CMS-4068-P-801

Submitter : Miss. Linda Huynh **Date & Time:** 10/03/2004 05:10:57

Organization : UNC School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

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

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CMS-4068-P-802

Submitter : **Date & Time:** 10/03/2004 06:10:29

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-4068-P-802-Attach-2.doc

CMS-4068-P-802-Attach-1.doc

October 3, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

I appreciate having the chance to voice my comments on the proposed regulation to implement the Medicare prescription drug benefit. As a student pharmacist, the final regulations will have an effect on me as a future pharmacist. Therefore, I would like to offer my comments for consideration as CMS develops the final regulation.

Subpart C: Benefits and Beneficiary Protections

Please revise the pharmacy access standard to require plans to meet the TRICARE requirements on a local level, not on the plan's overall service level. This is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.

If plans are allowed to charge a higher price for an extended supply from a community pharmacy, CMS should make it clear that the price difference must be directly related to the difference in service costs, not the cost of the drug product. It was identified in the colloquy of Senators Grassley and Enzi that they oppose making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice.

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

Plans must be required to pay the same fee for MTMS to all providers. For instance, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same services.

CMS must carefully evaluate each plan's application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

In conclusion, I urge CMS to revise the regulation to:

- Have pharmacy access standard require plans to meet the TRICARE requirements on a local level
- Make it clear that the price difference must be directly related to the difference in service costs, not the cost of the drug product
- Plans must be required to pay the same fee for MTMS to all providers
- Examine the fee the plan proposes to pay for MTM services

Thank you for considering my comments.

Sincerely,
Linda Huynh

208 Finley Golf Course Rd
Chapel Hill, NC 27517
Linda_Huynh@unc.edu

October 3, 2004

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

Re: CMS-4068-P

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Subpart C: Benefits and Beneficiary Protections

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Plans must be required to pay the same fee for MTMS to all providers. For instance, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same services.

CMS must carefully evaluate each plan's application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

In conclusion, I urge CMS to revise the regulation to:

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- Make it clear that the price difference must be directly related to the difference in service costs, not the cost of the drug product
- Plans must be required to pay the same fee for MTMS to all providers
- Examine the fee the plan proposes to pay for MTM services

Thank you for considering my comments.

Sincerely,
Linda Huynh

208 Finley Golf Course Rd
Chapel Hill, NC 27517
Linda_Huynh@unc.edu

CMS-4068-P-803

Submitter : Miss. Heather Liber **Date & Time:** 10/03/2004 06:10:27

Organization : University of Toledo College of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I feel that it is crucial that PHARMACISTS are named the health care professionals that are priamry providers of the medication therapy management (MTM) program. Though other health care providers may have a basic knowledge to assist patients with basic needs, the pharmacist is the medication EXPERT with endless knowledge and readily available resources that would be extremely beneficial to patients with chronic disease states and multiple drug treatments. With pharmacy evolving into a patient centered practice, it should also be mandatory that a designated area in each pharmacy be set aside for patient counseling for the MTM program. Also, CMS must clarify that plans cannot require beneficiaries to obtain MTM services from a specific provider/preferred pharmacy. This is necessary because with such restrictions, the existing patient/pharmacist relationship is disrupted which is not in the interest of the patient. If this program is implemented into law, patients will become more compliant and more educated about their disease states and drug therapies, and pharmacists will become even more well respected as health care professionals.

CMS-4068-P-804

Submitter : Mr. Phillip Owen **Date & Time:** 10/03/2004 06:10:34

Organization : University of Tennessee College of Pharmacy

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Phillip Owen

CMS-4068-P-804-Attach-1.txt

September 28, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense's TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than "on average" in a regional service area.
To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.
Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a "clinical pharmacist." I recommend changing "clinical pharmacist" to "pharmacist." CMS should not limit monitoring to "clinical pharmacists," as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a "Clinical Pharmacist" in its rules and regulations. Nationally, there is no clear definition of a "clinical pharmacist."

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create "preferred" pharmacies and "non-preferred" pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one "preferred" pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only "preferred" pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require

plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from the pharmacy provider of their choice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan's network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in service costs, not the cost of the drug product.
Under Medicare Part D, all rebates, discounts or other price concessions should be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements should be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Phillip Owen

Submitter : Ms. Sandra Carlson **Date & Time:** 10/03/2004 06:10:09

Organization : Linking Employment, Abilities & Potential

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:
The proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632 concerns me in that it does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. I am especially concerned with the 7 million dual eligible who will lose all Medicaid prescription drug benefits they now have. Please DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES, as Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. I am very concerned that, for these 7 million people with disabilities, the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into institutions to get needed medications that have become unaffordable in the community, which is contrary to the Olmstead and the Freedom initiative supported by CMS. Please DELAY THE IMPLEMENTATION OF THE PART D PROGRAM UNTIL ITS IMPACT ON TWWIIA (Ticket to Work/Work Incentives Improvement Act), PASS (Plan for Achieving Self Support) AND OTHER SOCIAL SECURITY WORK INCENTIVES IS DETERMINED. Advocates have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. As a vocational rehabilitation service provider, I follow a mission to help people with disabilities become employed and gain self-sufficiency. This would counter such efforts. Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need. I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress. Thank you for your consideration.
Sincerely,
Sandra Carlson

CMS-4068-P-806

Submitter : Dr. Tremayne Trial **Date & Time:** 10/03/2004 07:10:06

Organization : CVS/Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

BENEFITS AND BENEFICIARY PROTECTIONS

Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan's overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that ALL BENEFICIARIES have convenient access to a local pharmacy. Pharmacy patients who have developed a relationship with their Pharmacy and Pharmacist should be able to continue to have access to the pharmacy of their choice. 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 copays, negating the benefit of access standards. Only preferred pharmacies should count when evaluating whether a plan has met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress' intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

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

I believe that Pharmacists are the ideal health professionals to provide MTM services and determine which services each beneficiary needs. Community/Retail pharmacies can provide Blood Pressure Screening and management, Cholesterol screening and mgmt, Diabetes mgmt, and can also help manage many other disease states. It has been demonstrated that Pharmacists can have a positive impact on medication management, patient compliance, and a patients overall well-being. Pharmacists are the most accessible health care professional and Plans should be encouraged to use the services that Pharmacists can provide. Pharmacists are key to providing MTM services and in coordination with other health care professionals can have a significant positive impact on the health care system. This would result in less frequent ER visits, better medication compliance, and greater patient ownership of healthcare. Concering the dispensing definition sought by CMS. I am in favor of Option 1, however, there should be provisions made for cognitive services provided at additional fees.

ELIGIBILITY, ELECTION, AND ENROLLMENT

I agree with the idea of publishing the negotiated drug prices on the CMS website, but I encourage CMS to consider that many people who will elect part D, do not have access to or do not understand how to navigate the internet. Another method should be considered to get the prices offered to individuals. The best way to do this would be to mail the prices to individuals, however, that is not very cost effective. Perhaps local pharmacies could play a role in this as well, by providing copies of the prices to Community/Retail Pharmacies seniors would have a readily available outlet to locate prices as well as a Pharmacist to offer insight.

GENERAL PROVISIONS

I feel that Part D of the Medicare program should be available at a cost that is based on the individuals income level. I feel that this would ensure fairness across the board and would help offset the cost of the program. Individuals who are at a higher income level should have to pay proportionally more than someone at a lower income level, I believe this would help extend the benefit to the greatest number of people.

CMS-4068-P-807

Submitter : **Date & Time:** **10/03/2004 07:10:34**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the new Medicare prescription drug benefit. Under section D, please include the stipulation that plans be required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are in the best position to provide these services face-to-face to benficiaries.

CMS-4068-P-808

Submitter : Mr. Kyle Utecht **Date & Time:** 10/03/2004 07:10:45

Organization : Mr. Kyle Utecht

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file for comments.

CMS-4068-P-808-Attach-1.pdf

October 3, 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:

I would like to 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:

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

I recognize that different patients will require different medication therapy management (MTM) services based on their specific health needs such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I appreciate that CMS recognizes that pharmacists will probably be the primary providers. I am, however, concerned that leaving the decision to the plans may allow for the choice of a less qualified provider to provide MTM services to patients.

Pharmacists **are** the ideal health care professionals to provide MTM services and determine which services each patient requires because pharmacists **are** the medication experts in the health care world. I strongly encourage the use of pharmacist services to help patients make the best use of their medications. It is a role that only pharmacists can play! I also strongly encourage a provision requiring equal payment to any health care provider who plays the role of a MTM.

Regarding Subpart C: Benefits & Beneficiary Protections

I would ask that you please consider revising 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 of the patients' choice.

I am also concerned that the proposed regulation allows plans to establish 'preferred' and 'non-preferred' pharmacies with no minimum requirements on the number of 'preferred' pharmacies a plan must have in its network. Thus plans could easily identify **one** 'preferred' pharmacy, which would coerce patients to use it by enforcing lower co-payments. This compromises the promise of access standards. **Only** preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access

standards so as to avoid the problem illustrated above. Allowing plans to count their 'non-preferred' pharmacies will **conflict** with Congress' intent to provide patients with fair access to local pharmacies of their choice. CMS should require that plans offer a standard contract to **all** pharmacies because it is in the patients' best interest.

In conclusion, I urge CMS to revise the regulation in order to uphold congress' promise to allow patients choose their pharmacy and to be sure that pharmacists are implemented, with equal pay, as the primary medication therapy management health care professional.

Thank you for considering my views.

Sincerely,

Kyle Utecht

Kyle N. Utecht, DPh2
UW School of Pharmacy
Membership VP & Webmaster
Wisconsin Society of Pharmacy Students
http://wsps.rso.wisc.edu

CMS-4068-P-809

Submitter : Ms. Sara Hammer **Date & Time:** 10/03/2004 07:10:20

Organization : APhA - ASP

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4068-P-809-Attach-1.doc

October 3, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I would like to begin by stating that I will soon finish my pharmacy education and will have invested seven years of my life in becoming a drug expert. I would hate to see the full opportunity to utilize my skills be taken away from me after my investment in my education. I would like to comment on Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans. I appreciate that CMS recognizes the need for MTM services and that beneficiaries will require them. I also appreciate that CMS recognizes that pharmacists will likely be the primary providers of these services, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide the MTM services. As I stated, upon graduation I will have dedicated seven years to becoming a drug expert, and would therefore be the ideal health care professional to provide MTM services and determine which services each beneficiary needs. As proof that pharmacist make a difference in MTM services I would like to mention the *Asheville Project* which proved that pharmacists providing MTM services not only saved everyone money but also helped in managing patients diseases.

In conclusion, I urge CMS to revise the regulation so that pharmacists are recognized as the provider of MTM services and the decision is not left up to the plans. Thank you for considering my view.

Sincerely,
Sara Hammer
shammer@email.unc.edu

CMS-4068-P-810

Submitter : Mr. Chris Killmeier **Date & Time:** 10/03/2004 08:10:31

Organization : Mr. Chris Killmeier

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thanks for the opportunity to comment on the proposed regulations to implement the new Medicare prescription drug benefit.
Under Subpart C, the plan must make sure that all beneficiaries have access to the local pharmacy of their choice. Please revise the pharmacy access standards to ensure that plans meet the TRICARE pharmacy access requirements on a local (zip code) level, not on the plan's regional or "average" overall level. CMS should insure that Congress' intent to provide a fair and level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.
Under subpart D, Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries. Please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries.
Thank you for making the needed revisions to best serve all Medicare beneficiaries.

Submitter : **Date & Time:** 10/03/2004 08:10:26

Organization :

Category : Health Plan or Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Subpart C.4. Access to Covered Part D Drugs: b. Formulary Requirements (Section 423.120 b)
Issue: Many dually eligible individuals have multiple chronic medical and behavioral health conditions. Adverse selection is a potential issue among MA Special Needs plans, as well as MA-PD or PDP plans that enroll large numbers of dual eligibles. MA Special Needs plans may have an incentive to structure their formularies to minimize enrollment of specific types of high needs dually eligible individuals. The proposed rule does not appear to establish any additional formulary requirements for MA Special Needs plans that provide prescription drug coverage.

Proposed Revision of Rule: We recommend that CMS consider requiring MA Special Needs plans to provide more extensive coverage of certain types of prescription drugs than required for other MA-PD or PDP plans. In particular, CMS should consider mandating more extensive coverage of anti-retrovirals and mental health drugs. This may help to prevent some of the potential adverse selection that could occur through formulary design.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Subpart J. Coordination Under Part D with Other Prescription Drug Coverage and Coordination of Benefits (Section 423.464) - Coordination of Benefits with other Providers of Prescription Drug Coverage.
Issue: This section delineates the drug coverage under Part D with respect to coordination of benefits for drugs covered by other plans, including Medicaid. It states there is relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs because drugs that must be excluded from Medicare coverage are drugs that also may be excluded from Medicaid.

Proposed Revision to Rule: Drugs such as benzodiazepines are frequently utilized in the Medicaid population; this coordination issue will result in a large number of medically necessary drugs that must be covered by State Medicaid plans. Additionally, coverage of Drugs under Part B must meet very strict approval criteria. According to Medicare guidelines, certain medical services which are deemed reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are covered services. FDA approval is often one of the main criteria of Medicare?s coverage guidelines for drugs and biologicals. However, in the case of chemotherapeutic agents, for example, FDA approval does not always keep pace with clinically indicated efficacy. Therefore, the need exists to address off-label drug uses which have been validated by clinical trials. Otherwise a large number of drugs potentially covered under Part B will fall on Part D plans. There is also the potential for 'double-dipping' for drugs potentially covered under Part B and Part D. Ideally, Part B drug coverage should be eliminated altogether (with all drugs covered through Part D).

ELIGIBILITY, ELECTION, AND ENROLLMENT

B.2. Part D Enrollment Process (Section 423.34)
Issue: This section invites comment on the auto-enrollment process for full benefit dual eligible individuals who do not select a MA-PD or PDP plan. Medicaid managed care plans that are potential MA Special Needs plans currently provide prescription drug coverage to full benefit dually eligible individuals.

Proposed Revision of Rule: We recommend that CMS consider auto-enrollment of full benefit dually eligible individuals who do not select an MA-PD or PDP plan into an MA Special Needs plan, if that plan currently provides prescription drug coverage under Medicaid to such individuals. This would help CMS maintain continuity of care and to minimize potential beneficiary disruption.

PAYMENTS TO PDP AND MA-PD PLANS

Subpart G.5. Payments to PDP Sponsors and Medicare Advantage Organizations Offering MA-PD Plans for all Medicare Beneficiaries for Qualified Prescription Drug Coverage (Section 423.329) - Determination of Payments
Issue: This section addresses submission, review, negotiation and approval of bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and determination and collection of enrollee premiums.

Proposed Clarification of Rule: Federal Medicaid law prohibits the denial of prescription drugs or other services if a Medicaid beneficiary, including dually eligible individuals, cannot or does not make a copayment. Please clarify whether dually eligible individuals could similarly refuse to pay copayments charged by MA Special Needs Plans and MA-PD plans.

CMS-4068-P-812

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

Organization :

Category : Congressional

Issue Areas/Comments

Issues 1-10

BACKGROUND

I'm against the exclusion of benzodiazapines in the Medicare/Medicaide 2006 plan. Please continue the payment of these highly addicted drugs til sufferers are tapered safely off them. A cold turky taper can cause death.

CMS-4068-P-813

Submitter : **Date & Time:** **10/03/2004 08:10:52**

Organization :

Category : **Health Plan or Association**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Subpart C.6. Benefits and Beneficiary Protections (Subpart C 423.128) - Dissemination of Plan Information
Issue: This section describes the means for disseminating information to beneficiaries and proposes that plans maintain Web sites for dissemination of information to current and prospective Part D enrollees. Plans would be required to post current versions of their formularies and update those formularies at least weekly.

Proposed Revision to Rule: We recommend that CMS require quarterly rather than weekly updates to plan formularies. Plans do not make major revisions to their formularies on a weekly basis, and requiring quarterly updates would reduce administrative burden without reducing the quality of information provided to the beneficiary.

Submitter : Brent Talley **Date & Time:** 10/03/2004 11:10:43

Organization : UNC - Chapel Hill School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-4068-P-814-Attach-1.doc

October 3, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

- Thank you for allowing me to comment on the proposed regulation to implement the Medicare prescription drug benefit. Please take into consideration the following comments directed toward the final development of the regulation by CMS.

- **Subpart C: Benefits & Beneficiary Protections**
- I suggest that revisions be made to the pharmacy access standard. Plans should be required to meet the TRICARE pharmacy access requirements on a local level instead of the overall service level. Requirement of the overall service level will not meet the needs of all beneficiaries. Having the requirements implemented on a local level ensures the easy, attainable access to a local pharmacy to all beneficiaries.
- Further revision will need to be considered in the case of preferred/non-preferred pharmacies. Plans could make access (determined by the pharmacy access standard) become irrelevant by deeming one pharmacy preferred over another. CMS should require that plans offer all pharmacies equal and standard contracts. Without this revision, the quality of health care disbursed by local pharmacies would be varied, thereby offering beneficiaries unequal opportunity.
- If plans are to be able to charge a higher price for an extended days supply of medication, then CMS should clarify that the difference in costs are directly related to service costs and not drug cost.

- **Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans**
- I agree that MTM will optimize therapeutic outcomes for targeted beneficiaries. I also appreciate the fact that CMS believes pharmacists will be the main providers of MTM services. It is important for plans to inform pharmacists of what patients are eligible for MTMS. Plans should also inform beneficiaries of their eligibility to receive MTMS.
- CMS should clarify that plans cannot require beneficiaries to obtain MTMS from certain providers. This will violate the patient's access to services, and it may decrease the quality of care obtained.

- I am a third-year student at the UNC-Chapel Hill School of Pharmacy, and I can assure you that we future pharmacists are being well trained to take on this

responsibility. Please take into consideration these suggestions, so that we can work together to improve health care in our state.
Thank you for considering my view.

Sincerely,
Brent Talley
btalley@email.unc.edu

CMS-4068-P-815

Submitter : **Date & Time:** 10/03/2004 11:10:16

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I am writing in concern about the Medicare Prescription Drug Benefit Subpart D on the Medication Therapy Management Program. I appreciate that CMS recognizes that MTM services are an important part of patient therapy and that pharmacists should get reimburssed for these services. However, I believe some of the issues need to be more clearly defined. Working as a hospital pharmacy intern, I see many times patients that have two or more drugs which the pharmacists most of the time counsel. It should specifically state 2 or more, instead of multiple, chronic diseases and drugs. In addition, I believe this MTM program will entice more pharmacists to counsel patients in these situations.

Submitter : Dr. Arin Passmore **Date & Time:** 10/03/2004 11:10:38

Organization : ASCP, CGP, ACCP, APhA

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Certified Geriatric Pharmacist

BENEFITS AND BENEFICIARY PROTECTIONS

An ability to help others and practice an enjoyable job

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

would have to work on that. I have never been given the chance. It would be something seen on paper and I would not be involved in the money. The costs would be noticeable on your end with reduced costs from emergency room visits, drug interactions, and utilization of unnecessary medications.

ELIGIBILITY, ELECTION, AND ENROLLMENT

licensed voter

GENERAL PROVISIONS

An able mind and body to carry out the process

PAYMENTS TO PDP AND MA-PD PLANS

Payments would be directly to patients for medications but to me for my separate billing. The billing/payment could only be made by professionals.

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

Sorry I would have to give this good thought. I would like to be paid just as any other MD is paid. I would like to be able to provide these patients care by being paid not only by you but by insurance companies. I could work to find patient lower cost drugs just by searching on the internet for lower cost medications which the government is probably more qualified to do and more qualified.

CMS-4068-P-816-Attach-1.doc

CMS-4068-P-816-Attach-1.doc

CMS-4068-P-816-Attach-1.doc

CMS-4068-P-816-Attach-1.doc

CMS-4068-P-816-Attach-1.doc

CMS-4068-P-816-Attach-1.doc

CMS-4068-P-816-Attach-1.doc

Impressive and thrilling this is for me. The time has come. A time when you want to know how to save money and provide the seniors of our nation with the best care possible. The realization that this cannot be done with a medical diagnosis alone. So the prescription card is implemented and now what do you do with it?

We may be living longer but we are also digging an enormous crater in the funding provided by the federal government. Not something thought about in the years in the past nor by seniors wanting to understand why they have to work more years to get more.

I believe, from my history -- and I have not had it in a while --, the system was created to allow freedom to the senior; to enable them to be able to save there money and look for a time when they could retire and not be a burden to their family. The family unit itself went through a revolutionary change as a result of this as well. It is not often we look to the older person to be like them -- full of insight and wisdom and the best in story telling.

We as pharmacists can do a lot. However not all pharmacists are qualified to provide the care that seniors need. You need medical professionals in place implementing programs with Geriatricians, those that are physicians, nurses, pharmacists, nurse practitioners, any that have gone out of their way to practice in the areas of geriatrics.

As a Geriatrician, a PharmD., certified in geriatric medicine, I must continue to update my license. It is not a static thing. I must continue to educate myself in practice with patients. This does not mean filling prescriptions behind a counter and counseling a patient -- I am presently in an area where I am limited to only being able to do this). It does mean having an office or going to the patients home. It is like practicing the old fashion way of the past.

Most social workers will tell you they are able to tell more about a patient the moment they walk into their living environment than before they speak to them.

I know pharmacists can eliminate the number of medications patients take; the number of hospitalizations caused by adverse drug reactions, drug interactions, improper prescribing by general practitioners unfamiliar with geriatric change (i.e. they are not 40 anymore), patients taking medications available over the counter without consultation with a pharmacist -- a geriatrician assigned to them
prior to taking that medication. I could add more to this list. There are so many things we can do.

Seniors want care. They want services but they will not pay me, it is hard to say no. I do not always pass on helping. Every once in a while, when I see a family falling apart, and they ask a second time I usually succumb. My reward is the saving the family money, watching the patients dementia often diminish or go away, and sometimes seeing them go home again to live with there children. That is my reward. Sometimes the reward can be simple -- keeping a patient off a high dose medication and changing them to a less expensive one. How about preventing the side effect because the doctor wrote for an

incorrect dose for an elderly patient? It happens every day. The drug software does not correct for this and pharmacists in pharmacies do not know anything about this.

