciates the opportunity to comment and make recommendations. If there are any questions about these comments, please contact Dr. Anne Marie Murphy, Illinois Medicaid Director at (217)782-2570.

Sincerely,

Anne Marie Murphy, Ph.D.
Illinois Medicaid Director
Illinois Department of Public Aid
201 S. Grand
Springfield, IL 62763

[16] "Savings for individual states may not be proportional to the overall amount" A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit July 2004 found at www.cbo.gov/showdoc.cfm?index=5668&sequence=2&from=0

CMS-4068-P-1364

Submitter : **Date & Time:** **10/04/2004 11:10:16**

Organization :

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-1364-Attach-1.doc

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-11-24
Baltimore, MD 21244-1850

Dear Dr. McClellan:

On behalf of Oregon Medicare beneficiaries, I would like to thank you and your staff for the immense work already completed on the implementation of the numerous facets of the Medicare Modernization Act of 2003. The expansion of access for necessary medications will benefit many Oregonians. However, I believe that the proposed current regulation implementing the Part D medication benefit could inadvertently and negatively impact some vulnerable Oregonians. I would like to highlight the following concerns:

- We need to carefully plan the transition for Medicare/Medicaid dual eligibles into the new Medicare Drug plans, each with their own formulary and network of pharmacies. Six weeks is not adequate time to complete the necessary tasks, especially for those living in congregate care. Under separate cover, the Oregon Department of Human Services is submitting detailed comments that offer potential solutions. This issue must be resolved in order to protect the health of these Oregonians.

- I believe that Oregon already fulfills the duty outlined in the Act to determine eligibility for the Medicare low-income subsidy. We determine eligibility for the various Medicaid-related programs that will be deemed eligible for the subsidy. In the days of very limited resources, I ask that the regulation be revised to make clear that Social Security, not state Medicaid offices, will determine eligibility for the remainder of the population.

- The regulations need to guarantee access to long-term care pharmacies, at no additional cost for Medicare/Medicaid dual eligibles in nursing and other facilities. They provide necessary safeguards to protect from medication errors.

Oregon remains a committed partner in increasing pharmacy access for seniors and people with disabilities. I appreciate your consideration of Oregon's comments on the regulations. Medicare beneficiaries, as some of the most vulnerable Oregonians, deserve our concerted effort to fairly implement their medication benefits under the Medicare Modernization Act.

Sincerely,

THEODORE R. KULONGOSKI
Governor

TRK:EKS/ejb
c: Oregon Congressional Delegation
The Honorable Peter Courtney, President, Oregon Senate
The Honorable Karen Minnis, Speaker, Oregon House of Representatives
Gary Weeks, DHS

CMS-4068-P-1365

Submitter : Dr. Brenda Warren **Date & Time:** 10/04/2004 11:10:51

Organization : Accredo Health Group

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I recommend that beneficiaries be given the right to 'choose' their pharmacy. All persons need interaction with their pharmacist in order to properly comply with their medication regimen. My experience as a Community Pharmacist indicates that this is especially true of Sr. Citizens. There is no substitute for personal interaction with the pharmacist. I believe that any pharmacy provider willing to accept the terms of the plans contract should be able to participate. Beneficiaries should not have to pay more to continue service with their usual pharmacy because it is not designated as 'in network'.

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

I propose that Medication Therapy Management be further defined such that patients with two chronic disease states and two or more medications be eligible for medication therapy management services. A beneficiary would also qualify if on a high cost medication (possibly defined as greater than $10,000 per year). Pharmacists, as the health care professionals who are experts on medication management, should be the preferred provider of these services.
Medication therpay management needs to have real value to the beneficiary and be more than the reimbursement-type DUR messages that PBMs currently provide.