Senior love to save money. Allow us to do it. Pick the proper people to give this authority to. I am for pharmacists but there are still many out there to earn the losses they have lost due to the rising cost of medications.

By choosing the correct medical professionals to provide you with the evidence you need, i.e., American Society of Consultant Pharmacist have run some studies; evidence that will not deplete the funding but hopefully bring you within rage of your costs needed to pay for this program or maybe some of the others already in existence take a chance on caring for the geriatric patients "senior citizens" the proper way the first time.

CMS-4068-P-817

Submitter : Miss. barbara bohm **Date & Time:** 10/03/2004 11:10:03

Organization : spirit iii, inc.

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

on page 26790 --it says that retired people , who, through working, now have drug coverage which works for them, AT NO NEW COST TO THE GOVERNMENT --TAXPAYERS--- will have to change that , like it or not.
many employers may take this window to not continue to offer drug
coverage seperate from their main medical insurance, for retires.
if there is a mass "dump" into medicare claims, as retirees are almost all on at least 1 medicine, can the government afford it?

GENERAL PROVISIONS

i don't know where this goes- it is on page 46646. I don't use this clause. But, i have heard 'durable medical equipment' if you are too poor to easily buy it yourself,is not well covered, and, none is cheap. Here is states the intent NOT to cover things like blood suger test strips (not cheap), if you have to buy just one brand, as a condition of getting a 'free'
readout machine from a company. Well, NEITHER are cheap--the machine OR the supplies! at least now, ONE is kinda 'free'.

Issues 11-20

MEDICARE CONTRACT DETERMINATIONS AND APPEALS

This section is hard reading, and i qualify for MENSA! Most, if denied coverage, would try and look up the "rules" and see if they really "should" have had it covered. With these, they might have well just dug out Tarot Cards! You find out, in most cases, IF you win, you will get your med's filled within 60 days, but, if more "urgent" might be 14 day deadline OR by 72 hours Or by 24 hours AT the LATTEST, if life and death. Mind you, if "life and death", one wonders why it was not filled!

CMS-4068-P-818

Submitter : Mr. Thomas Olcese **Date & Time:** 10/03/2004 11:10:28

Organization : Tom Olcese Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am concerned over the implementation of rules developed for the Medicare Part D benefit. My hope is medicare recipients may be able to choose their own pharmacies. Hopefully measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies. Elderly citizens need the support of their
local pharmacies to help them with their concerns about their health and medicines that are prescribed for them. Many of the medicare recipients need delivery and prescription pickup. Thank for your consideration.

Sincerely,

Thomas F. Olcese RPh.

CMS-4068-P-819

Submitter : Ms. Laura Hershey **Date & Time:** 10/03/2004 11:10:05

Organization : Ms. Laura Hershey

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

I would like to offer my comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am an adult with significant physical disabilities who is dually eligible for Medicare and Medicaid. I'm very concerned that the proposed rule does not provide sufficient protections for the 13 million
Medicare beneficiaries with disabilities and chronic health
conditions, especially those who are dually eligible. I am urging you to delay the implementation of the Part D Program for dual eligibles.

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. I am very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual- eligibles in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006), 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.

Thank you for your attention to my comments.

Sincerely,
Laura Hershey
1466 S. Lincoln St.
Denver, CO 80210
Laura@cripcommentary.com

CMS-4068-P-820

Submitter : Mr. Wayne Jeffrey **Date & Time:** 10/03/2004 11:10:25

Organization : Ramsey Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Regarding CMS-4068-P, Please ensure that all pharmacies will be able to be equal providers under the regulation. There should be the same contract offered to all pharmacies. I have grave concern that plans would allow some pharmacies to be 'preferred' over other pharmacies, giving an advantage to some pharmacy providers, and a financial penalty to patients who would go to a 'non-preferred' pharmacy. In my experience as an independant pharmacy, I am fearful that the smaller, independant pharmacies like myself may not be allowed or offered the opportunity to be a 'preferred' pharmacy. That would indeed be an injustice to the many small pharmacy businesses across the USA. And it is those same smaller, pharmacies that give the most individual attention to, and the best chance for medication therapy management for, the patients they serve. Please allow ALL pharmacies to be equal provider. There MUST be a level playing field between all the pharmacy providers; between local indepedant pharmacies and chain pharmacies and mail order pharmacies. Allow the same terms and co-pays to the patient for all, and the same contract terms for all
the pharmacies.

Please also ensure that MTM services WILL include pharmacists. Also please ensure that the pharmacists who are providing the prescription services to a patient will also be able to to be the MTM provider.

Thank you for allowing my input. Sincerely, Wayne Jeffrey. Ramsey Pharmacy 763.427.3341. 5300 Alpine Drive NW Ramsey MN 55303

Submitter : Mr. Stephen Jakubowycz **Date & Time:** 10/04/2004 12:10:35

Organization : The Self-Help Center of New Brunswick

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Medication management is critical for mental health consumers' health. Mental health medication has improved dramatically in the recent years. Newer medications are more effective with less side effects. Reverting back to older mediactions through these proposed changes will cause great setbacks clogging up the mental health system which is undergoing chnges. The mental health movement has made great strides and going back to changing to older, less expensive meds will only exasberate problems.

ELIGIBILITY, ELECTION, AND ENROLLMENT

This ia a complex problem. Whatever the deal is, should mental health consumers who are on Medicare or Medicaid and then go onto only Medicaid, will have their quality of life and recovery jeoparized. Having mental health consumers revert back to older and/or cheaper drugs will cause symptoms to reappear and cause hospitalization sending psychiatric bills beyond reason. Mental health consumers need these newer medications. I was on Haldol, an anti-pychotic drug. I was still deluded and alwayhs tired. My personal hygiene lacked. The medication made me confused. I was a total mess. Zyprexa and Wellbutrin have stopped the delusions which plagued me for a decade and a half. Wellbutrin finally took my depression away. I am a new person ready to go back into the work force and payh my taxes the soones available moment.

CMS-4068-P-822

Submitter : **Date & Time:** **10/04/2004 12:10:05**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C, Re: "Pharmacy Access Standards" Please revise to require plans meet TRICARE pharmacy access requirements on a local (zipcode) level. This will ensure beneficiaries have access to the local pharmacy of their choice, rather than favoring "preferred" networks or mail order pharmacies.

Under Subpart D, please revise to include community pharmacists in the delivery of Medication Therapy Management (MTM), since they are in the best position to provide these services within the community of the patient.

CMS-4068-P-823

Submitter : Mrs. Melissa Lefler **Date & Time:** 10/04/2004 12:10:07

Organization : Mrs. Melissa Lefler

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Dear Sir or Madam:

I, as a future pharmacist, am writing to you to express my concern regarding the upcoming decisions on the Medicare Prescription Drug Benefit plan. In particular I would like to address the area of Medication Therapy Management (MTM) program. It appears as though some of the phrasing is in need of clarification. First, on the issue of 'targeted beneficiaries,' once a beneficiary is defined, by the plan as well as pharmacists and physicians, (that hold justifiable documentation for their identification of a beneficiary), that patient should remain eligible for the benefits of MTM for at least one year. As well, once a patient is deemed eligible, the patient should be informed and given proof, (perhaps an id card) of their eligibility that can be presented to his/her physician and/or pharmacist.

Secondly, in regards to 'providers,' the title and responsibility of the providers of MEDICATION Therapy Management should be allocated to pharmacists, who of the health care team are the professionals that have the most knowledge and expertise in regards to medications. It is the intense education and training that makes pharmacists the ideal 'providers.'

In regards to fees assessed from such management services, CMS should require that, just as with any other medical service, the provider of the MTM be compensated fairly. Identifying that there is much to gained from both sides. In order to justify time away from the practice, the pharmacist must be reasonably compensated; thus the benefit reaped on the side of the provider. While on the side of the plan providers, compensation will be attained in the amount of money saved through a decrease in the number of claims related to medication errors and/or medication mismanagement.

Finally, in regards to the 'services' provided, MTM in addition to being offered during the dispensing of the medication, MTM should be offered as a stand alone benefit as well, meaning that the service can be provided independently of dispensing of a medication. Also, CMS must realize the importance of patient individuality in regards to medication management and thus the importance of face-to face interaction between the patient and the pharmacist, with the initial assessment always being of this type of management session.

I thank you for your time and am grateful for your consideration and recognition of the important medication issue that is pressing upon the population eligible for Medicare coverage.

Sincerely,

Melissa Lefler
melefler@yahoo.com

Pharmacy Student
University of Toledo
Toldeo, Ohio

Submitter : **Date & Time:** 10/04/2004 12:10:04

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart D, please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries.

CMS-4068-P-825

Submitter : Mrs. Janice Miner **Date & Time:** 10/04/2004 12:10:47

Organization : Tom Olcese Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist and owner of Tom Olcese Pharmacy. As a community pharmacist, I am concerned with three aspects of the Medicare D proposed rules and recommend that CMS enable the following three policies.

Medicare recipients must be able to choose their own pharmacies.

Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.

Plan sponsors should be required to establish specified MTM services

Thank you for your consideration.
Sincerely,
Janice Miner RPh.

CMS-4068-P-826

Submitter : Ms. Tammy Birkel **Date & Time:** 10/04/2004 12:10:44

Organization : Ms. Tammy Birkel

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C, please change the pharmacy access standards. These standards need to meet the Tricare pharmacy access requirements on a local level by zip code. These standards should not be on a regional or average overall level. The only way the ensure that all beneficiaries have access to the local pharmacy of their choice is to require the plan to meet the standard on a local (zip code) level. CMS should make sure that the intent of Congress is to provide a level playing field for all community pharmacies and that mail order pharmacies aren't favored by inappropriate use of 'preferred' networks.

Under Subpart D, please make sure that Medication Therapy Management services can be provided by community pharmacists and community pharmacies. These pharmacists are the ideal health care professionals to provide these services conveniently, face-to-face, to beneficiaries.

Thank you in advance for making these revisions to best serve all Medicare beneficiaries.

CMS-4068-P-827

Submitter : **Date & Time:** **10/04/2004 01:10:22**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I feel that patients have a right to chose their own pharmacy and all pharmacies that chose to participate in the preferred pharmacy program. Pharmacies should also be able to fill 90 days supplies, and people shouldn't be forced to use mail order.

CMS-4068-P-828

Submitter : Mrs. Joann McCormick **Date & Time:** 10/04/2004 01:10:17

Organization : Mrs. Joann McCormick

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 3, 2004

Centers for Medicare & Medicaid Services
US Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244?8014

Attention: CMS-4068-P

To Whom It May Concern:

I would like to voice my concerns about your intentions to exclude Benzodiazepines as a covered prescription by Medicare Part D. I think this will be a serious mistake that would cause low income people on fixed incomes to cold turkey a very addictive medication. This could very well kill many old people who cold turkey this medication since their bodies are less apt to be able to tolerate such a long drawn out, severe trauma. Another scenario could be that they will become seriously ill with withdrawal symptoms that will cause them to seek medical help for a cure that essentially doesn?t exist and will only serve to drive up medical costs. Most doctors do not know how to treat Benzodiazepine withdrawal and their offered forms of treatment may actually only make things much worse for the withdrawing patient.

In reiteration, Benzodiazepines should continue to be covered by Medicare Part D or I shudder to think what may happen. Actually, pharmaceutical companies should also be concerned about these patients resorting to a cold turkey of these medications because the wide spread increase in severe withdrawal symptoms at epidemic levels (so to speak) will only put even more scrutiny on an ever increasingly scrutinized area of medicine...psyhotropic drugs. This is a good thing, but not at the expense of innocent people.

Sincerely,

Joann McCormick

CMS-4068-P-829

Submitter : **Date & Time:** 10/04/2004 01:10:24

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom it my concern:

I have been a Pharmacist for 31 years and have many many patients that I have taken care of for many of those years. In discussing Subpart C with some of my peers and some of my patients I am concerned that I will no longer be able to service them.

We had a tremendous negative impact on our customers lately with UAW going mandatory mail order and under the current pharmacy access standards we could lose another substantial base to my customers access at the local store. The way I understand this we need to ensure the plans meet Tricare pharmacy access requirements on a local zip code level and not a regional level.
This would allow a level playing field for community pharmacies and not favor mail order pharmacies in preferred networks.
Help make an adjustment in the language of this CMS 4068 P and also under subpart D . Please be sure that you support Pharmacist in the local community so my customers get direct pharmacist attention & consultation while dispensing medications and I have an opportunity to assist them.I know too many Seniors would simply quit taking their medication as they would be so confused and the end result would be driving up the Health Care costs more as they will have more need for hospitalization.

Thankyou for your time.

Murray Smith, R.Ph

CMS-4068-P-830

Submitter : Mr. Earl McCormick **Date & Time:** 10/04/2004 01:10:50

Organization : Mr. Earl McCormick

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 3, 2004

Centers for Medicare & Medicaid Services
US Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244?8014

Attention: CMS-4068-P

To Whom It May Concern:

Please do not let Medicare Part D stop covering Benzodiazepines for Medicare recipients. Many of them are low income and will not be able to continue these prescriptions because they will not be able to pay for them. In not knowing better, many of them will either cold turkey these medications or do a rapid taper of them. If they do either of these things to these medications instead of tapering very slowly, they may very well experience horrific withdrawal for which there are no medical treatments. Most doctors will try to treat them medically with more prescription medications (SSRI?s) and will most likely only make them worse. With regards to this happening with an elderly person or someone with heart problems or some other serious issue, it could very well kill them or cause them to take their own life to avoid the tremendous pain associated with this withdrawal.

Please continue to cover Benzodiazepines as part of Medicare Part D. People?s lives can only be saved by doing so...

Sincerely,

Earl McCormick

Submitter : Mrs. Joann McCormick **Date & Time:** 10/04/2004 01:10:20

Organization : Mrs. Joann McCormick

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 3, 2004

Centers for Medicare & Medicaid Services
US Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244?8014

Attention: CMS-4068-P

To Whom It May Concern:

I would like to voice my concerns about your intentions to exclude Benzodiazepines as a covered prescription by Medicare Part D. I think this will be a serious mistake that would cause low income people on fixed incomes to cold turkey a very addictive medication. This could very well kill many old people who cold turkey this medication since their bodies are less apt to be able to tolerate such a long drawn out, severe trauma. Another scenario could be that they will become seriously ill with withdrawal symptoms that will cause them to seek medical help for a cure that essentially doesn?t exist and will only serve to drive up medical costs. Most doctors do not know how to treat Benzodiazepine withdrawal and their offered forms of treatment may actually only make things much worse for the withdrawing patient.

In reiteration, Benzodiazepines should continue to be covered by Medicare Part D or I shudder to think what may happen. Actually, pharmaceutical companies should also be concerned about these patients resorting to a cold turkey of these medications because the wide spread increase in severe withdrawal symptoms at epidemic levels (so to speak) will only put even more scrutiny on an ever increasingly scrutinized area of medicine...psyhotropic drugs. This is a good thing, but not at the expense of innocent people.

Sincerely,

Joann McCormick

Submitter : Mr. Austin Mooring **Date & Time:** 10/04/2004 01:10:04

Organization : UNC School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 3, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for taking the time for allowing me to comment on the proposed legislation implementing the Medicare prescription drug benefit. Below are listed some comments I feel should be considered as CMS develops the final regulation.

Subpart C: Benefits and Beneficiary Protections
I feel the pharmacy access standards should be revised to meet the TRICARE pharmacy access requirements on a local level, instead of the plan?s overall service level. This is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that they may continue to use the pharmacy they have been using for years.

I am also concerned with the way the proposed plan will establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Under this, plans could choose one particular pharmacy and make patients go to that pharmacy by allowing lower co-payments. This would negate the benefit of the access standards. Allowing plans to count their non-preferred pharmacies conflict with Congress? intent to provide fair access to all local pharmacies.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Plans
I welcome that CMS recognizes that different people will need different MTM services and also CMS recognition that pharmacists will likely be the primary providers. However, I am concerned that leaving that decision to the plans may not be the correct answer. This could allow plans to choose less qualified providers to provide MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determine with services each beneficiary needs.

Thank you for your time and for considering my view

Sincerely,

Austin Mooring
UNC School of Pharmacy
mooring@email.unc.edu

Submitter : Dr. Gene Bishop **Date & Time:** 10/04/2004 01:10:16

Organization : PennCare-Spruce Internal Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The complexity of the law, as epitomized by these regulations, makes it very difficult for beneficiaries or practicing physicians to understand. The intentions noted in the preamble ? that all users of this system, including beneficiaries, physicians, and pharmacists- must have clear and accurate information about what is on a formulary, and what changes have been made, and what procedures are necessary to appeal a decision is a standard which must be applied to every sub-portion of the regulations.

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.

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

As a practicing physician, I am asked daily for information on these issues. I watched with dismay in the past as patients were victims of door to door enrollment and telemarketing schemes. I also know that many of my patients need assistance with enrollment because of limited education, English proficiency, or mental or physical disabilities. I am aware that many community advocacy organizations work closely to protect beneficiaries from fraudulent schemes, and poor information, and I urge the Department to carefully review more detailed comments from these organizations.

I feel strongly that telemarketing should be prohibited, as should the ability of PDP?s to market other services. This puts vulnerable senior citizens at risk for marketing schemes whose damage is discovered only after many people have been irrevocably harmed.

GENERAL PROVISIONS

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.

As a practicing physician, I am aware that very little research work has been done on the impact of formulary management on patient outcomes. I would encourage the Department to fund the MMA Section 1013 ?Research on Outcomes of Health Care Items and Services.? The law authorized $50 million for this in FY 2004, but no funds were requested and Congress provided none. But the law says ?such sums as may be necessary for each fiscal year thereafter.? Adequate funding of this research could achieve enormous savings, in lives and money, in the years to come, and I urge the Department to make this a funding priority.

CMS-4068-P-834

Submitter : Miss. Lauren Williams **Date & Time:** 10/04/2004 02:10:57

Organization : UNC School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4068-P-834-Attach-1.doc

October 3, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulations to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

Subpart C: Benefits & Beneficiary Protections
Please consider making some changes to the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plant'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 of their choice. I want my patients to be able to continue to use my pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress' intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. Plans should be encouraged to patients to use services that will make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to enforce the TRICARE access standards on the local level, as well as make sure that there are many pharmacies in their preferred network so as not to deny patient with the choice of what pharmacy to go to and still receive great prices. I also encourage CMS to recognize that pharmacist truly have the best access to patients to offer them MTM services that will maximize their health care.

Thank you for considering my view. Sincerely,
Lauren Williams
140 BPW Club RD Apt D10
Carrboro, NC 27510

lauren_williams@unc.edu

Submitter : Dr. Judith Sommers Hanson **Date & Time:** 10/04/2004 02:10:03

Organization : Dr. Judith Sommers Hanson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to see that CMS recognizes that pharmacists can make improvements in the overall care of Medicare beneficaries through Medication Therapy Management Services (MTMS). However, CMS has failed to define what exactly what MTMS is and who it should be provided for. CMS is aware of what beneficaries are in the greatest need of these services and this needs to be defined. Leaving decisions up to the PDP's on defining this service and coverage will only limit the service that will be provided. These services will become services of limited scope and of very little imptact. If left for the PDP's to decided MTMS will become limited to drug utilization switch programs that provide little change in overall positive health outcomes. Standardization by CMS is needed before this benefit can be put into place. We have seen a very limited response to the Medicare Discount Card Benefit. I would hate to this be the case for an innovative program such as this when providing Americans with the MTMS that would have a positive imptact on their health.

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

I want to be able to serve all my Medicare patients. CMS needs to revise the access standard to require that all plans must meet TRICARE requirements on a LOCAL level. This will ensure that all beneficaries get the access to their willing pharmacy providers. Congress promised Senior Americans that they would have access to any willing provider-this needs to be a fair process. If PDP's are allowed to charge a higher price for an extended supply obtained in a community pharmacy, CMS must clarify that the price difference is directly related to the difference in service costs-not the cost of the drug product.

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

CMS must clarify and define MTMS in greater detail A working definition has been proposed by 11 national pharmacy organizations. This document is available at www.aphanet.org/lead/MTMS_definition_FINAL.pdf This criteria is to serve as the 'gold-line' standard of what these serives are. Beneficiaries should be able to maintain exsisting relationships with their pharmacist to obtain these services. Plans must be required to pay the same fee for all MTMS services to ALL providers. CMS must carefully evaluate all DPS's and MD-PD application describing the MTMS they are wishing to provide beneficiaries. Does what they intend to offer meet the intent of MTMS?? Fees offered by the plan must be appropriate to cover the cost of service and provide an enconomic incentive for them to participate. Face to face provision of MTMS is preferred. This method can provider more direct and positive outcomes. There needs to be a mechanism in place to handle a variety or referral sources for beneficiaries to receive these services. How will pharmacist bill PDP's for the services they provide? The process of seeking reimbursement can not be so labor intensive that defeats the ability to provide this service. This service can be provided without the provision of drug therapy product.

ELIGIBILITY, ELECTION, AND ENROLLMENT

All patients eligible for MTMS should have this made known to them. This information should be shared with their physician in order to target these patients. Pharmacists are to be allowed to provided MTMS services to all patients regardless of eligibility. Benificaries who are not eligible for the service would be billed directly for the serivce. All eligible beneficiaries should receive MTMS for 1 year. New problems will extend the provision of services for a 1 year as the medications are being managed.

GENERAL PROVISIONS

Define and standardize the requirements for MTMS. This already done with other Medicare Provided services. Leaving this to PDP's to decide will prevent the goal set by CMS when creating this benefit. An open exchange between DPD's and health care providers offering MTMS needs to

be created for patients to understand their ability to receive this benefit. Identify and target areas of greatest need such as diabetes, chronic obstructive lung disease, smoking cessation, congestive heart failure, and cardiovascular disease for the chronic disease that are eligible for MTMS.

Submitter : Ms. Jenny Hellman **Date & Time:** 10/04/2004 02:10:50

Organization : Ms. Jenny Hellman

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

Sec. 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."

I have many concerns about the provisions starting at Sec. 423.44 on disenrollment by the PDP. First, two of the grounds for disenrollment are extremely problematic for older consumers and those with disabilities and must be removed and/or revised. Second, the regulations fail to allow consumers to appeal disenrollment decisions, including decisions refusing to reenroll a consumer.

The proposed regulation in Section 423.44(b)(2)(v) requires that a PDP disenroll a consumer who makes a ?material misrepresentation? about whether he/she has other creditable coverage. Requiring plans to disenroll a consumer for this reason and allowing the PDP to refuse reenrollment [423.44 (d)(6)(ii)] to that consumer is too severe a penalty. First, the term is not defined to clearly exclude accidents or inadvertent omissions Such errors should not be penalized, especially considering how complicated and confusing the concept of creditable coverage is and will become when the Part D Program rolls out. Second, a consumer should be given an opportunity to cure a misrepresentation.

Allowing PDPs to disenroll consumers for disruptive behavior [423.44(b)(1)(ii)] and refuse them reenrollment [423.44(d)(2)(vi)] could be discriminatory to persons with certain disabilities or conditions. In addition, it could severely harm lower-income consumers and those in rural areas who may end up with no coverage for months at a time. I am very concerned that this provision [423.44(d)(2)(i) could be interpreted to allow PDPs to diseneroll elderly consumers with dementia or Alzheimers, or other consumers with mental health or other disabilities, whose ?disruptive behavior? may arise out of their illness/condition. . I am certain that the ability of a PDP to disenroll for this reason . I am certain that the ability of a PDP to disenroll for this reason will have a chilling effect on consumers? filing grievances or appeals. We are also concerned that consumers could be disenrolled for disruptive behavior and denied reenrollment into what might be the only PDP serving their area. This provision must be removed from the regulations.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The final regulations must require notices and marketing materials to state for consumers the particulars of Part D and its interaction with other programs. A general concern about the proposed regulations is that there are numerous subparts that call for notices to be given to enrollees. There is no uniformity across the Subparts of the regulations as to what basic information all consumer notices must contain. Of specific import to the eligibility and enrollment section is that all marketing materials, application forms and notices must be clear about such things as 1) the impact of enrolling in a PDP or a MA-PD on access to other coverage, 2) the impact of failing to timely enroll into a PDP or MA-PD, 3) the right to special and annual coordinated election periods, and more. In this section, for example, the law requires that persons enrolled in an MA plan that becomes an MA-PD to obtain qualified prescription drug coverage through that plan. The proposed regulations, however, do not require adequate information to be provided so that the consumer understands this and the implications this will have on their ability to use other programs. This is especially important in Pennsylvania where many consumers over 65 use a Medicare+Choice plan for the Medicare Part A and B services but use our SPAP, the PACE Program, for their prescription drugs. In this instance, Consumers will have to be informed of how their MA-PD coverage will interact with other coverages they may have and the final regulations should require marketing materials, enrollment forms, and notices to explain this.

ELIGIBILITY, ELECTION, AND ENROLLMENT

I am very concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries, beneficiaries with mental illness, and other populations with special needs. 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, those who are homebound, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

In order to successfully enroll individuals with mental illness, cognitive impairments (like Alzheimer?s) and disabilities, outreach, education, and enrollment opportunities must be incorporated at multiple points within the health communities.

To respond to Congress?s concern with ensuring enrollment and comprehensive coverage for beneficiaries with special needs, CMS must partner with community-based organizations focused on addressing the needs of people with special disease and disability conditions, (such as mental illness) and state and local agencies that coordinate benefits for these individuals. It is to these organizations, that beneficiaries with disabilities know and trust, that they will likely turn with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with disabilities about the new benefit. CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (?423.48). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources. These additional resources must be available in different languages and accessible to the blind.

An extensive network of local, face-to-face counseling services will be needed. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate. SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and Area Agencies on Aging, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. I urge that SHIP/AAA funding be increased further.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. In addition, in their bids, PDPs and MA-PDs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness and homebound.

GENERAL PROVISIONS

The term ?personal representative? needs to be defined. Under the proposed regulations, the term is used but not defined. This is of major importance because Subpart P [423.774(d)(1)] and Subpart S [423.904(d)(2)] require a personal representative to sign off on lower-income subsidy application forms under penalty of perjury. Construed broadly, advocates, social workers, and others who generously assist consumers in completing application forms will be severely limited in their ability and willingness to assist out of fear of liability. This will have a significant chilling effect on applications for lower-income subsidies. I assist many older adults who do not understand applications or are not able to complete without assistance. Without assistance many seniors will fall through the cracks.

CMS-4068-P-836-Attach-1.doc

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CMS-4068-P-836-Attach-1.doc

Comments to the Proposed Medicare Prescription Drug Regulations prepared by Jenny Hellman, MSW, LSW a concerned social worker that works with older adults.

Subpart A—General Provisions

The term "personal representative" needs to be defined. Under the proposed regulations, the term is used but not defined. This is of major importance because Subpart P [423.774(d)(1)] and Subpart S [423.904(d)(2)] require a personal representative to sign off on lower-income subsidy application forms under penalty of perjury. Construed broadly, advocates, social workers, and others who generously assist consumers in completing application forms will be severely limited in their ability and willingness to assist out of fear of liability. This will have a significant chilling effect on applications for lower-income subsidies. I assist many older adults who do not understand applications or are not able to complete without assistance. Without assistance many seniors will fall through the cracks.

Subpart B—Eligibility and Enrollment

Overarching Concerns Regarding the Enrollment Process

I am very concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries, beneficiaries with mental illness, and other populations with special needs. 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, those who are homebound, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

In order to successfully enroll individuals with mental illness, cognitive impairments (like Alzheimer's) and disabilities, outreach, education, and enrollment opportunities must be incorporated at multiple points within the health communities.

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries with special needs, CMS must partner with community-based organizations focused on addressing the needs of people with special disease and disability conditions, (such as mental illness) and state and local agencies that coordinate benefits for these individuals. It is to these organizations, that beneficiaries with disabilities know and trust, that they will likely turn with questions and concerns regarding the new Part D drug benefit. Making information and educational materials

available at these sites will help inform beneficiaries with disabilities about the new benefit. CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (§423.48). But providing community-based organizations with pamphlets and brochures alone is not adequate.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources. These additional resources must be available in different languages and accessible to the blind.

An extensive network of local, face-to-face counseling services will be needed. Dual eligibles in particular will need personal help in picking the plan that is best for them, rather than just being arbitrarily assigned to a plan. The 1-800 number and literature alone will not be adequate. SHIPs, Area Agencies on Aging, and other local groups can provide the kind of detailed help needed, but they need additional resources. We believe that the SHIPs and Area Agencies on Aging, and related local counseling services are woefully under-funded. Current funding for SHIPs, even after the much-needed and welcome increases announced this spring, are about 50 to 75 cents per year per beneficiary. This is barely enough for 2 mailings per year, let alone the highly labor intensive one-on-counseling that is needed. The Senate-passed version of the MMA had originally proposed $1 per beneficiary for the SHIPs, but unfortunately that was deleted in the final law. I urge that SHIP/AAA funding be increased further.

CMS **must** develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and consumer advocacy organizations focused on the full range of physical, mental, and disability conditions. In addition, in their bids, PDPs and MA-PDs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness and homebound.

The final regulations must require notices and marketing materials to state for consumers the particulars of Part D and its interaction with other programs. A general concern about the proposed regulations is that there are numerous subparts that call for notices to be given to enrollees. There is no uniformity across the Subparts of the regulations as to what basic information all consumer notices must contain. Of specific import to the eligibility and enrollment section is that all marketing materials, application forms and notices must be clear about such things as 1) the impact of enrolling in a PDP or a MA-PD on access to other coverage, 2) the impact of failing to timely enroll into a PDP or MA-PD, 3) the right to special and annual coordinated election periods, and more. In this section, for example, the law requires that persons enrolled in an MA plan that becomes an MA-PD to obtain qualified prescription drug

coverage through that plan. The proposed regulations, however, do not require adequate information to be provided so that the consumer understands this and the implications this will have on their ability to use other programs. This is especially important in Pennsylvania where many consumers over 65 use a Medicare+Choice plan for the Medicare Part A and B services but use our SPAP, the PACE Program, for their prescription drugs. In this instance, Consumers will have to be informed of how their MA-PD coverage will interact with other coverages they may have and the final regulations should require marketing materials, enrollment forms, and notices to explain this.

Sec 423.34(b) Enrollment.

The final rule should provide that an authorized representative may complete the enrollment form on behalf of a Part D eligible individual.

The proposed regulations in Section 423.34 set forth the process for enrolling in a PDP but do not articulate a timeframe within which the PDP must make an enrollment decision and do not set forth any appeals process for consumers who are denied enrollment. Consumers must be provided a swift determination of whether a PDP will enroll them, especially where there is an annual coordinated enrollment period of only 6 weeks. The final regulations should establish a 14-day window for making an enrollment decision so that consumers have an opportunity to appeal or apply elsewhere. 423.24(c) should specify that the plans give written notice of their decision to the consumer. And, consumers must have an opportunity to appeal when they are denied enrollment, especially where there are factual disputes over whether they were eligible.

I have grave concerns regarding auto-enrollment for dual eligibles. **Auto-enrollment of dual eligibles into PDPs as proposed in Section 423.34(d) should occur on November 15, 2005, not May 15, 2006.** Dual eligibles should be auto-enrolled immediately to insure that they maintain access to drug coverage. There must be a safety net for this vulnerable population. A gap in prescription drug coverage will have chilling affects on dual eligibles and the health care system. Auto-enrolling dual eligibles on November 15, 2005 should be completed by the State and should be accompanied by detailed consumer information explaining that the consumers were auto-enrolled to prevent any gaps in coverage but that they may switch their coverage at any time. This consumer information should also include detailed information about the implications of disenrolling from the plan they were automatically enrolled into and not enrolling into a different Part D plan. Consumers need to understand that disenrolling from a Part D plan without enrolling in a different plan may

leave them without prescription drug coverage and also may cause them to pay a late penalty should they decide to delay enrollment into a Part D plan.

With regard to CMS's request for comment on how to auto-enroll dual eligibles who are in MA-only plans, I agree with Pennsylvania Health Law Project that these consumers be auto-enrolled into one of their MA-only company's MA-PD plan, even if that plan's cost exceeds the premium subsidy amount and that CMS require these plans to waive the additional premium charge for these individuals for six months to allow the consumer to select a new MA-PD plan.

It is essential that CMS develop an adequate solution to the issue of automatic enrollment and dual eligibles who are enrolled in MA plans that have a prescription drug benefit with a premium that is above the low-income benchmark. The solution should be the one least disruptive to medical care. Forcing a dual eligible to choose between continued MA enrollment, paying added premiums, or foregoing drug coverage is inherently disruptive.

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

The regulations should include a special enrollment period similar to the one for dual eligibles for all beneficiaries eligible for a full or partial-low income subsidy.

Special enrollment periods should also be provided for all institutionalized individuals, not just institutionalized dual eligibles, since their access to needed drugs may be compromised by the design of the plans and by pharmacy access requirements, (i.e., if their long-term care pharmacy is not required to be included in the network of all PDPs). Individuals with life-threatening situations and individuals whose situations are pharmacologically complex should have the same rights as well.

The final regulations for Section 423.38(c) must have distinct effective date timeframes for special election period enrollments. The proposed regulations would have the effective dates for enrollment during Special enrollment periods be determined by CMS, "which, to the extent practicable, will be determined in a manner consistent with protecting the continuity of health

benefits coverage". **This is too broad and imprecise. There must be parameters.**

Sec. 423.44 Disenrollment by the PDP.

Sec. 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.

I agree with Pennsylvania's suggestions on how CMS can better address this issue:

- **Require traveler benefits policies.** We believe the disruption and paperwork involved in this issue is so severe that we urge CMS to require as a condition of participation that plans have a system of visitor or traveler benefits.

- **Allow PDP exceptions.** We ask CMS to consider exempting regional PDPs and PDPs with out-of-network services from the disenrollment requirement. At a minimum, beneficiaries must have a clear understanding of how a plan will serve people temporarily out of the service area.

- **Require plans provide information on traveler benefits.** In addition to requiring traveler benefit policies, we urge that CMS require plans to provide prospective enrollees specific information on traveler benefits and "out-of-plan service policies." In many cases, 90 day mail order service and arrangements with other plans will make enrolling and disenrolling unnecessary. Beneficiaries who are traveling and need emergency pharmaceutical services need to know how their plan will (or will not) reimburse for those services.

- **Define time period.** The regulations should also clearly define the time period that a plan could consider an enrollee as "no longer resid(ing) in the PDP's service area."

I have many concerns about the provisions starting at Sec. 423.44 on disenrollment by the PDP. First, two of the grounds for disenrollment are extremely problematic for older consumers and those with disabilities and must be removed and/or revised. Second, the regulations fail to allow consumers to

appeal disenrollment decisions, including decisions refusing to reenroll a consumer.

The proposed regulation in Section 423.44(b)(2)(v) requires that a PDP disenroll a consumer who makes a "material misrepresentation" about whether he/she has other creditable coverage. Requiring plans to disenroll a consumer for this reason and allowing the PDP to refuse reenrollment [423.44 (d)(6)(ii)] to that consumer is too severe a penalty. First, the term is not defined to clearly exclude accidents or inadvertent omissions Such errors should not be penalized, especially considering how complicated and confusing the concept of creditable coverage is and will become when the Part D Program rolls out. Second, a consumer should be given an opportunity to cure a misrepresentation.

Allowing PDPs to disenroll consumers for disruptive behavior [423.44(b)(1)(ii)] and refuse them reenrollment [423.44(d)(2)(vi)] could be discriminatory to persons with certain disabilities or conditions. In addition, it could severely harm lower-income consumers and those in rural areas who may end up with no coverage for months at a time. I am very concerned that this provision [423.44(d)(2)(i) could be interpreted to allow PDPs to diseneroll elderly consumers with dementia or Alzheimers, or other consumers with mental health or other disabilities, whose "disruptive behavior" may arise out of their illness/condition. I am certain that the ability of a PDP to disenroll for this reason will have a chilling effect on consumers' filing grievances or appeals. We are also concerned that consumers could be disenrolled for disruptive behavior and denied reenrollment into what might be the only PDP serving their area. **This provision must be removed from the regulations.** Dual eligibles, for example, are losing their right to access any medication that meets Medicaid's definition of "medically necessary". It is easy to foresee a situation that would play out as follows: a dual eligible person loses Medicaid prescription coverage and is required to enroll in a PDP to access his medications; the PDP does not cover the medication the person had been using and that he had come to rely on to control his disability; without the medication, behavioral problems emerge; the consumer is then disenrolled because his lack of coverage led to "disruptive behavior". This is especially disconcerting in that the regulations do not clearly articulate that behavior that is attributable to a consumer's disability cannot ever be considered disruptive. The regulations fail to describe an appeal process, and even fail to state that the PDP must consider the information submitted to the PDP by the consumer before they disenroll the consumer and deny them reenrollment. And the proposed regulations are not clear that consumers who are dual eligibles and entitled to an SEP cannot be denied an SEP if disenrolled for disruptive behavior. In some locations dual eligibles who are disenrolled

might be denied access to the only PDP that serves their area, or which offers a PDP at the baseline premium amount.

The final regulations for Section 423.44 must be more specific about notice requirements related to disenrollments. In many places, the proposed regulations are not clear about when a notice must be sent and how much time must be given before the disenrollment becomes effective. Here, the proposed regulations state that notices of disenrollment are effective the first day of the calendar month after the notice is sent. The proposed regulations fail to articulate when notices must sent, how they must be sent, how they can be appealed, by whom they can be appealed, etc. This could be way too little notice if, for example, the notice is mailed on the 29th. Again, we recommend a separate Subpart on notice requirements.

The proposed Medicare Prescription Drug coverage is obliviously very cumbersome and will be extremely overwhelming the very population these regulations are supposed to help. I urge you to keep in the mind the consumer of this plan. These regulations should be finalized and approved with the best interests of seniors and others who have Medicare. I thank you for your time in reading my comments and hope that the concerns professionals working with this vulnerable population, seniors and others on Medicare, and the multiple advocacy groups are heard and taken into consideration.

Sincerely,

Jenny Hellman MSW, LSW

CMS-4068-P-837

Submitter : Mr. Steven Chang **Date & Time:** 10/04/2004 02:10:51

Organization : Parkway Pharmacy, Atlantic City, NJ

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I strongly urge CMS to implement Congress?s intent on Medicare Drug Coverage for the beneficiaries in the following areas:

1. Ensure beneficiaries can continue their current relationship with the Pharmacy/Pharmacist that providing the services they are satisfied
2. The ?COVERAGE AREA? are at the local level not a averaged by the national scope
3. Do not coerce beneficiaries' participation in mail-order program by implementing a differential co-pay structure, allow retail pharmacy/pharmacist assist beneficiaries to make that choice through Medication Therapy Management?s structured review

I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organization in July 2004, detail available at www.aphanet.org/LEAD/MTMS definition FINAL.pdf

I may be contacted at 609-345-5105 or email at parkwayrx@aol.com

Thank you for the consideration

CMS-4068-P-838

Submitter : Ms. Kathryn Gruchalla **Date & Time:** 10/04/2004 02:10:52

Organization : Student, UNM College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for allowing me to submit the following points to consider when revising the MPDB. As a student pharmacist, I want to know that my future patients receive the best benefit and choice protections possible. Pharmacy Access Standards: Pharmacists need to be able to serve their patients. To do that, the pharmacy access standard must be revised to require plans to meet the TRICARE requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy. If plans are only required to meet the pharmacy access standard, on average, across the plan's service area, the plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan's pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor. Any Willing Provider: I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could affect pharmacists' abilities to continue to serve their patients. Allowing plans to distinguish between pharmacies could allow plans to drive beneficiaries to a particular pharmacy. This goes against Congressional intent. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice. Only preferred pharmacies should count when evaluating whether a plan's pharmacy network meets the pharmacy access standard. That will help patients access a local pharmacy for their full benefit. Access isn't access if patients are coerced to use other pharmacies. Level Playing Field: If plans are allowed to charge a higher price for an extended supply obtained from a community pharmacy, CMS should clarify that the price difference must be directly related to the difference in service costs, not the cost of the drug product. Congressional intent, as identified in the colloquy of Senators Grassley and Enzi, opposes making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice. Thank you!

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

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation. I 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. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently see pharmacists providing MTM services at my internship site on a regular basis, and I myself am learning the skills needed to provide this valuable service within my PharmD education at the University of New Mexico. Optimizing drug therapy is achieved with the expertise of a pharmacist. I am concerned, however, that letting plans independently choose MTM providers will allow them to choose less qualified providers to provide MTM services. Plans should be encouraged to use pharmacist services allowing patients to make the best use of their medications. Please consider the following points for MTMS: Targeted Beneficiaries: Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS). Who will benefit from MTM can change, so plans should be required to identify new targeted beneficiaries on a monthly basis. Plans should be required to inform pharmacists who among their patients are eligible for MTM. Pharmacists and physicians should also be able to identify eligible beneficiaries. Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS. Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year. CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services. Providers Pharmacists, the medication expert on the health care team, are the ideal providers of MTMS. CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships. Fees: Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service. CMS must carefully evaluate each plan's application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS. Services: MTM services are independent of, but can occur in conjunction with, the provision of a medication product. I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as performing a health assessment, formulating a medication treatment plan, monitoring and evaluating a patient's response to therapy, etc. Face-to-face interaction between the beneficiary and the patient is the preferred method of delivery whenever possible. The initial assessment should always be face-to-face. I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004. (Definition and Criteria are

available at http://www.aphanet.org/lead/MTMS_definition_FINAL.pdf).

CMS-4068-P-839

Submitter : Dusty Allen **Date & Time:** 10/04/2004 02:10:18

Organization : American Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I'm a Pharmacy student at SWOSU College of pharmacy in weatherford, OK. As a student about to graduate I'm thinking of how this could impact me as a pharmacist. I've worked in pharmacy for the past 5 1/2 years.
SUBPART C ? BENEFITS & BENEFICIARY PROTECTIONS
There are many points that I would like to have changed,
1) I want to be able to serve my patients. To do that, CMS should revise the pharmacy access standard to require plans to meet the TRICARE requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.
2)If plans are only required to meet the pharmacy access standard ?on average? across the plan?s service area, the plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan?s pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor.
One thing that could be a problem for small community pharmacies is that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could affect my ability to continue to serve my patients. This could Allowing plans to distinguish between pharmacies could allow plans to drive beneficiaries to a particular pharmacy. This goes against Congressional intent. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice.
The next point I would like to make is concerning creating a level playing field. Plans must allow beneficiaries to obtain the same benefits at a community pharmacy that they can access at a mail service pharmacy. The benefits could include an extended supply of medications (such as a 90-day supply) which some plans have historically only made available through a mail service pharmacy. If plans are allowed to charge a higher price for an extended supply obtained from a community pharmacy, CMS should clarify that the price difference must be directly related to the difference in service costs, not the cost of the drug product. Congressional intent, as identified in the colloquy of Senators Grassley and Enzi, opposes making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice.
SUBPART D ? COST CONTROL & QUALITY IMPROVEMENT REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS
Medication Therapy Management Program: Plans are required to establish a medication therapy management (MTM) program. The purpose of the MTM program is to provide services that will optimize therapeutic outcomes for targeted beneficiaries (individuals with multiple chronic disease, taking multiple drugs, and likely to incur annual costs that exceed a certain level). CMS believes that pharmacists will be the primary providers of MTM services. Plans must establish fees for pharmacists and others that provide MTM services.
I think there should be Targeted Beneficiaries, which are patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS). Heres a list of items that I think should be considered concerning Targeted Beneficiaries
1)Plans should be required to inform pharmacists who among their patients are eligible for MTM.
2)Pharmacists and physicians should also be able to identify eligible beneficiaries.
3)Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
Providers
Pharmacists, the medication expert on the health care team, are the ideal providers of MTMS.
CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships.
Fees
Plans must be required to pay the same fee for MTMS to all providers.

Submitter : Mrs. Marci Daugherty **Date & Time:** 10/04/2004 03:10:23

Organization : Marsh Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

October 3, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

-- Subpart C: Benefits & Beneficiary Protections
Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan's overall service level. Requiring plans to meet the standard on a local level is
the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred
and non-preferred pharmacies with no requirements on the number of preferred
pharmacies a plan must have in its network. Plans could identify one preferred
pharmacy and coerce patients to use it through lower co-payments, negating
the benefit of the access standards. Only preferred pharmacies should count
when evaluating whether a plan has meet the pharmacy access standards.
Allowing plans to count their non-preferred pharmacies conflicts with Congress?
intent to provide patients fair access to local pharmacies. CMS should require
plans to offer a standard contract to all pharmacies.