CMS-4068-P-1366

Submitter : Mr. Timothy Becker **Date & Time:** 10/04/2004 11:10:27

Organization : Mercy Family Pharmacies

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

In determining who shall be able to bill for Medication Therapy Management I urge you to assess the Pharmaceutical Case Management program being using for high risk Medicaid patients in the state of Iowa. This program began as a demonstration project but has been funded past the study phase because of benefits to patient care. In PCM, local pharmacists in consort with physicians work to maximize the benefit of drug therapy while minimizing adverse events. The study was designed by researchers at the University of Iowa and is proof of the benefits to be derived by having patients interact with their local pharmacists face-to-face to manage medication therapies. Such results can not be extrapolated to phone conversations from pharmacists employed by PBM's in remote locations. For these reasons it is my fervent desire that CMS recognize pharmacists as valid providers of Medication Therapy Management services. Thank you.

CMS-4068-P-1367

Submitter : Ms. Judi Hilman **Date & Time:** 10/05/2004 12:10:59

Organization : Utah Issues

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Date: October 4, 2004

To: The U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
From: Utah Issues, Center for Poverty Research and Action
Re: Comments on Proposed Regulations
File Code [CMS-4068-P]

Thank you for the opportunity to provide feedback on the proposed MMA regulations. In lieu of specific feedback we would like to re-affirm the extensive feedback you have received from the Medicare Consumers Working Group and to elaborate on several points.

1. We strongly agree that the Preamble!|s !Ygood intentions!| should be reflected in the actual body of the regulation. For example:

?X 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. Requirement for written notice is critical and should be specified.
?X Further, clear instructions should be provided for receiving written notice in languages other than English.

2. Given the extensiveness and thoughtfulness of the feedback along with the large number of issues not yet addressed in the proposed regulations, please (revise the regulations, address the need for technical and corrective amendments) and then allow for a second round of feedback.

3. Please make provisions in the regulations to maximize cost reductions and facilitate cost containment strategies in the future. Also, please ensure funding for research that is needed to build savings into the program through disease management and other quality improvement initiatives.

4. Given the functional and cognitive barriers of the target population, please simplify the program as much as possible. Also please ensure practical understanding of the program and proposed changes for vulnerable populations, namely: the lower income, people with cognitive deficiencies, the sicker, and those with English literacy problems. Implementation of the drug discount cards falls short of the need in this respect.

Please consider the following additional request (not highlighted in the feedback from the Medicare Consumers Working Group):

5. Since state Medicaid programs will be asked to facilitate practical implementation and transition for low-income Medicare beneficiaries, they should be allocated sufficient funding for outreach, education, etc. State Medicaid budgets have yet to recover from the economic downturn. States like Utah that attempted to minimize harmful cuts, have paid the price by cutting back on resources for eligibility and outreach systems.

Thank you for your consideration of our feedback.

Judi Hilman

Health Project Director

Utah Issues, Center for Poverty Research & Action

331 S. Rio Grande Suite 60

Salt Lake City, Utah 84101

phone (801) 521-2035 ext. 103 toll free: (800) 331-5627

fax: (801) 355-7540

email: judi@utahissues.org

CMS-4068-P-1367-Attach-1.doc

UTAH ISSUES
Center for Poverty Research & Action
331 South Rio Grande, Salt Lake City, UT 84101
(801)521-2035; (800)331-5627; FAX (801)355-7540
judi@utahissues.org www.utahissues.org

Date: October 4, 2004

To: The U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
From: Utah Issues, Center for Poverty Research and Action
Re: **Comments on Proposed Regulations**
File Code [CMS-4068-P]

Thank you for the opportunity to provide feedback on the proposed MMA regulations. In lieu of specific feedback we would like to re-affirm the extensive feedback you have received from the Medicare Consumers Working Group and to elaborate on several points.

1. We strongly agree that the Preamble's 'good intentions' should be reflected 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. Requirement for written notice is critical and should be specified.
- Further, clear instructions should be provided for receiving written notice in languages other than English.

2. Given the extensiveness and thoughtfulness of the feedback along with the large number of issues not yet addressed in the proposed regulations, please (revise the regulations, address the need for technical and corrective amendments) and then allow for a second round of feedback.