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

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

Pharmacists are the ideal health care professionals to provide MTM services
and determine which services each beneficiary needs. I currently provide the
following MTM services in my practice: diabetes, hyperlipidemia.
Plans should be encouraged to use my services ? to let me help my patients
make the best use of their medications.

Thank you for considering my view.

Sincerely,
Marci Daugherty, RPh, CDM

Submitter : Michel Disco **Date & Time:** 10/04/2004 03:10:35

Organization : New Mexico Pharmaceutical Care Foundation

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

New Mexico Pharmaceutical Care Foundation
4800 Zuni S.E.
Albuquerque, New Mexico 87108

October 3, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
www.cms.hhs.gov/regulations/ecomments

Re: CMS-4068-P

Dear Sir or Madam:

The purpose of this letter is to comment on the Medication Prescription Drug Improvement, and Modernization Act of 2003 (MMA), specifically the Medication Therapy Management Program.

The New Mexico Pharmaceutical Care Foundation was established to provide resources for pharmacy education, research, projects in pharmaceutical care and disease management, education for pharmacists, pharmacy technicians and the public, and community screening and public health projects related to pharmaceutical care.

Currently, under New Mexico law, pharmacists can have full prescriptive authority under the supervision of a physician to provide medication therapy management limited only to the scope of the physician?s practice.

As the New Mexico Pharmaceutical Care Foundation, we make the following recommendations for successful implementation of the program, leading to improved patient care.

It is our position that CMS should include in the rules:
1. Rules to determine who is a qualified provider, and that pharmacists should be granted primary provider status within the regulations.
2. Under-use of medications often is as serious a drug-related problem as is over-use. Based upon this, targeted beneficiaries should not be limited, except to patients with at least one chronic disease condition.
3. Reimbursement rates must be determined nationally by CMS using any willing provider guidelines and ensuring appropriate coverage areas.
4. The patient must have freedom of choice of providers.
5. CMS must ensure that contractors have full coverage for patient and provider access in rural and underserved areas.

Signed,

Joy Donelson, RPh
President

CMS-4068-P-842

Submitter : Ms. Gwenda Cannard **Date & Time:** 10/04/2004 03:10:48

Organization : TRANX (Tranquilliser Recovery & New Existence)inc

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Re: benzodiazepine exclusion from Medicaid.
The proposal will disadvantage long term dependent users of these drugs by initiating drug withdrawal without the consent of the individual.Benzodiazepine withdrawal has been well documented and can be painful and protracted.Provision needs to be made to ensure that prescribing under Medicaid can continue for people who have been using the drugs long term and are unable to reduce their intake;and for those who need access to these drugs to implement a gradual reduction program to come off the bzds.Many people in this category are older people, who, through inappropriate prescribing, have become dependent on the bzds.Gradual reduction programs can take as long as six months to 1 year or even longer for people who have been taking these drugs for many years. Slow reduction is best practice in this area and minimises the severity of withdrawal.

CMS-4068-P-843

Submitter : **Date & Time:** 10/04/2004 03:10:09

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Here are a couple of items I would urge to be considered-:

Firstly Under Subpart C, please revise the pharmacy access standards to ensure that plans meet the TRICARE pharmacy access requirements on a local (zip code) level, not on the plan's regional or "average" overall level. Requiring a plan to meet the standard on a local level is the only way to make sure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intent to provide a level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

Secondly Under Subpart D, please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries.

Thanks again for considering these revisions.

CMS-4068-P-844

Submitter : Mr. Jayme Steig **Date & Time:** 10/04/2004 03:10:47

Organization : Mr. Jayme Steig

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a 27 year-old community pharmacist from North Dakota, I am concerned with this program for a variety of reasons. My general concern is that this bill does not do enough for help the Medicare recipient when compared to the cost of the program. I believe if you are going to do something, you should do it right; and this program does not do that. This program will not provide adequate coverage for seniors and will drain the medicare fund in the process.

Being from North Dakota, I am concerned about the access to pharmacies by rural North Dakotans on this program. The TriCare pharmacy access standards need to be implemented in order to assure access to pharamcies by all participants in the program.

This programs reliance on PBMs is also a concern. There needs to be transparency in rebates received by PBMs. Also, PBMs involved in the Medicare program should not be allowed from using economic incentives to push participants into the PBM's mail order services. This does a great injustice to the participants and the community pharmacists that serve them. I cannot count the number of times I have had to dispense medication to someone whose mail order medications were not received or provide counsultation to individuals that have received their medication through the mail but do not have adequate information to correctly use their medication. These needs can be met by community pharmacists.

As a young pharmacist with a Doctor of Pharmacy (Pharm.D.) degree, I am well trained and excited to provide quality medication managment to my patients. I have the clinical, pharmacologic, and communication skills necessary to help my patients achieve a higher quality of health. For these reasons, I support the medication therapy managment (MTM) program. I am afraid, however, that the MTM program will not meet its potential if it is not given more specificity. There needs to be definitions on who will be eligible to provide the service and how they will be reimbursed. Only through quality care by qualified pharmacists will MTM be the success it can and should be.

CMS-4068-P-845

Submitter : Miss. Mary Morgan **Date & Time:** 10/04/2004 03:10:23

Organization : UNC Pharmacy Student

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 3, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final program.

Subpart C: Benefits and Beneficiary Protections
? In order to be able to serve all patients, CMS should revise the pharmacy access standard to require plans to meet the TRICARE requirements on a local level, not on the plan?s service level.

? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This distinction could allow plans to drive beneficiaries to another pharmacy. This plan goes against Congress intent of ensuring that patients can use the pharmacy of their choice. Many patients trust their pharmacist, and being forced to change pharmacies will take longer for them to build trust with another pharmacist.

? If plans are changed to charge a higher price for extended supply medications, then CMS should document this change and inform patients of this change in cost. CMS should clarify that the price difference is due to service costs not on the cost of the drug.

Subpart D: Cost Control and 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. Plans should be made so that pharmacists are the MTM and not other less qualified providers. This is a service that can benefit many people and utilizes the skills of Pharmacists. As a student I cannot perform these services currently, but would like to be able to when I am a licensed pharmacist. I would like to provide services for patients with chronic disease states such as diabetes, hypertension, or hyperlipidemia. This decision would create a big impact on what my future career would entail. Plans should be encouraged so that patients can use services that allow them to make the best use of their medications.

In conclusion, I urge CMS to revise the regulation of:
? Revising pharmacy access to reach TRICARE requirements on a local level.
? There should not be a preferred/non-preferred pharmacy. Patients should be able to choose the pharmacy of their choice.
? Clarifying price changes with extended supply of drug
? Pharmacists should be the provider for MTM, because of their extended knowledge base and ability to help patients.

Thank you for considering my view.

Sincerely,

Mary Katherine Morgan

CMS-4068-P-846

Submitter : Mr. Douglas Stelling **Date & Time:** 10/04/2004 03:10:05

Organization : Mr. Douglas Stelling

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-846-Attach-1.doc

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

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

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

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

CMS-4068-P-847

Submitter : **Date & Time:** **10/04/2004 04:10:40**

Organization : **Oregon State Pharmacy Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachments.

CMS-4068-P-847-Attach-2.pdf

CMS-4068-P-847-Attach-1.doc

Medication Therapy Management Services
Definition and Program Criteria

Original: 4-May-04 (APhA MTM Services Working Group)
Last Revised: 7-Jul-04 (Pharmacy Profession Stakeholders)
Approved: 27-Jul-04 (by 11 Supporting Organizations)

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product.

Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

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

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

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

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

OREGON STATE PHARMACY ASSOCIATION
29702-B SW TOWN CENTER LOOP WEST • WILSONVILLE, OR 97070-6481 • 503-582-9055
www.oregonpharmacy.org

October 4, 2004

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

Re: CMS-4068-P

Dear Sir/Madam:

Thank you for the opportunity to comment on proposed rules to implement the Medicare Prescription Drug Benefit. I am writing on behalf of our member pharmacists and pharmacy technicians, who practice in independent and chain retail, hospital, senior care, mail service and specialty settings throughout the state of Oregon, in both the private and public sectors. These comments reflect their expert views and experience.

Due to the complexity and breadth of the issues at hand, our comments are organized into the following subject areas within the proposed rules: Dispensing; access to care; Medication Therapy Management Services; quality improvement; e-prescribing; contracting issues; and general administration of Part D benefits.

Definition of "Dispensing."

The proposed rules offer three options to define "dispensing." We support adoption of "Option 1," that is, "only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery and overhead." This is consistent with many private third-party contracts today, which usually offer only nominal dispensing fees that do not reflect the true cost of professional services rendered. We also support adoption of Option 2, which would include "amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered" – provided CMS requires MA-PDs and PDPs to pay appropriate fees to cover the costs of these products as well as the professional time usually necessary to demonstrate their use.

We oppose adoption of "Option 3," which includes services, such as "ongoing monitoring by a clinical pharmacist," that would be more properly within the scope of Medication Therapy Management Services.

Access to Care

CMS' proposed rules appear to reflect a fundamental misunderstanding of the statutory requirement to adopt the TriCare standards of pharmacy access, as well as a misunderstanding of the nature of pharmacy services provided to persons in community based residential care and skilled nursing facilities. These aspects of the proposed rules require considerable clarification and revision in order to meet statutory requirements and documented congressional intent. In only one area – the idea of a level playing field between mail order and other pharmacies – do the proposed rules appear to meet statutory requirements and congressional intent, but even then only partially so.

Long-term Care:

CMS states in its proposal (p. 46657): "It is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient pharmacies." This statement reveals a shocking disregard for the vital specialized services provided by pharmacies that service nursing homes, assisted living, adult foster care and other community based residential care settings. The policy choice at hand is not between "efficient pharmacies" and long-term care pharmacies. It is between appropriate specialty pharmacist care for the most vulnerable patients among seniors and allowing MA-PDs and PDPs to drive a reckless race to the bottom in standards of care.

Pharmacies that specialize in serving these populations are highly efficient, and indeed professional focus and efficiency is the very reason that the institutional pharmacy sector exists.

For purposes of Part D, we recommend that the definition of "long-term care" be expanded to include other forms of residential care typically serviced by senior care pharmacies. Specifically, in addition to patients in skilled nursing facilities, Part D should recognize the unique services and added costs of providing pharmacy services to persons in assisted living and adult foster care.

From a pharmacy perspective, the services required – unit dose packaging, managing medication therapy, working through intermediary caregivers – are very similar. Specialty long-term care pharmacies licensed as institutional pharmacies often provide such services, but retail pharmacies – particularly rural independent pharmacies – also provide similar services on a smaller scale; therefore, CMS should require MA-PDs and PDPs to base qualification for long-term care levels of reimbursement upon the services actually provided by a pharmacy, not on the pharmacy's classification. For example, MA-PDs and PDPs should be required to provide the same terms and conditions to all pharmacies for unit-dose or other customized packaging, consultant pharmacy services, and medication therapy management. Such an approach would benefit patients and taxpayers by avoiding perverse incentives to elevate patients to skilled nursing care in order to obtain appropriate pharmacy services.

Home Infusion Pharmacies:

We agree that it is important for both PDPs and MA-PDs to contract with a sufficient number of home infusion pharmacies in their service area, per section 1860D-4 (b)(1)(c), for reasonable access for beneficiaries. However, home infusion pharmacies should not be counted in the network for meeting TriCare access standards.

Tri-Care Standards:

The proposed rules suggest several ways that MA-PDs and PDPs could avoid the strict statutory requirement to meet or exceed the Tri-Care retail pharmacy access standards, among them: "Averaging access" measurement regionally, allowing plans to develop "preferred" and "non-preferred" networks and allowing plans to use Indian Health Service and tribal pharmacies in calculating access.

"Averaging" access: The Medicare statute and TriCare set out clear standards of access. The only way that CMS can meet the requirements of the law is to require MA-PDs and PDPs to calculate access on a local basis in each state, not regionally. This is particularly critical in largely rural states such as Oregon. If a regional average were allowed, then many seniors in remote areas effectively would be denied access to Part D.

"Preferred" and "Non-Preferred" Networks: If MA-PDs and PDPs were allowed to include "non-preferred pharmacies" – where patients presumably would be forced to absorb more cost sharing – for purposes of measuring access, then plans would be allowed to meet the statutorily required access standards without actually providing any access at all. This flies in the face of the clear congressional

intent to provide wide access to retail pharmacies. CMS should require all plans to offer all pharmacies of a similar nature (e.g. institutional, retail, rural, urban, suburban) the same contract terms.

Indian Health Service and tribal pharmacies: As CMS itself observes in its proposal, IHS and tribal pharmacies do not service the general population and purchase prescription drugs based on the Federal Supply Schedule (FSS). We agree that in some areas, such as Oregon's Warm Springs Reservation, failing to include tribal pharmacies in MA-PDs and PDPs would effectively deny access to Part D for tribal members. But the solution to this problem is not to allow plans to count IHS and tribal pharmacies for purposes of calculating whether a plan has met the TriCare access standards; that could have the equally damaging effect of denying non-tribal patients access to local pharmacies in communities near Indian reservations. For example, the Grand Ronde Tribe operates a pharmacy to serve tribal members in Grand Ronde, Ore. If that pharmacy could be counted toward meeting TriCare standards, then residents of the nearby communities of Sheridan and Willamina could be denied Part D access to their local pharmacies.

We therefore suggest an alternative to meet the needs of tribal members and seniors in nearby communities: CMS should require MA-PDs and PDPs to include IHS and tribal pharmacies in their networks, in addition to other pharmacies, under the same terms and conditions, adjusted for the lower acquisition costs reflected in the FSS.

"Level playing field" between retail and mail order pharmacies: We are pleased to see that CMS intends to pursue program designs which will serve to level the playing field between community based pharmacies and mail order pharmacies, as is clear in the statute and congressional intent (see, for example, the floor colloquy between Sens. Grassley and Enzi). However, we are concerned that the rule does not go far enough to ensure a true level playing field that favors beneficiary choice. Accordingly, we believes that CMS rules should clearly state that no PDP may create any incentive for the use of mail delivered benefits over community delivered benefits.

In addition, we are greatly concerned that CMS would allow a PDP or MA-PD to both manage a network of community pharmacies and promote its own mail order operation in direct competition with that pharmacy network, and even possibly use manufacturer rebates gained from the community pharmacy network to subsidize lower patient cost-sharing through their captive mail order pharmacies. Such a conflict of interest must be recognized by CMS and prohibited in its enabling regulation. Fragmenting patient care services for the sole purpose of promoting profits should not be dismissed by CMS as an acceptable risk in exchange for promises of "cheap drugs in a bottle".

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, consistent with Medicare rules for other health services.

Let us be clear in stating that we do not oppose the existence of mail order pharmacies or their participation in Part D. Mail service has a place in pharmacy, and it often works well for patients with uncomplicated medication regimens who choose mail service for reasons other than economic coercion. But many seniors want or need face-to-face interaction with community retail pharmacists to succeed in their drug therapies. To ensure that Medicare beneficiaries do not become targeted profit centers for PDPs, CMS should adopt rules to ensure full and uncompromised beneficiary choice of pharmacy providers.

Medication Therapy Management Services

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

Furthermore, the pharmacy benefits management (PBM) industry, which is likely to be among the PDPs, has demonstrated little consideration of provider costs or the needs of special populations such as seniors. In fact, the PBM industry's primitive focus on product cost at the expense of patient care services has resulted in diminished pharmacy access in rural areas and has impeded the adoption of pharmacy based patient care services that have been proven to be beneficial to patients and payers in numerous studies.

In order for this new Medicare program to succeed, CMS must assume a strong oversight and standards-setting role in Medication Therapy Management Services. This is not without precedent. In OBRA-90 the federal government declared minimum standards of pharmacy practice for patient counseling. CMS has a responsibility to play a similar role with Part D in the face of evidence that third-party payers are rife with both systemic and internal conflicts of interest against encouraging adoption of real MTMS as standards of practice.

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

In implementing MTMS, it is vital for CMS to remember that the purpose of Medication Therapy Management is to optimize drug therapy and health outcomes for targeted beneficiaries – individuals with multiple chronic disease conditions, taking multiple drugs and those whose annual health costs are likely to be high.

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

More specifically, CMS should:

- Require PDPs and MA-PDs to provide MTMS for patients with two or more chronic conditions and taking two or more prescription or prescribed over-the-counter drugs.
- Clarify the rules to ensure that pharmacists may provide fee-for-service MTMS to non-targeted beneficiaries, since MTMS is not a covered service under Part D for non-targeted beneficiaries.
- CMS rules must allow for all pharmacists to be included in MTMS, not limit MTMS to those who possess a certain advanced degree (e.g. Pharm.D.), title ("clinical pharmacist" or "pharmacist practitioner" or pharmacists practicing at an in-network pharmacy (some pharmacists work independently and are not attached to a particular pharmacy). The criteria MTMS payment

should be the quality of services rendered. MTMS services currently provided in the private sector not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary hospitalizations and expensive emergency room visits. Examples of MTMS include, but should not be limited to, anticoagulation therapy management, diabetes monitoring and education, asthma teaching, cholesterol monitoring, anemia therapy management, dosing of medication therapies in the elderly, compliance management education for HIV patients with complex medication regimens and assuring patients with chronic diseases such as heart failure are taking the right medications.

- All pharmacists practicing within a region (regardless of practice setting) should be afforded the opportunity to provide and be paid for MTM services such that plan sponsors should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service. Furthermore, all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.
- Plans should be required to inform pharmacists who among their patients are eligible for MTMS. Similarly, plans should be required to inform beneficiaries that they are eligible for MTMS.
- Pharmacists, as learned health care professionals, should be allowed to initiate MTMS and plans should be required to provide payment for such services. Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services and be eligible to provide MTM services to these patients. Identification of targeted beneficiaries should not be left solely to the plan. Plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription.
- MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services. They should not be allowed to discriminate and leave pharmacists engaged in direct patient care out.
- MTM services should be able to be provided in conjunction with and outside of product dispensing, and not necessarily incident to a visit to a physician or other non-pharmacist provider.
- An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.
- Plan sponsors should be required to establish at CMS-specified set of MTM services. The specified set of services should be a minimum set while additional services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, chronic and acute pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management, training for self-administration of drugs (e.g. insulin) and adverse drug event assessment and prevention should be included.
- CMS should consider developing a program to accredit plans that agree to meet the above stated conditions that add value to and lower the cost of care.
- CMS must outline specific quality assurance requirements that PDP must report to ensure appropriate implementation and ongoing operations of MTMP. Due to the adverse incentive for PDP to provide MTMP, it is imperative the CMS establish stringent reporting and accountability standards for MTMP. It would be appropriate for Quality Improvement Organizations to serve in this capacity. PDP should report how many beneficiaries received each type of MTM service and from which provider type. A specified percentage of beneficiaries within each PDP should receive MTM services, and these services should be diverse based on patient-specific needs. PDP must supply documentation that supports how individual beneficiary needs are identified and met, how the

appropriate MTM provider type was selected, and outcomes achieved through these services. Methods to ensure beneficiary choice of MTMP provider should also be documented.

- Information on effective MTMP services that could be publicized and used by beneficiaries (page 210): PDP have an adverse incentive to promote effective MTMP. For instance, an effective HIV/AIDS MTMP would stimulate more enrollment of beneficiaries with HIV/AIDS, diabetes and other high-cost diseases. Thus, more drug costs would be incurred by the PDP. Further, any savings in Medicare Parts A and B would be not be realized by the PDP. Therefore, it is critical that requirements for all PDP outline quality and other performance benchmarks. PDP should be held financially responsible for not meeting these benchmarks related to MTMP.

Quality Improvement Organizations

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

On page 235 of the proposed rule, CMS states that QIOs will be required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. In the proposed 8th Scope of Work Task 1d3: Part D benefit, QIOs are asked to comment on their role to implement quality improvement projects.

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

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

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

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

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

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

- Quality improvement projects will include the four bullets listed in Task 1d3 above.
- QIOs must have timely access to pharmacy and medical claims for quality improvement projects and quality oversight of the PDPs.
- Of the elements listed in the proposed rule as desirable for quality assurance systems, actionable, educational interventions and the assessment of those interventions are essential.
- Educational interventions are best done by QIOs or a third party (independent of the PDP) contracted by the QIO.
- Educational interventions will focus on significant and actionable therapeutic or cost containment issues to improve the quality of care provided.
- Quality improvement projects will be performed by the QIO or a third party (independent of the PDP) contracted by the QIO.
- Further definition of the Medicare Prescription Benefit will be necessary for QIO's to fully implement quality improvement programs.
- Oversight of formulary decisions and subsequent review of PDP formulary decisions could be key components necessary for QIO's to assess quality, especially in the dual-eligible long term care patients.
- CMS should take great care to avoid duplicating activities of state-based patient safety organizations, whether well-established or, as Oregon's Patient Safety Commission is, in their infancy.

E-Prescribing:

We are pleased that CMS has asked for specific suggestions on how to encourage more rapid adoption of electronic prescribing, which holds great promise to reduce errors and to improve both retrospective and prospective drug use review.

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

We believe one essential step toward broad adoption of e-prescribing would be for CMS to require all MA-PDs and PDPs to accept electronic prescription and dispensing records, including scanned records, as valid for purposes of payment audits. We have seen instances of third-party payers refusing to accept electronic records as evidence of accurate dispensing, which has forced pharmacies to actually create paper records from electronically transmitted prescriptions; such payer abuses exemplify the height of stupidity. Until payers fully accept electronic records, e-prescribing will be hindered.

Contracting Issues:

While we understand and support the notion that CMS should not determine the precise terms of every pharmacy contract, there is a significant oversight role for CMS to play in an area ripe for contract abuse absent strong CMS oversight. Our specific suggestions in this area are:

- MA-PDs and PDPs should be required to gain CMS approval of model contract language, and plans should be required to use only those contracts in agreements with pharmacies. Such a requirement could be crafted to leave reimbursement rates up to the discretion of plans.
- CMS must provide oversight of reimbursement rates, but without determining rates, to ensure that payment for pharmacy services is adequate to provide fair reimbursement to pharmacies for both basic dispensing services and other services, especially Medication Management Therapy Services. PDP sponsors or MA organizations should be required to substantiate a payment

setting process which considers reasonable standards and recognition of pharmacy provider costs. If traditional PBM practices are allowed to persist in the Medicare program, access and quality of care problems will surely emerge upon this vulnerable patient population.

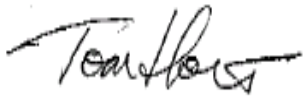
- Prior authorization processes must provide for reasonable therapeutic exceptions, taking into account the welfare of the patient (such as patient stability under complex multiple medication regimens) as well as cost of a particular products. MA-PDs and PDPs should be required to include in their contracts provisions to pay pharmacies to dispense emergency supplies for up to 96 hours of medication pending resolution of prior authorizations. This is the standard used in Oregon's Medicaid program, which allows a patient to get enough medication on a Friday to carry through to resolution of an issue the following Monday.
- MA-PDs and PDPs should be required to accept successful electronic adjudication of a claim as evidence of patient eligibility. We are fully aware of the fact that all plans will have a degree of "churn"; however, this should be factored into rate-setting, not shifted to pharmacies that must be able to rely upon the claims payment processing system.

General Administration Issues:

- CMS should consider requiring MA-PDs and PDPs to reimburse pharmacists for immunization services at the same rates paid to other immunization providers under Part B. Pharmacists have become a major source of immunization services in recent years, and CMS should take advantage of the claims processing efficiencies of Part D to increase immunization rates among the elderly.
- MA-PDs and PDPs should be required to maintain 24/7 help desk access for pharmacists and patients. Claims processing and medication therapy issues obviously can occur at any hour of the day or night, on any day of the week.
- MA-PDs and PDPs should be required to establish pharmacy and therapeutics (P&T) committees to oversee development of formularies, formulary exceptions processes, prior authorization processes, and retrospective drug use review. P&T Committees should be comprised of equal numbers of pharmacists and physicians, and should include both pharmacy and physician specialists.
- MA-PDs and PDPs should be required to adopt the NCPDP-approved patient claim card format, as CMS suggests.
- When patients must or choose to use an out-of-network pharmacy, expenses should be counted toward total out-of-pocket expenses. In addition, the rules should specify that pharmacies may charge their "usual and customary" fees to out-of-network patients, and those patients would then need to seek reimbursement from their MA-PD or PDP. Since an out-of-network pharmacy by definition will not have access to the preferred pharmacy rate for any product, this approach would appropriately balance patient choice with payment issues.
- We support the proposed requirement that pharmacies inform patients of the cost of a comparable, lower-cost generic drug if a generic drug is not being dispensed. This is simply good public policy; it would encourage patients to choose generics and thereby play a stewardship role in the program. Left unaware of cost differentials, patients may use more expensive therapies at taxpayer expense.
- We are extremely concerned that the transition of "dual eligible" patients from state-based Medicaid to the new Part D is fraught with peril for our nation's most fragile patients. CMS must take great care to ensure that "dual eligible" patients suffer an interruption in their drug therapies. MA-PDs and PDPs must be required to provide benefits information to patients, their caregivers and their involved physicians and pharmacies at least 45 days in advance of the changeover in order to provide adequate time to make the necessary adjustments in drug therapies without putting patients' lives at risk.

Conclusion:
We appreciate the opportunity to provide the above comments. The fact that Congress left much operational detail unwritten is reflected in the draft rules. We stand ready to work with CMS and other health care providers to make Part D a success.

Sincerely,



Tom Holt, CAE
Executive Director
Oregon State Pharmacy Association

Consensus Definition of MTMS Follows beginning on next page

Medication Therapy Management Services
Definition and Program Criteria

Original: 4-May-04 (American Pharmacists Association MTM Services Working Group)
Last Revised: 7-Jul-04 (Pharmacy Profession Stakeholders)
Approved: 27-Jul-04 (by 11 Supporting Organizations)

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

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

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

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

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

CMS-4068-P-848

Submitter : **Date & Time:** **10/04/2004 04:10:25**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

October 3rd, 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,

I would like to thank you for granting the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. Below are the comments I present to be considered as the final regulations are being developed by CMS.

Subpart C: Benefits & Beneficiary Protections
It is very important for patients to be able to have access to a local pharmacy. So in order to accomplish this goal, please make revisions on the pharmacy access standards. These revisions should require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Meeting standards on a local level is the absolute route for making sure that all beneficiaries have a convenient access to a local pharmacy.

I also have concerns about the proposed regulation that allow plans to make distinctions and designate pharmacies within the network as ?preferred? and ?non-preferred?. This could affect the ability of pharmacist to continue to serve their patients by driving them to a particular pharmacy. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments thereby affecting the benefit and purpose of the access standards. CMS should require plans to offer a standard contract to all pharmacies.

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I appreciate the fact that CMS understands that different beneficiaries will require different MTM services such as health assessment, a medication treatment plan, monitoring and evaluating response to therapy just to mention a few. I also appreciate CMS? recognition that pharmacists will likely be the primary providers because of the excellent training and great expertise in these areas compared to other health professionals. However, I am very concerned that leaving the decisions to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the drug experts and therefore would be the ideal health care professional to render MTM services and determine specific and more focused needs of each beneficiary. I currently provide patient counseling on drug therapy, including potential drug?drug, drug-food, and drug-illness interactions, side effects and other concerns of the patient during internship and while on rotations. Plans should be encouraged to use my services to allow me to facilitate and optimize patient care.

In conclusion, I strongly urge CMS to require plans: 1) to meet TRICARE pharmacy access requirements on a local level, 2) to offer standard contract to all pharmacies, 3) choose pharmacists to provide MTM services.

Thank you for considering my view.

Sincerely,
Gloria Johnson
Asuquo@email.unc.edu

Submitter : **Date & Time:** 10/04/2004 05:10:27

Organization :

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

As a pharmacy student I look forward to providing MTMS to my patients. Pharmacists are the ideal professionals to provide this service. It is important that plans do not require patients to have this service at a preferred pharmacy. This would damage the existing patient-pharmacist relationship. All providers should receive the same reimbursement for MTMS. Non-preferred pharmacies should not receive less.

CMS-4068-P-850

Submitter : Mr. Zachary Foucault **Date & Time:** 10/04/2004 06:10:36

Organization : Omni Diabetes, Inc.

Category : Media Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The definition of Covered Part-D Drugs includes "medical supplies associated with the administration of insulin." However, the proposed definition of these supplies does not include provisions for the safe disposal of more than 3 billion needles used annually in the home. Disposal of the used needle is an inevitable function of insulin administration, and safe disposal is crucial to the safety of the patient. This issue is supported by members of both the House and Senate. The Coalition for Safe Community Needle Disposal, including such organizations as the American Medical Association, the American Pharmaceutical Association and the American Association of Diabetes Educators agree that proper needle disposal is a medically necessary step in a patient's treatment regime. The societal, environmental and public health benefits of proper needle disposal should also be taken into serious consideration. I strongly urge you to cover the costs of such disposal in a manner that is simple, cost effective, and convenient to the person using sharps (syringes, lancets, etc.) to manage their diabetes. These sharpes can number as many as, but not limited to, 10 syringes per day and 15 lancets per day in order to effectively treat the disease state. These sharpes pose a threat to additional family members, including children, garbage disposal and waste process workers, neighbors, community members, and others that may come in contact with the materials post-patient-use. Without proper coverage and compensation for an effective disposal method, patients do not have the ability or financial means to ensure sharpes are effectively and safely destroyed.

CMS-4068-P-851

Submitter : Mrs. Paula Kwong **Date & Time:** 10/04/2004 07:10:47

Organization : Mrs. Paula Kwong

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

In order to allow convenient access to all beneficiaries it will be important to require plans to meet TRICARE pharmacy access requirements on a local rather than overall service level. In addition, creating "preferred" pharmacies will result in forcing beneficiaries to use a certain pharmacy which may limit or decrease access and therefore be contrary to the goal of Congress' intent to improve access to medications.

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

It is my understanding that plans do not have to choose pharmacists as the providers of MTM services. Pharmacists are the ideal providers of MTM services thru our education and training in appropriate drug use, developing medication treatment plans, and monitoring & evaluating response to therapy. I think plans should be encouraged if not required to use pharmacists as the providers of MTM services. Pharmacists are not only well trained but the most accessible of health care professionals.

CMS-4068-P-852

Submitter : Mr. Randall Witherspoon **Date & Time:** 10/04/2004 08:10:29

Organization : The Apothecary Shoppe

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

As CMS did not write this political rule, our legislators did with the help to the drug companies, insurance companies, and PBM's, please make sure that the drug companies, insurance companies and PBM's see no more than a 3% increase in sales and .6 to 1.9% increase in their nets. Until the government negotitiates the prices on drugs like they do with the VA, both Medicare and Medicaid will continue to get the shaft along with the American people. The combined buying power of Medicare and Medicaid dwarfs that of the VA. In the early 90's when I was paying $11.00 for a vial of insulin and selling it for 11.09, the VA was paying $1.00 for the same vial. Why?

BENEFITS AND BENEFICIARY PROTECTIONS

Sorry if this sounds bitter. I'm just skeptical of what you're about to do and have no idea of the consequences. Please listen to those who know. Our physicians are so tired of the endless stream of change to this drug phone calls, faxes, and needing PA's that more and more are dropping out of insurance altogether.

Respectfully submitted,

RCW

ELIGIBILITY, ELECTION, AND ENROLLMENT

I had a list already but the outcome is already predetermined. Haven't you learned anything from the 20+, 36, now 143 Medicare approved cards. I had one lady bring in 17 different applications and ask what she should do. The local pharmacist is the most accessible Healthcare provider out there. Someday, you're going to realize that, hopefully before it's too late as both chains and independents are hurt with shortsighted policies. Has anyone given anythought to how seniors are going to afford these wonderful increases in their medicare premiums with only 3% increases in their social security. Why do the PBM's who got $30.00 to enroll people in medicare (we did alot of talking for nothing), get 0.05 to .12 from us for electronic charges, get an additional $1.00 from the beneficary for each prescription that we have to explain? I do the work for $2.00 and they get $1.00 because of what? Please make sure there is a prompt payment rule (every 2 weeks maximum) otherwise these guys are going to go the limit on every claim. One good thing is that our State laws are superceeded so therefore they can't use them against us in their audits looking to recoup more money than they've paid us.

GENERAL PROVISIONS

How is there a "Level Playing Field" when retail while giving a 90 day supply, is charges the patient more (sending them to mail order). If that is the intent, and the patient choses mail order due to preferential pricing by both the drug manufacturer and the PBM, then they should be considered a mail order receipient and when they want something at retail, they pay cash. What happens when the mail order pharmacy (are they owned by is there a financial interest by the PBM's or insurers. If so should this not be considered under the Stark Act?), fail to deliever on time. The patients go without rather than pay cash because if the retail pharmacy sends in a claim, we get the message "Refill too soon", why not add a "denial override which states "Mail Order did not arrive" Local pharmacy reimbursed at their ususal and customary for a two week supply and the patient pays nothing. As soon as you all the PBM's to interpret anywilling provider their way or to make a "preferred -non preferred" pharmacy, you have taken away the patients freedom of choice. In our county, there are currently four independents and two chains. With the push to all mail order, there will soon be two of each left. I will not spend 20 minutes on the phone to solve an insurance or mail order problem any longer. You will need a toll free number for people to call to have a HHS employee drop the prescription off on their way home. I have read the proposed rules and other than the fact they have only the drug companies, PBM's and Insurance Companies in mind, not the elderly receipient who cannot wait 30 minutes for a response or play push button for 10 minutes the e prescribing was the only thing that would help. You don't have to provide dollars for it, just mandate it. And mandate the insurance companies put their formularies on E-Pocrates or some

similar service so the pharmacy knows if the product is covered. What I don't understand is all rebates and discounts have to be passed on to Medicaid/Medicare or at least that's how we've always done it. Why not pass a rule which states "favored nation" a term the insurance companies use on us, whatever the lowest fee we charge is what they pay before electronic charges. Simply use that on the drug companies. Whatever is the lowest price charged to any buyer on January 1st, 2004 is the price Medicare will pay, period. Forget the rest as you've just put over a trillion dollars into the system.

CMS-4068-P-853

Submitter : Ms. Darby Schultz **Date & Time:** 10/04/2004 10:10:01

Organization : Ms. Darby Schultz

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-853-Attach-1.doc

CMS-4068-P-853-Attach-2.doc

Darby Y. Schultz

1615 Emerson Street #2 * Honolulu, HI 96813

October 3, 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 would like 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. The following are critical recommendations:

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. I am very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006), I recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. I view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries.
I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

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

Darby Y. Schultz

1615 Emerson Street #2 * Honolulu, HI 96813

DESIGNATE SPECIAL POPULATIONS WHO WILL RECEIVE AFFORDABLE ACCESS TO AN ALTERNATIVE, FLEXIBLE FORMULARY:

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

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

* People who are dually eligible for Medicare and Medicaid
* People who live in nursing homes, ICF-MRs and other residential facilities
* People who have life threatening conditions
* People who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

In addition to providing for special treatment for certain special populations, I urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example I strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. I urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. I am also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including

Darby Y. Schultz

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off-label uses of medications which are common for many conditions. I strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process. I recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN EMERGENCIES:

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

Thank you for your consideration of my views.

Darby Y. Schultz

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October 3, 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 would like 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. The following are critical recommendations:

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES:

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. I am very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006), I recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. I view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries.
I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

FUND COLLABORATIVE PARTNERSHIPS WITH ORGANIZATIONS REPRESENTING PEOPLE WITH DISABILITIES ARE CRITICAL TO AN EFFECTIVE OUTREACH AND ENROLLMENT PROCESS:

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

Darby Y. Schultz

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Thank you for your consideration of my views.

Darby Y. Schultz

Submitter : Dr. Brian Stwalley **Date & Time:** 10/04/2004 11:10:15

Organization : Dr. Brian Stwalley

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thanks for allowing everyone a period in which to comment on this extremely significant piece of regulation. As the chairman of the Government Affairs Committee for the American Society of Consultant Pharmacists, I would only echo their extensive and well thought out comments re: this proposed regulation.

Sincerely,

Brian D. Stwalley Pharm.D. CGP FASCP

CMS-4068-P-854-Attach-1.pdf

American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, VA 22314-3563
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October 1, 2004

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

File Code: CMS–4068–P

Dear Dr. McClellan :

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

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Consultant pharmacists specializing in senior care pharmacy practice are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illness. In their role as medication therapy experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy. ASCP's 7,000 members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and in home and community-based care.

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

Outline

****

1.0 Introduction

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

- Dual eligibles (persons who qualify for both Medicare and Medicaid)
- The frail elderly (persons aged 85 and over)
- Residents of long-term care facilities

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

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

- Have multiple chronic conditions
- Take multiple medications
- Have diminished kidney or liver function
- Have difficulty swallowing or have a feeding tube inserted

- Reside in a nursing home or assisted living community
- Use home health care services or adult day services

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

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

2.0 Prescription Drug Plans and Medicare Drug Benefit Administration

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

2.1 Prescription Drug Plans—Incentives

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

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

1. Enroll as many individuals as possible into their plans to maximize revenue
2. Selectively enroll lower-cost individuals
3. Deny access to higher-cost medications through formulary exclusions
4. Encourage beneficiary use of lower-cost formulary medications through strategies such as tiered co-insurance requirements

5. Discourage beneficiary use of higher-cost formulary medications through strategies such as prior authorization requirements
6. Shift costs to other payers, such as requiring beneficiaries to be hospitalized to receive intravenous medications

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

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

On the other hand, consumer advocates have expressed concerns about the potential for these PDPs to deny access to medications, especially to dual eligibles. Without access to a wide variety of medications, and consumer protections, dual eligible individuals may lose access to critically needed medications. Medicare beneficiaries who are not dual eligibles may choose not to enroll in Part D when it becomes available.

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

2.2 Medicare Advantage Prescription Drug Plans (MA-PD)

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

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

3.0 Medications Excluded from Coverage Under Medicare Part D

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

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Outpatient drugs for which the manufacturer seeks to require associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale.
- Barbiturates.
- Benzodiazepines.

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

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

3.1 Benzodiazepines and Barbiturates

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

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

Meprobamate is an old antianxiety agent that is highly addictive and sedating. It is on the "Beers list" (5) of medications considered to be generally inappropriate

for use in the elderly. Antipsychotic medications can be used but can produce significantly more side effects, such as extrapyramidal symptoms. The atypical antipsychotics are also much more expensive than generic benzodiazepine medications.

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

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

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

3.2 Over-the-Counter (OTC) Agents

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

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

adjusted to allow the nursing home to purchase OTC medications and maintain them as floor stock for their residents.

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

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

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

3.3 Medications Used for Unintended Weight Loss

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

The incidence of unintended weight loss is measured through the Minimum Data Set (MDS) in every skilled nursing facility and reported to CMS. Specifically, the facilities must report weight loss of 5% in the past 30 days, 7.5% weight loss in 3 months, or 10% weight loss in 6 months, or a dietary intake of less than 75% at most meals.

Unintended weight loss is a significant problem with the frail elderly, and if left untreated creates serious side effects for the patient. Some of the consequences of unintended weight loss include; infections, falls, hip fractures, immune dysfunction, anemia, decreased cognition, muscle loss, osteoporosis, and

pressure ulcers. Several medications are utilized to increase weight or enhance appetite that may have other primary indications. Examples include:

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

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

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

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

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

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

4.0 Dispensing Fee Definition

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

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

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

Dispensing fees may also be developed and paid in response to specific services provided by the pharmacy. For example, separate fees could be provided for special packaging, delivery, and other pertinent pharmacy services. For each medication order, the applicable fees would be layered to determine the total dispensing fee.

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

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

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

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

5.0 Definition of Long-Term Care Facility

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

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

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

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

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

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

6.0 Pharmacy Access Standards

ASCP believes that it is important to preserve and enhance the "one nursing home – one LTC pharmacy" paradigm currently used in today's health care system. Although the preamble to the proposed regulations suggests that CMS views this as an important consideration (22), the proposed regulations themselves do not address the issue of a one nursing home - one LTC pharmacy relationship. Yet, the maintenance of this relationship is critical to providing prescription drugs to nursing residents in a safe and efficient manner. Without such a direct relationship, nursing facilities may not be able to meet federal requirements relating to pharmacy services and medication errors.

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

CMS requests comments on whether it should require or encourage PDP plans to contract with LTC pharmacies or allow LTC pharmacy to provide drugs to beneficiaries as out-of-network providers. ASCP believes that CMS has struck a reasonable balance by permitting LTC pharmacy to either provide the benefit as an "in-network" or "out of network" provider, as market forces will allow.

Without an out-of-network option, we expect plans to treat LTC pharmacy lno different than retail pharmacies, which, in turn, would preclude LTC pharmacies from providing the necessary suite of services that beneficiaries currently enjoy and require. By permitting, but not requiring or prohibiting LTC pharmacies to serve as "in-network" providers, CMS will give LTC pharmacies and PDPs the appropriate negotiating flexibility to reach mutually satisfactory arrangements for providing services to LTC residents.

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

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

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

We are also concerned that the provisions for fallback plans do not specifically require beneficiary access to out-of-network pharmacies, as is required for PDPs

and MA-PD plans in Section 423.124. CMS states in Section 423.855 that a fallback plans is required to be a PDP sponsor except that it does not have to be a risk-bearing entity. CMS also defines a Fallback Prescription Drug Plan as a plan providing access to negotiated prices, in the same manner as PDPs and MA-PD plans. Nevertheless, CMS does not clarify in Section 423.124 that fallback plans are subject to the same requirements as PDPs and MA-PD plans with regard to out-of network pharmacy access and payment. Therefore, we encourage CMS to make this requirement explicit in the final regulations.

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

Recommendation: ASCP proposes the following revision of Section 423.124:

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

Recommendations:

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

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

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

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

7.0 Formulary Requirements

7.1 Introduction

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

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

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

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

medications. But even with these procedures, the PDPs may still be able to deny access to medically necessary medications.

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

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

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

7.2 General Formulary Concerns

ASCP has three fundamental concerns with the application of drug formularies to elderly populations. J. D. Kleinke has noted, in an article in *Health Affairs* (23) that only three studies (24-26) have been conducted that explore the relationship between use of drugs and other services across large populations. All three are associative; two focus on narrow clinical areas; and two use proxies (formulary status and reimbursement) as markers for drug utilization. Most remarkably, all three studies prove the drug utilization management hypothesis in reverse: The more a third-party payer limits patients' access to drugs, the higher its total health care costs are in excess of drug-cost savings.

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

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

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

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

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

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

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

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

> little publicly available empirical evidence underlies the most common approaches used in managed care today."

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

7.3 Special Considerations for Dual Eligible and Frail Elderly Populations

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

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

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

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

A second major problem with having few medications on the PDP formulary is the *delay* in access to needed and appropriate medications. The CMS draft regulations permit delays from 72 hours to 14 or more days in obtaining permission from PDPs to use medications not included on the PDP formulary. An individual of "normal" income may be able to pay out of pocket for the medications for a limited period of time, but the dual eligible and frail elderly populations often do not have such financial resources. In some cases, a delay of

this magnitude could be life-threatening or could result in significant pain and suffering for the individual who must do without needed medication.

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

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

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

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

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

If the choice of medications available on the formulary is limited to a small number, or are not the appropriate medications to use in these populations,

physicians and patients will face substantial time involved in navigating administrative barriers to access.

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

> "Adverse selection is more likely to be an issue for drug classes that treat illnesses where treatment matching often involves trial and error. The reason is that once the patient finds a good treatment match, the patient and his or her clinician could be less willing to consider switching medications, and the patient could be more likely to seek a plan with generous coverage of these drugs. For example, a person with schizophrenia who responds well to Zyprexa, perhaps after unsuccessfully trying other antipsychotic medications, will be more likely to avoid a plan with a closed formulary that excludes coverage of Zyprexa, all else being equal.
>
> In the private insurance market, competitive pressures to avoid enrollees with higher expected spending could lead the market to provide an inefficiently low level of coverage by imposing tight formulary restrictions for psychotropics… The incentive exists for plans to limit coverage in this way."