3. Please make provisions in the regulations to maximize cost reductions and facilitate cost containment strategies in the future. Also, please ensure funding for research that is needed to build savings into the program through disease management and other quality improvement initiatives.

4. Given the functional and cognitive barriers of the target population, please simplify the program as much as possible. Also please ensure practical understanding of the program and proposed changes for vulnerable populations, namely: the lower income, people with cognitive deficiencies, the sicker, and those with English literacy problems. Implementation of the drug discount cards falls short of the need in this respect.

Please consider the following additional request (not highlighted in the feedback from the Medicare Consumers Working Group):

5. Since state Medicaid programs will be asked to facilitate practical implementation and transition for low-income Medicare beneficiaries, they should be allocated sufficient funding for outreach, education, etc. State Medicaid budgets have yet to recover from the economic downturn. States like Utah that attempted to minimize harmful cuts, have paid the price by cutting back on resources for eligibility and outreach systems.

Thank you for your consideration of our feedback.

CMS-4068-P-1368

Submitter : Ms. Alida Montiel **Date & Time:** 10/05/2004 12:10:22

Organization : Inter Tribal Council of Arizona

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See transmittal letter from the Inter Tribal Council of Arizona and the attached comments.

CMS-4068-P-1369

Submitter : Mr. Bill Donohue **Date & Time:** 10/05/2004 12:10:05

Organization : Piedmont Down Syndrome Support Network

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached word document

CMS-4068-P-1369-Attach-1.doc

October 4, 2004

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

To Whom It May Concern:

The Piedmont Down Syndrome Support Network welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The PDSSN is a Down syndrome parent support group. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning

of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

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

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

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

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

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

of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

- people who are dually eligible for Medicare and Medicaid
- people who live in nursing homes, ICF-MRs and other residential facilities
- people who have life threatening conditions
- people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and

appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Bill Donohue
Piedmont Down Syndrome Support Network

Submitter : Mr. Jeff Mitchell **Date & Time:** 10/05/2004 12:10:42

Organization : Pharmacy Student

Category : Congressional

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

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit.

As a pharmacy student, I know that this plan, and how it will be implemented, will have a direct effect on my future. But more importantly, it will affect the kind of care I will be providing to my patients. Therefore, I have a few suggestions and comments that I hope you will consider.

Subpart C: Benefits & Beneficiary Protections

Pharmacy Access Standards: CMS should revise the the current standard, which alllows plans to make distinctions and designate pharmacies within the network as "preferred" and "nonpreferred", to require plans to meet the TRICARE requirements on a local level, not on the plan's overall service level. This is the only way to ensure that all beneficiaries have convenient access to a local pharmacy, and I want to be able to serve all my patients.

Any Willing Provider: If plans can distinguish between pharmacies, it could allow plans to drive beneficiaries to a particular pharmacy. This is the exact opposite of Congressional intent, which was to ensure that patients could continue to use the pharmacy and pharmacist of their choice. "Access" would be a misnomer if patients are coerced to use other pharmacies. So I strongly feel that only preferred pharmacies should count when evaluating whether a plan's pharmacy network meets the pharmacy access standard.

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 helath care professionals to provide MTM services and determine which services each beneficiary needs. This is the one area in my school experience that is stressed more than any other concept. In short, this is exactly what I am being trained to do, and in my opinion more so than other health professional today.

Thank you for considering my views on these very important issues.

Sincerely,

Jeff Mitchell
(919) 451-2171
jmitch@unc.edu

CMS-4068-P-1371

Submitter : Ms. Alida Montiel **Date & Time:** 10/05/2004 12:10:03

Organization : Inter Tribal Council of Arizona

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Comments submitted by the Inter Tribal Council of Arizona, a tribal organization are attached. I experienced difficulty transmitting these comments a short time ago.