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

7.4 Pharmaceutical & Therapeutic Committee (P&T Committee)

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

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

CMS proposes that "at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled

individuals." ASCP recommends that CMS recognize the Certified Geriatric Pharmacist credential (33) as an appropriate way for a PDP to comply with the requirement that the pharmacist member of the P&T committee has this expertise.

7.5 CMS Oversight of PDP and MA-PD Formularies

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

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

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

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

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

7.6 Formulary Considerations for Dual Eligible Beneficiaries

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

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

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

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

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

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

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

7.7 Formulary Considerations in Long-Term Care Facilities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

One of the principles of quality improvement is that error reduction is improved when process variation is reduced. One of the keys to reducing errors and increasing efficiency, therefore, is to create an environment with consistency in as many areas as possible. Multiple formularies would create problems both for

nursing facilities and for the long-term care pharmacies that serve them. This would be a sharp contrast to the situation that exists today.

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

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

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

7.7.6 Incompatibility of Hospital and PDP Formularies

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

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

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

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

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

This same continuity of care issue is also a serious problem for the transition from Medicaid in December 2005 to Medicare Part D in January 2006 for the dual eligible population. If nursing home residents were to have this sudden change imposed to PDP formularies, with no opportunity for gradual transition, the result could be a substantial adverse clinical impact. See section 12.0 of these comments for more discussion of this issue.

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

The authors note:

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

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

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

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

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

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

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

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

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

The imposition of restrictive formularies in the long-term care population of frail elderly and disabled individuals would amount to a large-scale clinical

experiment. And it would be conducted without well-designed plans to capture data on resulting health outcomes or total health care spending. It is doubtful that any Institutional Review Board would approve such an experiment, if it were to be proposed by researchers.

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

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

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

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

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

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

> *Ms. Jones, an elderly nursing facility resident with Medicaid coverage, develops pneumonia. The physician orders ceftriaxone 1 gram to be administered intravenously every 24 hours for seven days. The standard of practice for treatment of pneumonia is to administer the first dose of medication within 4–8*

hours; otherwise the risk of mortality increases significantly. Because the PDP requires prior authorization for this drug, and no time exists for administrative delays, the resident is transferred to the hospital for immediate treatment.

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

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

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

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

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

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

Another comment from AMCP (38):

> "Other classes [in the draft USP Model Guidelines] may be inappropriate for an outpatient prescription drug benefit. For example, … classes addressing IV medications are not included on ambulatory formularies because of the need to be administered by a health care professional."

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

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

7.8 PDP Mid-Year Formulary Changes

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

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

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

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

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

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

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

8.0 PDP Plan Allowance

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

8.1 Treatment of the Full Benefit Dual Eligibles

We are concerned that the proposed regulation does not account for the fact that full benefit dual eligible LTC residents and those with low incomes are not responsible for the difference between an out-of-network pharmacy's usual and customary price for a covered Part D drug, and the plan allowance for the covered Part D drug under Section 423.124(b)(2). We believe that CMS must make explicit who will pay the cost differential between the out of network pharmacy price and the PDP plan reimbursement for full benefit dual eligibles and others with low incomes. As noted below, we believe the differential should be paid by the plan directly to the LTC pharmacy. The CMS payments to PDPs should recognize the differential cost between the usual and customary rate and the plan allowance, and therefore that plans should be directly responsible for covering the usual and customary rate. Otherwise, the most frail elderly, who are often also low-income, will be penalized by paying this higher cost.

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

reimbursement mechanisms. This would undermine the policy of allowing LTC pharmacies to bill out-of-network at the usual and customary rate to ensure that pharmacies are adequately paid to provide specialized services to LTC residents.

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

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

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

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

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

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

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

Recommendations:

- The final rule should reflect that plans will be responsible for paying out-of-network pharmacies the usual and customary price.
- CMS should clarify in its final rule that full benefit dual eligibles and other low-income beneficiaries residing in long term care facilities have no cost-

sharing for covered Part D drugs, whether or not they are on the formulary of the PDP or MA-PD plan.

8.2 Prompt Pay

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

Recommendation:

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

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

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

8.3 Disclosure of Cost of Generic Equivalent

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

CMS also requests comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies under Sec. 423.132(a). Not only must timing be considered, but also the recipient of such information. Over half of LTC residents have abnormal cognitive function, making disclosure

information confusing and possibly leading to poor treatment decisions by the patient based on the disclosed information. (40) It is conceivable that the information could lead a patient to distrust the physicians, nurses and other caretakers in the facility simply because the patient did not have the cognitive ability to understand why the information was being provided and what it meant.

Section 423.132(c)(5) gives CMS the discretion to waive the public disclosure requirement in such circumstances as CMS deems compliance to be impracticable. Because of the nature of the sale and delivery processes that LTC pharmacies use, ASCP requests that CMS waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies, rather than set a timeline for which disclosures must be made.

Recommendation:

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

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

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

9.0 Cost Effective Drug Utilization Management

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

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

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

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

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

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

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

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

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

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

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

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

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

A variation on the prior authorization requirement is the "fail first" requirement. The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a "fail first" requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug would not be as effective or cause adverse effects. The statute does not support allowing "fail first." In fact, for many enrollees, a fail first requirement in and of itself would cause adverse effects. A fail first standard might apply if the statute required the doctor to certify that the drug is not as effective or causes adverse effects.

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

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

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

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

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

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

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

- 19% (an estimated 11 million people) of all Americans age 50 and older have had their medication switched due to formulary restrictions: 12% switched from a drug they were stable on to a drug that was either covered or less expensive under their health plan; 12% had to fill their prescription with a different drug that was either covered or less expensive under their health plan; and 8% received a prescription from their healthcare provider because the drug was either covered or was less expensive under their health plan.
- Many people who switch medications have negative health outcomes. Of the patients who were given a drug formulary substitution in the past year, 13% (an estimated 1.1 million people) report that the new drug was ineffective in treating their condition and 22% of patients (an estimated 1.9 million people) say they experienced side effects from the new medication.
- Many patients also have serious health problems from switching medications. For example, 18% of those who have more than minor side effects from drug formulary substitutions report having to visit an urgent care facility to treat their problem; 14% report having to visit an emergency room, and 11% state that they needed to be hospitalized.

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

ASCP has long been concerned about the inappropriate application of medication cost-containment strategies in vulnerable populations. One example is the requirement by some managed care programs that enrollees obtain certain

medications in a higher dosage strength than they need, and then cut the tablets in half to save money for the managed care plans. Because the higher dosage strengths are approximately the same cost, the managed care plans can reduce their drug costs with this strategy. This strategy is particularly inappropriate in a population that includes many individuals with visual impairment, cognitive impairment, tremors from Parkinson's disease and other medical problems.

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

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

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

Just as prescribers use medications in combination, managed care plans also use cost-containment strategies in combination. Even in cases where each strategy may be appropriate, combining strategies can lead to curtailed access to necessary medications and adverse health outcomes.

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

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

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

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

- In states using 4 or 5 methods, 33% of recipients could not get a drug

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

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

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

- Require plans to submit studies or data to show that the strategy will not produce adverse health outcomes in the Medicare population
- Require plans to monitor the implementation of any approved cost-containment strategies, to identify and evaluate adverse health outcomes or transfer of costs to other payers, including Medicaid and Medicare Parts A and B
- Require plans to submit regular reports to CMS on the results of this ongoing monitoring
- Intervene to stop or modify any cost-containment strategies that produce an adverse health impact on beneficiaries or increase total health care spending

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

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

10.0 Quality Assurance

CMS is proposing to collect information or data on medication error rates. ASCP disagrees with this strategy. ASCP is a member of the National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP). (47) NCCMERP has adopted a position statement opposing the comparison of medication error rates. Differences in organization culture and attitudes toward

collection and reporting of medication errors, along with differences in methodology used, make comparisons misleading and inaccurate. The NCCMERP statement, "Use of Medication Error Rates to Compare Health Care Organizations is of No Value" is on their web site. (48)

11.0 Medication Therapy Management Services

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

11.1 Summary of ASCP Recommendations on MTM Services

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

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

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

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

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

11.2 Medication-Related Problems

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

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

11.3 Goals of Medication Therapy Management Services

MTM Services have the following purposes:

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

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

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

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

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

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

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

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

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

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

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

11.4 Types of Medication Therapy Management Services

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

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

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

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

The services provided by these pharmacists include:

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

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

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

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

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

11.5 Targeted Beneficiaries

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

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

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

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

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

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

- Clients of adult day service centers

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

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

11.6 Qualified Pharmacists

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

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

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

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

11.7 Payment for Medication Therapy Management Services

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

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

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

11.8 Ambulatory versus Institutionalized Medicare Beneficiaries

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

In the institutional setting (nursing homes), federal regulations require a monthly drug regimen review (DRR) by the pharmacist for all nursing home residents. This DRR is the responsibility of the nursing facility. The DRR may be performed by:

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

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

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

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

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

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

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

11.9 Conclusion

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

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

12.0 Transition of Dual Eligibles to Medicare Part D

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

It is expected that auto-enrollment would occur in early December, providing only a two-week window for dual eligibles to evaluate and enroll in a specific plan before being randomly assigned. Choosing from among multiple PDPs will

be a complicated decision for these individuals. Critical factors to be evaluated include:

- Whether the individual's pharmacy is included in the PDP network
- Whether the individual's medications are covered by the PDP formulary
- Whether prior authorization or other restrictions apply to any of the formulary medications taken by the individual
- The complexity of the appeals process and grievance procedure used by the PDP

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

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

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

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

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

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

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

12.1 Special Enrollment Periods

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

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

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

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

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

13.0 Disenrollment for Disruptive or Threatening Behavior

ASCP has a number of very serious concerns regarding provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44). These provisions create enormous opportunities for discrimination against individuals with mental illnesses, Alzheimer's, and other cognitive conditions. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result they could also be subject to a late enrollment penalty increasing their premiums for the rest of their lives.

Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage. This is especially important for dual eligible individuals, who lack financial resources to pay out of pocket for medications if their drug benefit is involuntarily discontinued.

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

13.1 Lower Involuntary Disenrollment Standard

CMS has proposed to lower the standard for involuntary disenrollment in these Part D regulations (as well as the proposed regulations for the new Medicare Advantage (MA) program) from that provided in similar provisions in the Medicare+Choice (M+C) program regulations (after which these regulations were clearly modeled). The preexisting M+C regulation allowing for disenrollment for disruptive behavior states that M+C plans may not disenroll an individual if the behavior at issue is "related to the use of medical services or diminished mental capacity." The NPRM for Part D plans (and the new requirements for MA plans) would lessen the degree of protection for beneficiaries against involuntary disenrollment for disruptive behavior. The proposed regulations state that "disruptive behavior may not be based on noncompliance with medical advice." This standard would unfairly deny protection for beneficiaries who complied with medical advice, for example, by trying a non-formulary drug instead of the drug needed, and as a result experienced a bad reaction causing their disruptive behavior.

Although the proposed regulations would also require that the behavior be committed by someone with "decision making capacity", this standard is not as broad as protections for people with diminished mental capacity as previously provided under the M+C program. It is patently unfair and discriminatory to deny protections for those whose allegedly disruptive behavior is a result of diminished mental capacity. Moreover, this lower standard would impose unacceptable risks to the health and well-being of these beneficiaries many of whom are likely to have very low incomes with no way to access needed

medications during the extended period when they would have no drug coverage as a result of being involuntarily disenrolled.

13.2 Addition of "Threatening" to List of Behaviors

The proposed regulations also add "threatening" to the list of behaviors that could merit disenrollment under the M+C program, in addition to disruptive, abusive, unruly, and uncooperative. Under the preexisting regulations, a beneficiary had to have at least taken some action to merit disenrollment. Moreover, the highly subjective term of "threatening" is not defined.

We strongly urge that CMS not include in the final regulation this lower standard for involuntary disenrollment for disruptive behavior that it has proposed in the NPRM.

13.3 Expedited Disenrollment

We are alarmed by CMS's proposal to establish an expedited disenrollment process in cases where an individual's disruptive or threatening behavior has caused harm to others or prevented the plan from providing services. The proposed expedited disenrollment process is itself undefined, and provides no standards, requirements or safeguards. Moreover, the NPRM allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms - terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply. We strongly oppose the inclusion of this expedited disenrollment process in the final rule.

13.4 Reenrollment

In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other drug plan in the area. These plans *must* be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify you and may in fact be an indication that one is in need of medical assistance. Congress clearly intended for all Medicare beneficiaries to have access to this benefit as evidenced by the fact that the Medicare Modernization Act requires that there be fallback plans available in areas where there are not at least two private drug plans.

The stigma that continues to surround mental illness and other cognitive impairments that could manifest in disruptive behavior all but assures that where these regulations open the door, such discrimination will occur. Congress' clear concern in the conference report for assuring access to needed medications for individuals with mental illness argues for exercise of the greatest care in the development of these regulations to ensure that avenues for potential

discrimination are barred. Absent such steps here, the disenrollment processes proposed in the NPRM will have a disproportionate impact on individuals with disabilities particularly those with mental illness and Alzheimer's, either because they will be used purposefully to discriminate against these individual or as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need.

In the preamble, CMS states that PDPs must apply policies for involuntary disenrollment consistently among beneficiaries enrolled in their plans, "unless we permit otherwise" and must comply with laws against discrimination based on disability. We question under what circumstances CMS would permit plans not to apply these policies in a consistent manner. There is already a significant and highly troubling risk that these provisions will be used to discriminate against certain individuals, and we urge CMS to review plans' requests for approval with the utmost scrutiny and to strictly require consistency in the applications of these provisions.

Individuals that are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications in the first place and given the high risk of discrimination presented by these provisions.

13.5 Protections to Include

At the very least, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well. In addition, we strongly recommend the following protections be included in the regulations implementing the Part D benefit and the Medicare Advantage program to lessen the grave risks inherent in authorizing sanctions on "disruptive behavior":

- PDPs and MA-PDPs must be prohibited from disenrolling an enrollee because he/she exercises the option to make treatment decisions with which the plan disagrees, including the option of no treatment and/or no diagnostic testing;

- PDPs and MA-PDPs may not disenroll an enrollee because he/she chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan;

- Documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an enrollee must include documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities, if applicable, in accordance with the Americans with Disabilities Act; and

- Documentation that the plan provided the enrollee with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment;

- PDPs and MA-PDPs must provide beneficiaries subject to involuntary disenrollment with the following notices:

    - Advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;

    - Notice of intent to request CMS' permission to disenroll the individual; and

    - A planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.

14.0 Grievances, Coverage Determinations, and Appeals

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

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

As a general comment, ***this entire subpart needs to be made much simpler***. To have two tracks, depending on (1) whether one personally pays for a drug and files an appeal or (2) does not obtain the drug and files an appeal, is far too complicated. The timeframes, the paperwork, and the processes should be simplified into one course of action that beneficiaries may hope to understand.

14.1 Expedited Review

All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. An enrollee would suffer adverse consequences if required to wait for the longer time periods; many people will simply go without prescribed medications pending the outcome of the review. Doubling the time frames and disallowing expedited review in cases when enrollees pay for their drugs out-of-pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

At a minimum, all requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that is no longer on the formulary, the plan should be required to process the request in 24 hours under the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour supply of the medicine, which is renewable if the plan decides to take longer than 72 hours.

14.2 Exceptions Process

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

14.3 "Fail First" Requirements

The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug would not be as effective or cause adverse effects. The statute does not support allowing "fail first." In fact, for many enrollees, a fail first requirement in and of itself would cause adverse effects. A fail first standard might apply if the statute required the doctor to certify that the drug is not as effective or causes adverse effects.

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

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

14.4 Physician Requests for Nonformulary Medications

The proposed rules set an impossibly high bar for receiving an exception by requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the formulary drug is likely to be

ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that a nonformulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle to prevent physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely up to the plan's discretion by including the catch-all phrase - "any other information reasonably necessary". The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

The regulations need to establish fixed criteria for evaluating the prescribing doctor's determination that using all formulary drugs would not be as effective or would cause adverse consequences to the enrollee. Requiring this amount of evidence would make it impossible to meet this standard. Instead the regulation should allow the weight of clinical evidence or the physician's experience to meet the standard.

- To meet the statutory standard, the burden should be placed on the plan to show why the doctor's decision is not definitive.

- The amount and type of evidence proposed in the certificate would make it impossible to meet the standard. "Gold standard" clinical trials generally do not include older people, people with disabilities, and people with co-morbidities. While some such evidence exists, there may not be this level of evidence for all drugs and conditions. Again, the regulations should require the certificate to meet the statutory standard (not as effective or adverse effects or both) rather than include information why the "preferred drug" is not acceptable for the enrollee. The criteria should recognize a physician's experience in evaluating whether the statutory standard is met.

- For dosing exceptions, the regulation states the standard is a showing that the number of doses that is available under a dose restriction for the prescription drug has been ineffective or based on both sound clinical evidence and medical and scientific evidence the drug regimen is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. The standard should include "or cause an adverse reaction or other harm to the enrollee".

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee - as provided in the proposed rules for other kinds of exceptions requests.

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

14.5 Timeframes for Exceptions

We are deeply concerned that the timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the needed drug. Beneficiaries' health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is unreasonable and bad health policy to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard time frame for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions.

Recommendation: Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests (42 U.S.C. 1396r-8(d)(5)(A)).

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

Nursing home and other LTC residents today have specialized drug therapy needs far different than the ambulatory Medicare beneficiary. To address those needs, over the past 25 years the LTC pharmacy industry has emerged to serve the unique needs of the nation's most frail elderly persons. We appreciate that

CMS, in its proposed rule, has already recognized the fact that LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what a typical retail pharmacy provides today. Because LTC residents' needs, the services currently being provided by LTC pharmacy, and the resulting cost savings to health care delivery all factor into ASCP's comments to the proposed rules, we expand upon them below.

15.1 Drug Therapy Needs of LTC Residents—More Intense

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

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

More recently, the 2000 National Medication Usage Study of 63,671 nursing home residents revealed an average of 8.07 routine medication orders per resident, with 41% receiving 9 or more routine medications per day. (59) The most commonly used drug classes were antidepressants (45%), analgesics (30%), antipsychotics (24%) and anxiolytics (11%). (52) The frequency of drug usage does not reflect an overuse of medications, but rather the increased efficacy of today's more advanced medicines, and the significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses.

15.2 Drug Therapy Needs of LTC Residents—Different Therapies

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

widely known outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

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

15.3 Drug Therapy Needs of LTC Residents—Enhanced Services

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

15.3.1 Unit Dose and Other Specialized Packaging

This packaging serves three important functions. First, the packaging allows for greater customization and quality control of the drugs and dosages to ensure that medications are taken appropriately and without error. The special packaging improves the accuracy of medication administration in the LTC facility.

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

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

15.3.2 Delivery of Medications

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

15.3.3 Emergency Services—"24/7"

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

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

15.3.4 Intravenous Therapy Services

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

15.3.5 Pharmacist Services—Pharmacy Provider

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

15.3.6 Pharmacist Services—Consultant Pharmacist

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

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

Critical for the provision of these important services is the need for the dispensing pharmacy and the consultant pharmacist to have a complete and accurate understanding of the patient's medical conditions, and, more importantly, current drug utilization. (62) Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than concurrent) basis is for there to be a single dispensing pharmacy for any given patient. (63) Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate utilization of prescriptions.

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

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

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

15.4 Primary Payer of LTC Medications—Medicaid

The vast majority of LTC residents currently receive prescription drug benefits under Medicaid. A recently completed Lewin Group study on "Payer -Specific Financial Analysis of Nursing Facilities," published in March, 2002, indicated that 66% of LTC residents are Medicaid beneficiaries, 12% are Medicare beneficiaries (receiving specific Medicare Part A pharmacy benefits, for example, within their "first 100 days") and the remaining 22% receive insurance benefits or are "private pay" patients. These findings are consistent with both the National Health Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for HealthCare Research and Quality. The National Health Expenses Chartbook also indicates that between 1987 and 1996 the number of LTC residents receiving prescription drugs outside of a Medicare or Medicaid benefit declined from 33.1% to 24.4%.

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

15.5 Federal Oversight of LTC Residents' Drug Therapy

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

15.6 Long-Term Care Pharmacy—Different from Retail Pharmacy

LTC pharmacy is different from the retail pharmacies that are likely to join PDP plans' networks, or those pharmacies contemplated by the MMA as serving the ambulatory Medicare population that will serve as the backbone of the PDP network. (66) There are three distinctions. First, retail offers other "items" for sale, and thus is not solely dependent upon appropriate drug reimbursement for

its revenue. Second, LTC pharmacy's cost structure is higher due to the far greater suite of services it provides. Third, LTC pharmacy is far more dependent on the Medicare population as a customer base than retail pharmacy.

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

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

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

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

- the dispensing of drugs in specialized packaging systems, such as unit-dose packaging, that reduce the possibility of medication errors and are the standard of care in nursing homes;
- the need for round-the-clock delivery of critical and emergency medications to meet LTC regulatory requirements;
- the preparation and dispensing of intravenous medication solutions, a service that retail pharmacies typically do not provide;
- a high percentage of business reimbursed by Medicare and Medicaid, resulting in higher receivables, greater working capital requirements, and

a higher percentage of bad debts than generally experienced in the retail setting; and
- the provision of considerable on-site support and consultation to nursing homes and other institutional provider-clients.

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

15.7 Electronic Prescribing

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

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

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

These discrepancies can easily happen if the physician is interrupted or delayed between the two interactions. The physician may recall the verbal medication order slightly differently from what was actually said, and give the pharmacy a

different order (e.g. three times per day versus four times per day, or 20 mg versus 30 mg dosage strength). When these discrepancies occur, the physician must be contacted again to clarify the intent, and orders resubmitted. This increases the workload on the physician and other staff, and increases the risk of error.