CMS-4068-P-1371-Attach-1.doc

CMS-4068-P-1371-Attach-2.pdf

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 these comments 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. (Note: In Arizona where specific American Indian data is collected, it is noted in Arizona Health Status and Vital Statistics 2001 that the American Indian life expectancy is 54.3 years).
- 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 Medicare, Medicaid and SCHIP Benefits Improvement Act (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.

[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.

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

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

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

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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.

would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

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

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

- 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 to protect 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**

[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.

$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 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.*

[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."

***

"§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 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

[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

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.

19 TRIBES

INTER TRIBAL COUNCIL of ARIZONA

MEMBER TRIBES
AK-CHIN INDIAN COMMUNITY
COCOPAH TRIBE
COLORADO RIVER INDIAN TRIBES
FORT McDOWELL YAVAPAI TRIBE
FORT MOJAVE TRIBE
GILA RIVER INDIAN COMMUNITY
HAVASUPAI TRIBE
HOPI TRIBE
HUALAPAI TRIBE
KAIBAB-PAIUTE TRIBE
PASCUA YAQUI TRIBE
QUECHAN TRIBE
SALT RIVER PIMA-MARICOPA INDIAN COMMUNITY
SAN CARLOS APACHE TRIBE
TOHONO O'ODHAM NATION
TONTO APACHE TRIBE
WHITE MOUNTAIN APACHE TRIBE
YAVAPAI APACHE NATION
YAVAPAI PRESCOTT INDIAN TRIBE

October 4, 2004

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

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

Dear Administrator:

On behalf of the Inter Tribal Council of Arizona (ITCA), 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 Inter Tribal Council of Arizona appreciates the efforts of the Tribal Technical Advisory Group to the Centers for Medicaid and Medicare Services (CMS) and the Medicare and Medicaid Policy Committee (MMPC) of the National Indian Health Board in providing assistance and clarification of these issues.

The attached comments address issues related to the impact the 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 an 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 the Center for Medicare and Medicaid Services (CMS) to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely,

Alida V. Montiel,
Health Systems Analyst

Attachment -- Part D Comments

2214 North Central Ave. • Suite 100 • Phoenix, Arizona 85004 • (602) 258-4822 • Fax (602) 258-4825

CMS-4068-P-1372

Submitter : Kimberly Holdener **Date & Time:** 10/05/2004 01:10:09

Organization : University of Wisconsin Hospital and Clinics

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file for my comments

CMS-4068-P-1372-Attach-1.doc

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

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As a clinical pharmacist in the hospital and ambulatory clinic settings, I am deeply concerned with the rules as they are currently proposed.

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

The new Medicare Part D rules are important to me because I currently am involved in what can be defined as "Medication Therapy Management Services." I work at the ambulatory Kidney Clinic associated with the hospital at which I am employed to monitor and manage anemia therapy for chronic kidney disease patients. Under a collaborative practice agreement with the nephrologists, I evaluate and order labs, meet with and educate patients, and adjust doses of erythropoeitic hormones and iron used for anemia. Many publications have shown that pharmacist managed anemia therapy of kidney disease patients is at least as effective as physician managed anemia therapy if not better.

I also provide many important MTM services in my role as a clinical pharmacist on the inpatient transplant unit at the hospital for which I work. On a daily basis I monitor and adjust patients' medication therapy in the areas of CMV prophylaxis, renal dosing, and pharmacokinetic monitoring. I also educate patients about transplant medications in group and individual settings.

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

CMS rules must allow for hospital pharmacies to be included not precluded. Plan sponsors should be required to establish CMS specified MTM services. In addition, MTM services should be able to be provided in conjunction with and outside of product dispensing.

CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM

services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber. Plans should also be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services. Co-payment reductions should not be provided to beneficiaries who receive care at "preferred" pharmacy providers as this will create incentives for beneficiaries to use low cost and potentially low quality providers which will ultimately increase the cost of patient care.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services. Plans should not be able to limit the number of pharmacy providers, and all pharmacies should be able to dispense prescription medications for beneficiaries who receive care in their facilities.

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors, otherwise many of the nation's foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerely

Kimberly E. Holdener, PharmD
Clinical Pharmacist
University of Wisconsin Hospital and Clinics

Submitter : Mr. Jason Makii **Date & Time:** 10/05/2004 01:10:24

Organization : The Ohio State University College of Pharmacy

Category : Individual

Issue Areas/Comments

Issues 1-10

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

Pharmacists have more access to patients than any other medical profession. They also know the most about the medications the patientis on, and are THE ideal provider of medication therapy management services. If pharmacies are separated into preferred and non-preferred sub categories, the benefit to the Patient will decrease dramatically. Numerous patients have established and trusting relationships with their pharmacist, and a preferred/non-preferred list would ruin that valued relationship. Patients would have to leave their current pharmacy and seek medication information and therapy guidance from someone that they do not know and more importantly do not trust.
I feel that the MTM program is a move in the right direction for not only the profession of the pharmacist, but for the overall positive well being of the target population: The Patient.

Submitter : Mrs. Marialice Bennett **Date & Time:** 10/05/2004 02:10:06

Organization : The Ohio State University

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:

Wanted to thank you for all of your hard work in revising and updating Medicare regarding the prescription drug benefit. I would like to take this opportunity to offer some comments for CMS to consider as you develop the final regulations.

Regarding Subpart C: Benefits and Beneficiary Protections:

I would like to suggest that you revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local, and not the plan's overall, service level. If plans meet the standard on the local level, that is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and would allow my patients to continue to use the pharmacies near their home or work.

Additionally, 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 may identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Further, plans should not be allowed to count their non-preferred pharmacies when evaluated as to whether they meet the access standards. Congress seems to have intended that patients have fair access to their local pharmacy. As the regulation is currently written, it could lead to a restriction of access for many of my patients and Americans in general. I would ask that CMS require plans to offer a standard contract to all pharmacies.

Regarding 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 am also excited to see that CMS has recognized that pharmacists will likely be the primary providers of MTM services. However, I am concerned that leaving the decision to the plans to choose their provider may lead to the choice of less qualified providers, or worse, providers that they pay to perform these services is a conflict of interest to say the least.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently work in a physician's office practice and offer medication management services for diabetes, hypertension, depression, and smoking cessation to highlight a few. Plans should be encouraged to use my services and the services of all pharmacists helping patients each and every day. I believe that I speak for my profession when I say that our primary goal is to help patients gain the best benefit from their medications, with the highest level of safety, and at the lowest possible cost to both the patient and the system.

In conclusion, I would like to thank you for allowing me the opportunity to express my views and applaud you for all of your hard work.

Thanks so much,

Marialice S. Bennett, RPh

Pharmacy Director
University Health Connection

The Ohio State University
500 West 12th Ave., Room 100
Columbus, OH 43210
(614)688-0713
bennett.10@osu.edu

CMS-4068-P-1375

Submitter : Mr. charles joiner **Date & Time:** 10/05/2004 02:10:27

Organization : alabama pharmacy association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am commenting as a community pharmacist and the role we play as a provider of health care. I believe community pharmacies should have a level playing field in regard to mail order pharmacies. We should be able to offer a 90-day supply of maintenance medication just like mail order facilities. You say that plans may charge more when they use a local pharmacy instead of a mail order facility. This is not a level and fair playing field.

Secondly, CMS should require all plans to offer a standard contract to all pharmacies who want to participate and the plans should not be allowed to negotiate different terms and conditions with a subset of pharmacies. If plans are allowed to establish preferred pharmacies, they are using coercion and manipulation to lower their costs, not true competition. This will negate the pharmacy access standard. Patients will use the pharmacies that give them the best service.

In closing, I would like to thank you for allowing us the opportunity to comment on the proposed regulations.