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

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

15.8 Summary of Recommendations Relating to Long-Term Care Pharmacy

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

PDP-LTC Pharmacy Relationship:

- CMS should encourage, but not require, PDP plans to contract with LTC pharmacies.
- CMS also should explicitly preserve, and enhance, the language in proposed section 423.124 to specifically permit LTC residents to access LTC pharmacies as out-of-network providers.
- The final rule should explicitly state that fallback plans are subject to the requirements in Section 423.124 for out-of-network pharmacy access and payment.
- CMS should clarify in its final rule that full benefit dual eligibles and other low income beneficiaries have no cost-sharing for covered Part D drugs, whether or not they are on the formulary of the PDP or MA-PD plan.
- CMS should provide for prompt payment of pharmacy claims by PDP and MA-PD plans.
- Plans should not be allowed to presumptively include LTC pharmacies in their pharmacy networks based on pre-existing relationships outside the context of Part D.

Disclosure of Generic Equivalents:

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

Formulary:

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

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

P & T Committee:

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

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

Enrollment:

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

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

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

Dispensing Fees:

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

system that "layers" the appropriate fees for a prescription or medication order based on the services provided for that prescription.

Medication Therapy Management Program:

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

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

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

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

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

LTC Facility Defined:

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

16.0 Conclusion

ASCP appreciates the diligent work of CMS to interpret and implement the provisions of the Medicare Modernization Act. We recognize the challenges that this entails, including the difficulty of balancing the needs of managed care organizations, and their desires for control and flexibility in administering the

benefit, with the need for protection of vulnerable Medicare beneficiaries. We hope that our comments will prove to be useful to CMS in achieving the proper balance.

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

Thank you.

Sincerely,

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CMS-4068-P-855

Submitter : Mrs. janet white **Date & Time:** 10/04/2004 11:10:46

Organization : Promesa ADHC

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

THE AAHIVM andI are encouraging that the CMS might consider that people with HIV/aids may have extenuating circmstances that could necessitate exempting them as a "special population" under the regulation. By doing so, CMS could then protect this population from life-threatening formulary restrictions and grant them special protections against cost- sharing requirements and other cost-contaiment measues that mingt impede access to vital therapeutic regimens. I strongly recommend with the AAHIVM that people living with HIV"VIDS should be designated a "special population" under Part D because of the complicated , interconnected factors in successfully managing this population, including adherence, toxicities, drug interactions, and comorbid conditions. The implications of not adequately managing this disease extend past just the medical management of the individual patient to larger public health implications including increased HIV transmission from inadequately treated individuals as well as increased health care costs for those who become further infirmed. The Academey and I offers their assistance to CMS in outlining the specific protections that might be approptiate for people with HIV/AIDS and requests that CMS engage the Academy and other expert organizations before issuing a second notice of proposed rule making (NPRM) on these critical revisions to the regulation.

CMS-4068-P-856

Submitter : **Ms. Jean Langendorf** **Date & Time:** **10/04/2004 12:10:46**

Organization : **United Cerebral Palsy of Texas**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-856-Attach-1.doc

United Cerebral Palsy of Texas
5555 N. Lamar Blvd., Suite L139
Austin, Texas 78751
Phone: 512-472-8696
Fax: 512-472-8696
ucptx@onr.com

October 4, 2004

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

To Whom It May Concern:

United Cerebral Palsy of Texas (UCP Texas) is pleased to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. **UCP Texas** is a private, non-profit organization and member of a national network of over 100 affiliates that provides direct services and advocacy on behalf of individuals with disabilities. Since its inception in 1954, **UCP Texas** has been on the forefront in developing and providing quality, innovative programs and services to help advance the independence of people with disabilities. UCP Texas operates offices in Austin and El Paso. We share the concerns of many other organizations 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. Cerebral palsy is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. A recent study found that approximately 38% of children with cerebral palsy have epilepsy. Many individuals with cerebral palsy also use medications to treat dystonia and muscle spasticity. 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:

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.

Sincerely,

Jean Langendorf

Jean Langendorf
Executive Director

CMS-4068-P-857

Submitter : Ms. Tracey McCutcheon **Date & Time:** 10/04/2004 12:10:15

Organization : CMS

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

TEST - to see if this mailbox is accepting comments today.

CMS-4068-P-857-Attach-1.doc

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

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CMS-4068-P-858

Submitter : Eric Graf **Date & Time:** 10/04/2004 12:10:19

Organization : Eric Graf

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Pharmacists provide a vital link and are an integral part in the health care continuim especially for the elderly. As a pharmacist I often hear of the confusion created to the public in the forcing of pharmacy provider rather than their choice. This is magnified by mail order situations when people do not have the ability to interact in a meaningful way. As people age the confusion only inceases.

Any Medicare benefit must focus on:

1. Providing the benefit at a community pharmacy level

2. The tax basis of the entire country will pay for this benefit. DO NOT take our tax money and spend it ourside the community where it came from. Support the local businesses!

3. Pharmacists have saved the healthcare system dollars in many ways for years. It is time that remuneration were given to them as health care providers. After all, just imagine the void in a healthcare system without community pharmacists.

4. If mail order is involved DO NOT create an un-level playing field by offering differential benefits. This is an in justice to consumer choice.

Politicians and political appointees are to serve the people of this country. Serve the people in their needs! Serve the local communities that provide the tax basis of this country!

CMS-4068-P-859

Submitter : Dr. Anne Cardile **Date & Time:** 10/04/2004 12:10:01

Organization : Unity Health Care

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services

To Whom it may concern:

I am responding to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit.

CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV guidelines.

As a physician who works with the underserved in DC, I see first hand the extent of HIV/AIDS among our Capitol's most vulnerable citizens. Adequate care requires that these individuals have access to the full range of anti-retrovirals in order to control their HIV disease. The importance of the availabilty of the full complement of ARs is highlighted by a July issue of JAMA, finding that the average length of the first HAART regimen for patients is 1.6 years, secondary to the development of resistance and intolerance. As HIV becomes increasingly a chronic illness, physicians who care for these patients NEED OPTIONS in order to best control a patient's disease.

CMS-4068-P-860

Submitter : Mrs. Rebecca Lofton **Date & Time:** 10/04/2004 12:10:21

Organization : UT Pharmacy School

Category : Pharmacist

Issue Areas/Comments

Issues 11-20

EFFECT OF CHANGE OF OWNERSHIP OR LEASING OF FACILITIES DURING TERM OF CONTRACT

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries:
I believe it was the intent of Congress to assure Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from the pharmacy provider of their choice. As such, plans must permit beneficiaries to obtain covered outpatient drugs and medication therapy management services at any community retail pharmacy in the plan.s network, in the same amount, scope, and duration that the plan offers through mail order pharmacies. According to the proposed regulation, the only difference a beneficiary would have to pay between retail and mail order prescriptions should be directly related to the difference in service costs, not the cost of the drug product.
Under Medicare Part D, all rebates, discounts or other price concessions should be credited equally to reduce the cost of prescription drugs no matter where they are dispensed. The benefits from these arrangements should be required to be used to directly benefit the Medicare beneficiary in terms of lower cost prescriptions.

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Rebecca Lofton
Student Pharmacist (3rd year)

CMS-4068-P-861

Submitter : **Date & Time:** 10/04/2004 12:10:12

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Under Subpart C, please revise the pharmacy access standards to ensure that plans meet the TRICARE pharmacy access requirements on a local (zip code) level, not on the plan's regional or "average" overall level. Requiring a plan to meet the standard on a local level is the only way to make sure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intent to provide a level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

Under Subpart D, please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries.

Thank you for making the needed revisions to best serve all Medicare beneficiaries.

CMS-4068-P-862

Submitter : **Date & Time:** **10/04/2004 12:10:15**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Under part C, please revise the pharmacy access standards so that plans meet the TRICARE pharmacy access requirements on a local (zip code) level. This is the only way to make sure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intent to provide a level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

Under part D, please require plans to include community pharmacists in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently. Additionally this group is most likely to have a significant relationship with the patient.

Thank you for taking these into consideration.

Submitter : Ms. Mary Schlegel **Date & Time:** 10/04/2004 01:10:48

Organization : Mental Health Association of Fauquier County

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

As advocates for people with or at risk of mental illness, we recognize that access to psychiatric medications is a critical component of community-based care, and deem it critical that the Medicare drug benefit provide coverage for all medically necessary mental health medications. We appreciate the enormous challenges associated with implementing this new benefit, but urge that CMS substantially revise the proposed rule in accordance with these comments to ensure adequate access to mental health medications for the many Medicare beneficiaries who need them. As Congress itself recognized in the conference report on the Medicare Modernization Act, Medicare beneficiaries with or at risk of mental illness have unique, compelling needs that must be given special consideration in implementing this important new benefit.

Many Medicare beneficiaries face mental illness. Research has shown that some 37% of seniors show signs of depression when they visit their primary care physician. Yet most are not receiving the mental health services they need. In fact, seniors have the highest rate of suicide of any age group in the country. It is estimated that only half of older adults who acknowledge mental health problems actually are treated by either mental health professionals or primary care physicians (US DHHS, 2001). Beneficiaries who qualify for Medicare based on a disability also frequently experience mental illness and studies have shown that over half of all under-65 disabled beneficiaries have problems with mental functioning (Kaiser Family Foundation, 1999).

We urge CMS to address the following concerns (discussed more fully below) in the final rules for the Medicare Part D drug benefit.

Coverage of Dual Eligibles. Ensure continuity of care for dual eligibles by:
? extending the deadline for switching their coverage from Medicaid to Medicare; and
? grandfathering coverage of medications on which mental health consumers have been stabilized.

Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses. For other Medicare beneficiaries with mental health needs and particularly dual eligibles , require plans to use alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution.

Involuntary Disenrollment for Disruptive Behavior. Establish greater protections for beneficiaries threatened with and subjected to involuntary disenrollment by their drug plans for disruptive behavior.

Appeals Procedures. Simplify the grievance and appeals procedures to prioritize ease of access and rapid results for beneficiaries and their doctors and provide a truly expedited process for individuals with immediate needs, including individuals facing psychiatric crises.

Outreach and Enrollment. Partner with and provide resources to community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.

Coverage of Dual Eligibles (? 423.34)
Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. There is a high rate of mental illness among this segment of Medicare beneficiaries: according to Medpac, 38% of dual eligibles have cognitive or mental impairments (Medpac, 2004). CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.
Based on our work with this population, we are gravely concerned that the proposed regulations would cause harmful disruption in care for dual eligibles as well as inadequate drug coverage for other beneficiaries with mental illness. In p

Submitter : Mr. Thomas Koch **Date & Time:** 10/04/2004 01:10:49

Organization : Vermont Health Access Oversight Commission

Category : State Government

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Section 423.120(b) Access to covered Part D drugs - Formulary requirements

(2) Inclusion of all therapeutic categories and classes
Although the mandate of the Act is to require at least two covered drugs in each therapeutic category, nothing prohibits CMS from requiring greater coverage. For reasons of patient safety and effective treatment, CMS should require a PDP or MA-PDP to include more than two covered Part D drugs within each therapeutic category, thus ensuring a comprehensive choice of medications to treat specific illnesses and chronic diseases.

A PDP or MA-PDP should be required to cover prescription drugs that are not on the plan's formulary if a physician determines that a specific drug is medically necessary, and the drug on the formulary is not medically appropriate for the patient. The plan could require prior authorization for drugs that are not on the formulary in order to encourage use of the drugs on the formulary and still ensure that the patient receives the most medically appropriate drug as determined by the physician.

Adequate treatment of chronic disease and specific illnesses is necessary to ensure that a patient's other medical costs are not increased, thus increasing the costs to Medicare or Medicaid. In addition, this approach would not require making special exceptions to certain populations who have specific drug needs, as is suggested as an option for individuals in long-term care facilities on pg. 46661 in the General Comment section of the proposed regulations. This simplifies the rules for beneficiaries, physicians, pharmacists, states, and plan sponsors.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Section 423.464(e)(2) Coordination of Benefits with other Providers of Prescription Drug Coverage - Coordination with State Pharmaceutical Assistance Programs

Subsection (e)(2) requires a PDP sponsor to exclude payments by SPAPs for covered Part D drugs in calculating the out-of-pocket threshold provided under section 423.104(e)(5)(iii). Reading the definition of a covered Part D drug in section 423.100 together with the rule on drug formularies in section 423.120(b), it appears that specific drugs that are not covered by a plan's formulary would still be considered a covered Part D drug for the purpose of the out-of-pocket threshold calculation. In other words, if an SPAP covers a medically necessary drug which is not on a plan's formulary but is in a therapeutic class covered in the plan, the cost of the specific drug would not be included in the calculation of the individual's out-of-pocket threshold. If an SPAP is providing 'wrap around' services for medically necessary drugs which are not actually paid for by Part D, this amount should be included in the out-of-pocket threshold calculation.

Issues 11-20

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

Section 423.772 Definitions

The definition of 'institutionalized individual' should include Medicaid eligible individuals who receive long-term care services in the community pursuant to a 1915c Home and Community Based Waiver. These individuals, absent the waiver, would be institutionalized, as their health problems require the same level of care as institutionalized individuals. The MMA treats individuals eligible for QMB, SLMB, and QI as full subsidy individuals. If there is a clear legislative intent to provide full subsidy eligibility to these individuals, it stands to reason that there is an intent to provide the same eligibility to a more vulnerable population who would be institutionalized, absent a state's 1915c Home and Community Based Waiver.

CMS has the authority to include 1915c Home and Community Based Waiver beneficiaries as full subsidy eligible individuals. Section 1860D-14(a)(3)(B)(v)(I) of the MMA does not require CMS to use the same definition of 'institutionalized individual' as in 1902(q)(1)(B) of the Social Security Act and does not require that a distinction be made between individuals requiring the same level of care who happen to receive such care in different settings.

Both Vermont and federal public policy has a growing emphasis on providing individuals with care in the setting of their choice. The definition used by CMS undermines these policies by providing a greater subsidy for those who choose institutional care over those who choose to obtain their care in the community.

SPECIAL RULES FOR STATES

Sections 423.908 and 423.910

CMS should specify that Vermont's spending on pharmacy programs authorized under a section 1115 waiver should not be factored into the State's phased-down contribution to the federal government.

Sections 423.908 and 423.910 of Subpart S of the proposed rules concern the phased-down State contribution to drug benefit costs assumed by Medicare, as required by section 103 of the Act. Calculation of the State contribution reflects, in part, enrollment and costs associated with 'full-benefit dual eligibles.' Accordingly, the definition of a full-benefit dual eligible --in particular, whether it includes Medicaid beneficiaries enrolled under a section 1115 waiver-- has significant financial implications.

The above-referenced rules do not define 'full-benefit dual eligible.' Section 423.4 of the General Provisions of the rules, however, defines a full-benefit dual eligible beneficiary as 'an individual who meets the criteria established in section 423.772, regarding coverage under both Part D and Medicaid.' Section 423.772 specifies that a full-benefit dual eligible individual 'does not include individuals under Pharmacy Plus program demonstrations.'

Vermont's pharmacy benefit packages authorized under a section 1115 waiver (VHAP Pharmacy and VScript) are similar to Pharmacy Plus program demonstrations in that they offer only limited pharmaceutical coverage to eligible beneficiaries. Equal treatment would suggest that Vermont's section 1115 waiver beneficiaries should not be factored into the State's phased-down contribution to the federal government.

This interpretation is consistent with the definition in the Act, which specifies in section 103(b) that the term 'full-benefit dual eligible' means an individual who--

(i) has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA-PD plan under part C of such title; and
(ii) is determined eligible by the State for medical assistance for full benefits under this title for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for medical assistance for full benefits under this title, as determined by the Secretary.

There is no mention of individuals enrolled under a section 1115 waiver. Rather, the definition includes only individuals who receive medical benefits under Medicaid, not those who receive pharmacy only benefits or another partial benefit under Medicaid.

Other eligibility definitions in the Act specify if they are meant to apply to pharmacy-only beneficiaries. For example, the definition of a 'discount card eligible individual' includes, in relevant part, a person 'who is enrolled under title XIX (or under a waiver under section 1115 of the requirements of such title).' See MMA, Section 101, Subpart 4, Sec. 1860D?31(b)(1)(B) (emphasis added).

Section 423.910

The proposed formula for calculating the 'claw-back' relies on national factors to inflate per capita spending for dual-eligibles from a 2003 base. States which have had some success in reducing their rates of growth in pharmacy spending will not have this positive outcome reflected in their future liability.

We suggest that states whose per capita growth in remaining Medicaid pharmacy spending is lower than the national figure be allowed to use that rate in the calculation of their payment.

CMS-4068-P-864-Attach-1.doc

CMS-4068-P-864-Attach-1.doc

CMS-4068-P-864-Attach-1.doc

CMS-4068-P-864-Attach-1.doc

115 STATE STREET
MONTPELIER, VT 05633
TEL: (802) 828-2228
FAX: (802) 828-2424

STATE OF VERMONT
GENERAL ASSEMBLY

October 1, 2004

Centers on Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P

Comments submitted electronically to http://www.cms.hhs.gov/regulations/ecomments

On behalf of the Vermont Health Access Oversight Committee, I am submitting the following comments to the proposed rule which would implement the new Medicare Prescription Drug Benefit. The Vermont Health Access Oversight Committee is a joint House-Senate bi-partisan committee, which reviews health care issues in Vermont. The Committee is very concerned that some of the rules proposed by CMS would have an adverse impact on Vermont citizens who currently receive prescription drug benefits through Vermont's Medicaid program and the state's Medicaid expansion prescription drug programs established under an 1115 waiver. We are also very concerned that the state will suffer an adverse fiscal impact if we are to maintain current prescription drug coverage for Vermonters. Thank you for the opportunity to comment on the rules, and we look forward to your response to our suggestions.

Subpart C – Voluntary Prescription Drug Benefit and Beneficiary Protections

Section 423.120(b) Access to covered Part D drugs – Formulary requirements

(2) Inclusion of all therapeutic categories and classes

Although the mandate of the Act is to require at least two covered drugs in each therapeutic category, nothing prohibits CMS from requiring greater coverage. For reasons of patient safety and effective treatment, CMS should require a PDP or MA-PDP to include more than two covered Part D drugs within each therapeutic category, thus ensuring a comprehensive choice of medications to treat specific illnesses and chronic diseases.

A PDP or MA-PDP should be required to cover prescription drugs that are not on the plan's formulary if a physician determines that a specific drug is medically necessary, and the drug on the formulary is not medically appropriate for the patient.[1] The plan could require prior authorization for drugs that are not on the formulary in order to

[1] The standard under Vermont law is that the formulary drug has not been effective or there is a reasonable certainty that it will not be effective in treating the patient's condition, or the formulary drug causes or is reasonably expected to cause adverse or harmful reactions in the patient. 33 V.S.A. section 1999(a)(2)(A)(i)-(ii).

encourage use of the drugs on the formulary and still ensure that the patient receives the most medically appropriate drug as determined by the physician.[2]

Adequate treatment of chronic disease and specific illnesses is necessary to ensure that a patient's other medical costs are not increased, thus increasing the costs to Medicare or Medicaid. In addition, this approach would not require making special exceptions to certain populations who have specific drug needs, as is suggested as an option for individuals in long-term care facilities on pg. 46661 in the General Comment section of the proposed regulations.[3] This simplifies the rules for beneficiaries, physicians, pharmacists, states, and plan sponsors.

Subpart J – Coordination Under Part D With Other Prescription Drug Coverage

Section 423.464(e)(2) Coordination of Benefits with other Providers of Prescription Drug Coverage – Coordination with State Pharmaceutical Assistance Programs

Subsection (e)(2) requires a PDP sponsor to exclude payments by SPAPs for covered Part D drugs in calculating the out-of-pocket threshold provided under section 423.104(e)(5)(iii). Reading the definition of a covered Part D drug in section 423.100 together with the rule on drug formularies in section 423.120(b), it appears that specific drugs that are not covered by a plan's formulary would still be considered a covered Part D drug for the purpose of the out-of-pocket threshold calculation. In other words, if an SPAP covers a medically necessary drug which is not on a plan's formulary but is in a therapeutic class covered in the plan, the cost of the specific drug would not be included in the calculation of the individual's out-of-pocket threshold. If an SPAP is providing "wrap around" services for medically necessary drugs which are not actually paid for by Part D, this amount should be included in the out-of-pocket threshold calculation.

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

Section 423.772 Definitions

The definition of "institutionalized individual" should include Medicaid eligible individuals who receive long-term care services in the community pursuant to a 1915c Home and Community Based Waiver. These individuals, absent the waiver, would be institutionalized, as their health problems require the same level of care as institutionalized individuals. The MMA treats individuals eligible for QMB, SLMB, and QI as full subsidy individuals. If there is a clear legislative intent to provide full subsidy eligibility to these individuals, it stands to reason that there is an intent to provide the same eligibility to a more vulnerable population who would be institutionalized, absent a state's 1915c Home and Community Based Waiver.

CMS has the authority to include 1915c Home and Community Based Waiver beneficiaries as full subsidy eligible individuals. Section 1860D-14(a)(3)(B)(v)(I) of the MMA does not require CMS to use the same definition of "institutionalized individual" as in 1902(q)(1)(B) of the Social Security Act and does not require that a distinction be

[2] Vermont law also includes other consumer protections to ensure that patients can receive a necessary drug quickly or on an emergency basis while pursuing the prior authorization process. See 33 V.S.A. section 1999(e).

[3] Other examples of populations which need special exemptions should CMS allow a strictly closed formulary would be individuals with mental illness, dual eligibles, and individuals with HIV/AIDS.

made between individuals requiring the same level of care who happen to receive such care in different settings.

Both Vermont and federal public policy[4] has a growing emphasis on providing individuals with care in the setting of their choice. The definition used by CMS undermines these policies by providing a greater subsidy for those who choose institutional care over those who choose to obtain their care in the community.

Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

Sections 423.908 and 423.910

CMS should specify that Vermont's spending on pharmacy programs authorized under a section 1115 waiver should not be factored into the State's phased-down contribution to the federal government.

Sections 423.908 and 423.910 of Subpart S of the proposed rules concern the phased-down State contribution to drug benefit costs assumed by Medicare, as required by section 103 of the Act. Calculation of the State contribution reflects, in part, enrollment and costs associated with "full-benefit dual eligibles." Accordingly, the definition of a full-benefit dual eligible—in particular, whether it includes Medicaid beneficiaries enrolled under a section 1115 waiver—has significant financial implications.