CMS-4068-P-1376

Submitter : Mr. NEIL DAVIDSON **Date & Time:** 10/05/2004 02:10:06

Organization : LUBBOCK STATE SCHOOL PARENTS' ASSN

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

October 4, 2004

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

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

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

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

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

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

Thank you for your consideration.

Sincerely,

Neil Davidson
President, Lubbock State School Parents!| Assn.
5221 28th Street
Lubbock, Texas 79407
Hm (806) 793-0134
Wk (806) 745-1021 ext. 1412
Email: neilandroseanna@yahoo.com

CMS-4068-P-1376-Attach-1.txt

Voice of the Retarded

5005 Newport Drive, Ste 108 * Rolling Meadows, IL 60008 * 847-253-6020 * 847-253-6054 fax * vor@compuserve.com * http://www.vor.net

September 22, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21224-8014

Sent by regular mail and electronically (http://www.cms.hhs.gov/regulations/ecomments)

On August 3, 2004, the Centers for Medicare & Medicaid Services released proposed regulations relating to section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Included within this new law is a shift of payment authority from the states to the federal government for the purpose of providing medication coverage to people eligible for both Medicare and Medicaid ("dual eligibles"). Starting in 2006, this new Medicare prescription medication benefit will replace Medicaid prescription coverage for low income beneficiaries. Although a state may continue to provide "wrap around" prescription medication benefits through its Medicaid plan to compliment the new Medicare coverage, any such supplemental coverage will be at the state's option.

Long term care facilities receive special mention in the new law. Although certain dual eligibles will be subject to Medicare premiums and cost sharing, full dual eligibles, including dual eligibles in "long term care facilities," are exempt from co-payments. According to the proposed regulations, the definition of "long term care facility" is in question:

> "We request comments regarding our definition of the term long-term care facility in §422.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in §440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs." [69 Fed. Reg. 46648-49 (Tuesday, August 3, 2004)].

VOR strongly agrees. As noted later in the regulations –

> "It is particularly important to ensure that the drug needs of institutionalized Part D enrolles – most of whom are dually eligible for Medicare and Medicaid – are met. The institutionalized population is generally more sensitive to and less tolerant of many medications." [69 Fed. Reg. 46661 (Tuesday, August 3, 2004)].

CMS, in this statement, makes the best claim for including in the definition of "long term care facilities" ICFs/MR. Residents of ICFs/MR are the most fragile of the population with mental retardation (see attached, "*Characteristics of Large State MR/DD Facilities*"). In addition to severe and profound mental retardation and multiple functional limitations, most ICF/MR residents also experience chronic medical conditions requiring prescription medication intervention (e.g., seizures, psychosis, etc.). Although the exact number of ICF/MR residents that are also dually eligible for Medicare and Medicaid is difficult to quantify statistically, existing information indicates that they are a significant number. This hypothesis is especially compelling when one considers that nearly 66% of all individuals in public ICFs/MR are more than 40 years old and may receive Medicare survivor benefits from a deceased parent(s), in addition to their Medicaid eligibility (see attached, "*Characteristics of Large State MR/DD Facilities*").

With regard to accessing medications, most ICFs/MR contract with long term care pharmacies and it is critical that individuals continue to access prescription medications through these established vendors. For any population, continuity of medication benefits is critical.

Given that ICFs/MR are the present safety net of the system for persons with mental retardation who also experience complex medical conditions – the "intensive care unit" of our service system – VOR also supports including individuals receiving home and community-based waiver supports in the definition of "institutionalized." Waiver placement eligibility criteria is **identical** to eligibility for ICF/MR placement. Due to ongoing, wholesale efforts to serve almost all of the ICF/MR-eligible population in less restrictive waiver settings, it seems misguided and even dangerous to transfer or divert these individuals from ICF/MR supports and then also restrict their prescription medication options simply because of where they are now living. As established, the severity of cognitive disabilities and related medical conditions in community waiver settings will mirror the conditions of ICF/MR residents. Furthermore, as individuals age, or the severity of a medical condition worsens, some waiver participants will be (re)admitted to ICFs/MR. Continuity of benefits would be enhanced if the definition of "institutionalized" includes our waiver population.

For all the above reasons, eligible individuals on waiting lists for ICFs/MR and HCBS services should also be included.

Thank you for the opportunity to comment and for your consideration of VOR's submission. For more information please contact:

Mary McTernan
President
Voice of the Retarded
201 Brooksby Village Dr., Apt. 508
Peabody, MA 01960
978-535-2472 phone
978-535-0472 fax

Tamie Hopp
Executive Director

5005 Newport Drive, Suite 108
Rolling Meadows, IL 60008
605-399-1624 direct
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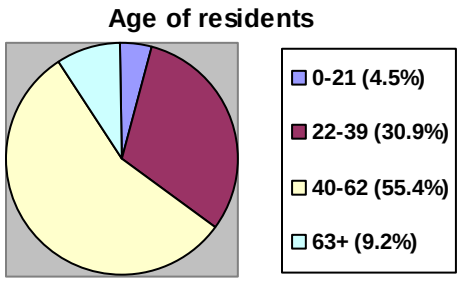
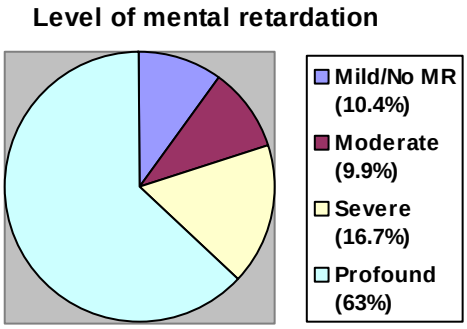
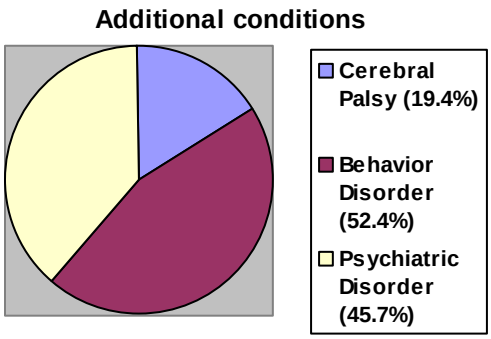
847-253-6054 alternate fax
vor@compuserve.com

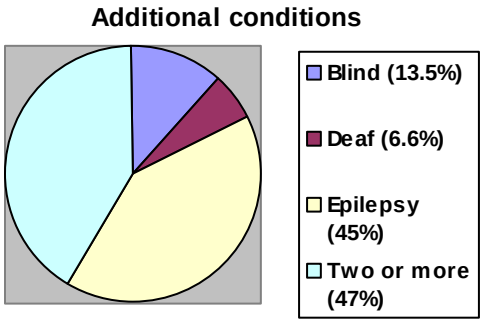
Characteristics of Residents of Large State MR/DD Facilities
June 30, 2002

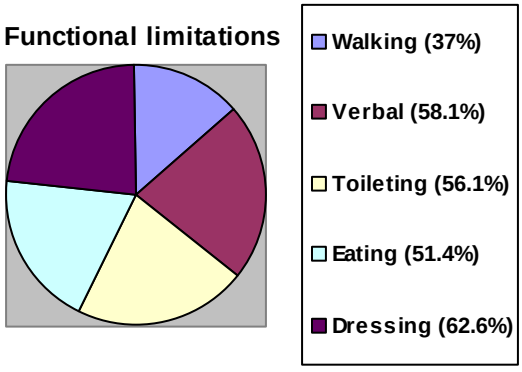
Source: "Residential Services for Persons with Developmental Disabilities: Status and Trends Through 2002," Research and Training Center on Community Living, Institute on Community Integration/UCEDD, University of Minnesota (June 2003).











Submitter : Dr. Bella Mehta **Date & Time:** 10/05/2004 03:10:39

Organization : Dr. Bella Mehta

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

Centers for Medicare and Medicaid Services
Dept Health and Human Services
Attn: 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 drug prescription benefit. As a practicing pharmacist and an educator, I would like to offer the following items for consideration as CMS draws final regulations:

Subpart C Benefits and Beneficiary Protection
1) I am concerned that the intent of Congress to provide fair access for patients to all pharmacies is not being addressed. I believe that CMS should offer patients the access to a standard contract to all pharmacies to ensure equal opportunity and access for patients to receive quality health care.
2) Please consider revision to meet the TRICARE pharmacy access at the local level to better serve the needs of the patient

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Plan
1) I appreciate that CMS recognizes pharmacists as the primary providers for services and that it allows for consideration of individualization of patient management to allow for items such as health assessments, medication therapy plan and monitoring of medications. Please also consider that allowing the decision of who will provide the necessary up to the plans may allow for less qualififed providers to try to provide these vital services.

2)Given the easy access, the skilled training, and the knowledge base, pharmacists are the ideal professionals to provide MTMS services. I currently provide these services at The Ohio State University College of Pharmacy Clinical Partners Program. Please encourage plans to use my services so that I can continue to provide quality care to my patients.

Thank you for considering my views.
Bella Mehta, Pharm.D., R.Ph.

Issues 1-10

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

As a pharmacist from Columbus Ohio who provides services to improve patient health outcomes, I would like to comment on MTMS services under Part D. Pharmacists are the recognized medication experts on health care teams and are therefore the most qualified health professionals to provide MTMS. I hope that CMS takes into consideration the following:1) That patients with 2 or more disease states or on 2 or more medications qualify for MTMS, 2) That plans notify pharmacists who can qualify for MTMS and that this is done at minimum every 2 months, 3) That plans must be required to pay the same fee for all providers of MTMS services, 4) That plans do not require members to obtain services from a specific place/pharmacy - that there is choice for the beneficiaries, 5) and that MTMS can occur independent of a product or in conjunction with a product. I fully support the Medication Therapy Management Services and Program Criteria as defined by the 11 national pharmacy organizations. (http://www.aphanet.org/lead/MTMS_definition_FINAL.pdf)

CMS-4068-P-1378

Submitter : Mr. Eric Appleberry **Date & Time:** 10/05/2004 03:10:28

Organization : Mr. Eric Appleberry

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-1378-Attach-1.doc

October 4, 2004

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

To Whom It May Concern:

I welcome the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions, which includes me.

I am permanently and completely disabled with a spinal cord injury, have chronic neuropathic pain and going to be on numerous controlling medications for the rest of my life.

The following are critical recommendations from me are in the name those with disabilities:

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

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

DESIGNATE SPECIAL POPULATIONS WHO WILL RECEIVE AFFORDABLE ACCESS TO AN ALTERNATIVE, FLEXIBLE FORMULARY:

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death,

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

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

* people who are dually eligible for Medicare and Medicaid
* people who live in nursing homes, ICF-MRs and other residential facilities
* people who have life threatening conditions
* people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN EMERGENCIES:

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

Thank you for your consideration of our views.

Eric Appleberry

Submitter : Dr. Jennifer James **Date & Time:** 10/05/2004 03:10:42

Organization : UConn School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Medication therapy management services should be available to all patients with benefits. MTMS appropriately establishes the pharmacist as the provider of health care related to medications. Pharmacists are the best educated members of the health care team when it comes to drug therapy expertise. The existing network of pharmacists practicing in our community pharmacies is ideally positioned to provide these services. Adequate compensation should be afforded the pharmacist both for the time to render and document the service as well as the value of their expertise.

CMS-4068-P-1380

Submitter : Dr. Paul Bush **Date & Time:** 10/05/2004 04:10:49

Organization : Medical University of South Carolina

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4068-P-1380-Attach-1.doc