The above-referenced rules do not define "full-benefit dual eligible." Section 423.4 of the General Provisions of the rules, however, defines a full-benefit dual eligible beneficiary as "an individual who meets the criteria established in section 423.772, regarding coverage under both Part D and Medicaid." Section 423.772 specifies that a full-benefit dual eligible individual "does not include individuals under Pharmacy Plus program demonstrations."

Vermont's pharmacy benefit packages authorized under a section 1115 waiver (VHAP Pharmacy and VScript) are similar to Pharmacy Plus program demonstrations in that they offer only limited pharmaceutical coverage to eligible beneficiaries. Equal treatment would suggest that Vermont's section 1115 waiver beneficiaries should not be factored into the State's phased-down contribution to the federal government.

This interpretation is consistent with the definition in the Act, which specifies in section 103(b) that the term "full-benefit dual eligible" means an individual who –

> (i) has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA-PD plan under part C of such title; and
> (ii) is determined eligible by the State for medical assistance for full benefits under this title for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for medical assistance for full benefits under this title, as determined by the Secretary.

[4] The President's New Freedom Initiative, which arose from the deinstitutionalization mandate reflected in the 1999 U.S. Supreme Court case of Olmstead v. L.C., 527 U.S. 581, provides states with flexibility to provide individuals requiring institutionalization with care in the community through the 1915c Home and Community Based Waivers. Vermont currently has such a waiver.

There is no mention of individuals enrolled under a section 1115 waiver. Rather, the definition includes only individuals who receive medical benefits under Medicaid, not those who receive pharmacy only benefits or another partial benefit under Medicaid.

Other eligibility definitions in the Act specify if they are meant to apply to pharmacy-only beneficiaries. For example, the definition of a "discount card eligible individual" includes, in relevant part, a person "who is enrolled under title XIX (or under a waiver under section 1115 of the requirements of such title)." See MMA, Section 101, Subpart 4, Sec. 1860D—31(b)(1)(B) (emphasis added).

Section 423.910

The proposed formula for calculating the "claw-back" relies on national factors to inflate per capita spending for dual-eligibles from a 2003 base. States which have had some success in reducing their rates of growth in pharmacy spending will not have this positive outcome reflected in their future liability.

We suggest that states whose per capita growth in remaining Medicaid pharmacy spending is lower than the national figure be allowed to use that rate in the calculation of their payment.

Thank you for the opportunity to comment on the regulations.

Sincerely,

Thomas F. Koch
Chair

CMS-4068-P-865

Submitter : Dr. Mary Lee **Date & Time:** 10/04/2004 01:10:46

Organization : Midwestern University Chicago College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I strongly urge CMS to place at a priority the role of pharmacists in Medication Therapy Management. The focus of pharmacy education in the U.S. is on all of the services listed in the program criteria. Pharmacists could develop and supervise systems in which pharmacists and other qualified health care provideers could ensure that reliable Medication Therapy Management Services are implemented.

Much medical literature has been published that identifies patients at high risk for drug-related adverse effects. Other literature also documents the role of pharmacists in improving patients' compliance with drug therapy, thereby reducing unnecessary hospitalizations or emergency room visits.

The current role of pharmacists includes dispensing information about medications to improve patients' responses to treatment. In this capacity, pharmacists can definitely lead in the development, implementation, and evaluation of medication therapy management services.

Thank you.

Submitter : Mr. FRED OCHS **Date & Time:** 10/04/2004 01:10:36

Organization : THE MEDICINE SHOPPE #0527

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AS A PRACTICING PHARMACIST I URGE YOU TO ALLOW PHARMACIES TO BE DESIGNATED AS PROVIDERSOF MEDICIATION THERAPY MANAGEMENT (MTM) PROGRAMS. THE LOCAL INDEPENDENT COMMUNITY PHARMACIST IS WELL POSITIONED TO SERVE THE PATIENTS SERVED BY THE PHARMACY IN THE MANAGEMENT OF DRUG THERAPY. THE PHAMACIST IS IN ROUTINE CONTACT WITH THE PATIENT, AND THE PATIENT HAS EASY ACCESS TO THE PAHRMACIST. THIS EASY ACCESS ALLOWS THE PATIENT TO ASK QUESTIONS OF THE PHARMACIST AND ALLOWS THE PHARMACIST TO GUIDE THE PATIENT IN PROPER USE OF MEDICATIONS FOR THE MANAGEMENT OF THE PATIENT'S DISEASE STATE.

CMS-4068-P-867

Submitter : Ms. Kathryn Hafford **Date & Time:** 10/04/2004 01:10:48

Organization : Virginia Department of Health

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the Virginia Department of Health (VDH), Division of HIV, STD, and Pharmacy Services, 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. Ensuring that the implementation of the Medicare Part D prescription drug benefit ensures a comprehensive benefit for people living with HIV/AIDS is extremely important.

CMS-4068-P-867-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

Dear Sir/Madam:

On behalf of the Virginia Department of Health (VDH), Division of HIV, STD, and Pharmacy Services, 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. Ensuring that the implementation of the Medicare Part D prescription drug benefit ensures a comprehensive benefit for people living with HIV/AIDS is extremely important.

SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS

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

We are especially concerned 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.

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. 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. Not allowing ADAP expenses spent on premiums, deductibles, cost-shares or the amount spent filling in the donut hole to be used toward incurred costs could result in people living with HIV/AIDS falling through the cracks.

In several places in the proposed 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.

We are very concerned that the regulation also disallows state-appropriated dollars spent by ADAPs to be counted 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.

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. Even though Virginia does participate in the 340B program, we believe 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.

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. 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.

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

We strongly support 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.

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))

We strongly support 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

We strongly recommend strengthening the language regarding coverage of drugs for off-label use. Prescription drug plans must 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.

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. 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 Kathryn.Hafford@vdh.virginia.gov or 804-864-7955 if you need further information.

Sincerely,

Kathryn A. Hafford, Deputy Director
Division of HIV, STD, and Pharmacy Services

CMS-4068-P-868

Submitter : Dr. James Vergeront **Date & Time:** 10/04/2004 01:10:14

Organization : WI Division of Public Health, AIDS/HIV Program

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-4068-P-868-Attach-1.pdf

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

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

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3. The document was protected file and would not allow for CMS to attach the ile to the original message.

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

Submitter : Mrs. Frances Finkelstein **Date & Time:** 10/04/2004 01:10:05

Organization : Mrs. Frances Finkelstein

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

16 Hummingbird Lane
Toms River, NJ 08755
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 am the parent and legal guardian of Eugene Kessler, my 45 year old son with a developmental disability and dual diagnosis. My son is dually eligible for both Medicaid and Medicare and he has the following diagnoses: mild retardation, bipolar disorder mixed with psychotic features, impulse control disorder, pervasive developmental disorder, austistic characteristics, mild to moderate high frequency loss, right ear, hypothyroidism, hyperlipidemia, pituitary tumor. He is taking these prescription medications: syntheroid, lipitor, cogentin, depakote, resperidol and topomax.

I am very worried about the Medicare plans that will change the way my son receives prescription medication. Currently, all of the prescription medications that Eugene takes are paid for by Medicaid. I am especially worried about the federal government's plans for the Medicare formulary, which will restrict his access to all of the necessary medications. There have been times in the past when some of his medications were no longer efficacious and changes had to be made, sometimes quickly. Eugene cannot afford to pay for these medications if they are not on the formulary. I am worried that when this new Medicare system starts on January 1, 2006. Eugene will not be able to get all of the medications that he needs, and, not only will his health suffer, but his quality of life will be negatively affected. It is also .unfair that Eugene will have to pay a co-pay for each medication under the new Medicare plan, when he doesn't have to pay anything to get medications under the Medicaid system. It is also unfair that the co-pay for medications will probably increase every year. My son lives at the New Lisbon Developmental Center in New Jersey (which is an ICF-MR) with many other individuals similarly afflicted. It is my understanding that the dual eligibles in ICFs-MR will also be required to enroll in the Medicare drug benefit. It would be especially unwieldy and harmful for persons living in institutions to be enrolled in the Medicare drug plan. Please allow all persons who live in an ICF-MR to have a waiver that will allow them to continue to receive their medications from the Medicaid system and also save the state the burdensome administrative work associated with the proposed process.

I don't think that Congress intended to have any individual with mental retardation, and particularly those with concomitant disorders, be worse-off under this new Medicare drug plan. But that is what will happen to all of the dual eligibles unless you can fix the problems that I have described in this letter. If the new Medicare drug plan does not cover the specific medications that the dual eligibles need to keep them healthy, then they should be allowed to have their medications provided through the Medicaid system, without having to pay for them.

Very truly yours,

Frances Finkelstein
Parent/Guardian
Member ? New Lisbon Family and Friends Association

CMS-4068-P-870

Submitter : Ms. Nancy Garcia **Date & Time:** 10/04/2004 01:10:02

Organization : STIC

Category : Individual

Issue Areas/Comments

Issues 1-10

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

How does the government expect the disabled to come up with the money for their own medications?! It's already difficult enough just surviving, with many making minimum wage. If we as a nation truly value individual rights, which is a principle this country was founded on, we need to ensure that those of us who have a disability can obtain necessary medications, without having to worry whether or not we can pay the rent as well. Would those in power enjoy the privilege of choice? I'm speaking of the choice between paying the rent, or obtaining medications necessary to maintain optimal health. What this proposed legislation is really saying, is that the disabled do not have the same level of importance as the fully-abled. We need to assist those who cannot assist themselves. After all, we are not looking for a handout, just a handup. The disabled community, by and large, wants to be as self-sufficient as anyone else. This particular piece of legislation stinks of self-interest in the highest degree. This is the same government who continually hides vital information from the people who need it, namely, the public. There are a whole host of disabilities that would not even exist today, if more stringent safety measures were effected at all levels of government. Thus, it is the government's responsibility to assure the people affected by its own shortcomings, of adequate medical care. This responsibility should not fall on the shoulders of the disabled themselves.

CMS-4068-P-871

Submitter : Ms. Martha Gabehart **Date & Time:** 10/04/2004 01:10:54

Organization : Kansas Commission on Disability Concerns

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,

The Kansas Commission on Disability Concerns is very concerned about the proposed regulations to implement the Medicare Modernization Act of 2003 (MIMA). If the law is implemented as currently written:
1. People with disabilities who have both Medicaid and Medicare coverage (dual-eligible) that are Buy-In participants of Medicaid will no longer be able to access prescription drugs through Medicaid.
2. Dual-eligible participants in the buy-in program will not be able to access the waived co-payments for prescriptions if the individual cannot meet a co-payment requirement.
3. The variety of drugs covered by Part D are likely to fall short of those covered under Medicaid since Part D plans have more flexibility to limit the array of drugs they will cover.

In short, these regulations work against employed people with disabilities and efforts in the federal government implemented to encourage employment of people with disabilities (such as the Buy-In Program and Ticket to Work, etc.) Your time in reviewing the implications of these policies before implementing this Act will benefit your agency, support the federal initiatives already in place, and keep people with disabilities employed and productive tax payers in our nation.

Sincerely,

Martha K. Gabehart
Executive Director
Kansas Commission on Disability Concerns

Submitter : Dr. Richard Sain **Date & Time:** 10/04/2004 01:10:19

Organization : Reeves Sain Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Level Playing Field -
All pharmacies need to be able to compete and do business on a level playing field, and have the same opportunities given that any other pharmacy might have. For instance, if a mail order can do a 90 day supply, then a retail pharmacy should be able to do the same. Each entity should have to abide by the same rules.

Any Willing Provider - Please adhere to this law. If a pharmacy is willing to accept the same rates, then they should be allowed to provide the same service. It concerns me that there could be preferred pharmacies and non-preferred pharmacies. This should not be allowed if each entity is willing to accept the same rates.

Pharmacy Access Standards - I want to be able to serve my patients. To do that CMS should revise the Pharmacy Access Standard to require plans to meet the Tri-Care requirements on a local level, and not the plans overall level.

CMS-4068-P-873

Submitter : Mr. Kim Essler **Date & Time:** 10/04/2004 01:10:30

Organization : Chase Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

#1) Access Standards-
I feel that it is important to apply the access standards by State, for rural areas. If we in ND are lumped in with MN &/or Ill. the plans may meet the CMS standards, but we may have reduced access and participation in rural areas.

#2) Preferred Pharmacies-

I am concerned with any "Preferred Pharmacy" clause in a provider contract. Pharmacies are looking to lose the only "competitive" population of patients we have left, and we look at facing reduced revenue (or cost sharing) in the process. I think it will be detrimental to access for patients in the long run to include preferred pharmacies, because at further reduced prices we will see some rural pharmacies close because of reduced utilization &/or profit. Also, the "Preferred Pharmacy" clause is in contradiction to "Any Willing Provider" language. There are no stipulations as to how many Preferred Providers there may be for a plan, or if a plan can limit it's "Preferred Status" to it's mail order facility. Also, a large number of recipients will be paying more than if all pharmacies were treated the same.

#3) Equal Access-

I am concerned that the regulations have no language to prohibit differential copays for Mail Order Pharmacy. If you allow a lower copay from a mail order facility, you will drive people out of their home town pharmacies. We are struggling to survive on our small limited populations now, and see many Insurances offering Mail Order Incentive- lower copays. If this is allowed, you will see a huge hit on rural pharmacies, and ultimately some closures, again adding to a problem with access for patients.

#4) Medication Therapy Management-

There is a lack of language relating to minimum amounts allowed for these services.

#5)Fallback Plans-

Plan sponsors will have less incentive or ability to negotiate discounts with drug companies. Premiums will be higher and so will Out-Of-Pocket expenses for these patients.

CMS-4068-P-874

Submitter : Mr. Justin Emerson **Date & Time:** 10/04/2004 01:10:58

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I appreciate the chance to comment on the proposed regulation to implement the new Medicare prescription drug benefit.
Subpart D. Please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management services to beneficiaries. Commnity pharmacists are the ideal health care professionals to provide these valuable services conveniently, face to face, to beneficiaries.

Thank You

CMS-4068-P-875

Submitter : Ms. Laurel Haroldson **Date & Time:** 10/04/2004 01:10:58

Organization : North Dakota Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Laurel A. Haroldson, R. Ph.
230 17th Ave NE
Jamesstown, ND 58401
lharold@csicable.net
701-252-8579

October 4, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P Baltimore, MD 21244-8014
Re: CMS-4068-P
Dear Sir or Madam:
? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies. . I have several patients over the age 65 who are required to use a mail order pharmacy to get their insurance benefits. They do not understand, nor will they ever, how to order. They pay more at our pharmacy than they would by mail. We provide the service and counseling that they need to be able to function in their homes.

? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice, prescription counseling, nursing home consultation. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.
? I also call your attention to the comments provided to you by the North Dakota Pharmacists Association. The bulk of negotiated price discounts should be passed on to the consumer. The dispensing fee to pharmacies should be enough to allow a profit.
Thank you for the opportunity to express my opinions.

Sincerely,

Laurel Haroldson, R. Ph.

CMS-4068-P-876

Submitter : **Date & Time:** **10/04/2004 01:10:41**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Under Subpar C, please revise the pharmacy access standards to ensure that plans meet the TRICARE pharmacy access requirements on a local(zip code)level, not on the plan's regional or "average" overall level. Requiring a plan to meet the standard on a local level is the only way to make sure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intent to provide a level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

CMS-4068-P-877

Submitter : **Date & Time:** **10/04/2004 01:10:05**

Organization : **Argus Health Systems, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

See attached file - Statutory Exclusions Comment

CMS-4068-P-877-Attach-1.doc

Comments to 42 CFR Parts 403, 411, 417, and 423
Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule
Submitted by Argus Health Systems, Inc., 1300 Washington Street,
Kansas City, MO 64105-1433

II. Provisions of the Proposed Rule; C. Voluntary Prescription Drug Benefit and Beneficiary Protections, a. Covered Part D Drug (page 46646)

Comment to the Statutory Exclusions of Benzodiazepines and Barbiturates

In reviewing the statutory exclusions contained in the Medicare Modernization Act, two significant classes of drugs, benzodiazepines and barbiturates are impacted. This could jeopardize patient care. By definition, drugs that are covered by the drug card program "are used for a medically accepted indication." It goes on to instruct plan sponsors, when "constructing their formularies, [to] include, at a minimum, the types of drugs commonly needed by beneficiaries." The exclusion of these two classes of drugs is not consistent with this guidance.

Commonly used in therapy, benzodiazepines constitute five of the top 150 most-prescribed drugs in 2003. Due to their versatility, they are a preferred class of medication. Their onset of action is relatively rapid, allowing for flexible dosage regimens. Indications include anxiety disorders, convulsive disorders, involuntary movement disorders, panic disorders, insomnia, amnestic, and alcohol detoxification. They play a pivotal role in patients with terminal illnesses to ease anxiety and allow them to rest comfortably.

There is the potential for abuse with these drugs. It is not, however, commonplace. *The American Academy of Family Physicians* explains, "benzodiazepines are rarely the preferred or sole drug of abuse" (April 1, 2000. "Addiction: Part I. Benzodiazepines—Side Effects, Abuse Risk and Alternatives"). The DEA web site further states that

> "given the millions of prescriptions written for benzodiazepines (about 100 million in 1999), relatively few individuals increase their dose on their own initiative or engage in drug-seeking behavior. Those individuals who do abuse benzodiazepines often maintain their drug supply by getting prescriptions from several doctors, forging prescriptions, or buying diverted pharmaceutical products on the illicit market. Abuse is frequently associated with adolescents and young adults who take benzodiazepines to obtain a 'high'" (www.usdoj.gov).

Benzodiazepines have a proven track record for their performance and have established themselves an essential part of therapy. By excluding this class of medications, people who would otherwise benefit from the medication are forced to suffer because of the actions of a few.

Like benzodiazepines, barbiturates have earned inclusion in the drug program. Though not as commonly employed as in the past, their utilization remains effective for a portion of the public. These drugs are indicated for use as sedative-hypnotics, headache relief, and anticonvulsants. Patients may also find barbiturates more obtainable due to their affordability.

Barbiturates are often overlooked for their role in therapy, in favor of newer agents. Nonetheless, they are still a useful treatment option. It is important to note, however, that this class of drugs is not suited for every patient. Health specialists should consider its use on an individual basis, taking into account each patient's medical history. *The British Medical Journal* further suggests that they "may be considered a drug of last resort" (Volume 318(7176) 9 January 1999 pp 106-109).

CMS-4068-P-878

Submitter : **Date & Time:** **10/04/2004 01:10:13**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subpart C
Please revise access standards to make sure plans meet TRICARE rx access levels on a local level (not regional or average overall). This is the only way to ensure all beneficiaries can use the local pharmacy of their choice. CMS should implement Congress' intent to have a level playing field for community pharmacy is implemented. Mail order should not be favored by inappropriate use of preferred networks.

Subpart D
Plans should require community pharmacists to be involved in the delivery of Medication Therapy Management services. We are the ideal resource to provide these valuable services because of our accessibility to patients in the community.

CMS-4068-P-879

Submitter : **Date & Time:** 10/04/2004 01:10:11

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

No definition is given for a "standard benefit" yet CMS proposes that: a. Plans can offer different benefit packages and differnet copayments as long as the benefits are the same as the standard plan. Who judges that the benefits are the same as the standard plan? If they are, why not just make them the same as the standard plan? b. Why are plans allowed to limit the drugs that are covered or require certain preferred drugs- or even have prescriptions "approved" (by whom - the physician, another physician, a pharmacist, a nurse ..) before they will cover the prescription? How is approval qualified? c. If the plan may require that you try and fail on other medications before covering the one your doctor prescribes, then the "plan" itself (a corporation) is practicing medicine without a license to do so. Does "the Plan" think it knows more than the doctor treating the patients? And if the err in prescribing, they should be liable for malpractice. Moreover if the patient dies while going through this trial and error, the Plan should be liable for murder. d. If the drug is not covered by your plan, you will pay out of pocket for it and the amount you pay cannot be applied towards fulfilling the yearly deductible, the first $2250 which you must pay to receive the 75% benefits, and the doughnut hole of $3600. Therefore, if you are so unfortunate as to have been driven into a plan which does not cover a medication, you will not get as much "benefit" as you are entitled to.

How does one learn which plans covered needed drugs, since one is locked into a plan for a year? Who is responsible for educating patients about which plan is available in their area and suitable for them? Considering the cognitive abilities of many Medicare beneficiaries, CMS must be able to point out specific plans for such individual Part D enrollees instead of just a general education about what benefits may happen to them. It is proposed that plans can disenroll members for "disruptive behavior" or "misrepresentation about creditable coverage". What are the specific definitions of these behaviors? If a person is disenrolled, where can he find another plan if none will consider him? CMS cannot just leave him hanging in a void when he is needy.

The enrollment period is from November 15, 2005 to May 15, 2006. Dual Eligibles will lose their drug coverage under Medicaid on January 1, 2006 unless they are enrolled in Part D by December 31, 2005. There is no emphasis about this date, only a statement that dual eligibles who fail to enroll in Part D by May 15, 2006 will be auto-enrolled into a plan, any plan, whether it fits them or not and they will be without drug coverage for at least 6 months. They may also be liable for the late enrollment penalty. It seems to me that the Department of Welfare should be required to alert and help those on Medicaid to follow this guideline, and CMS should be the agency to require this.

My comments about the so-called benefits proposed for Part D: 1. I can agree with the $250 deductible each year though I disagree with the rule that if the plan will not cover a specific drug, the cost of the drug cannot be used to satisfy the deductible or the $2250 or the doughnut hole. 2. The $2250 worth of drugs for which I will pay only 25% will mean $562.50 out of pocket because the $2250 includes the total cost of the drugs, not just the part I pay. 3. After that, $3600 must be out of pocket before the plan will pay anything. By this time, I will have paid out of pocket a total of $4412.50 besides the monthly premium of $35(?) - so the cost to me will be $4832.50 before the final coverage kicks in and I might benefit. The cost to the taxpayers will be what if paid out of pocket, the bookkeeping and paperwork costs of these complex regulations, the enforcement of these rules, the profits of the pharmacies/pharmaceutical houses, and the frustrations of all Medicare participants.

CMS-4068-P-880

Submitter : Marianne Campbell **Date & Time:** 10/04/2004 01:10:05

Organization : DaVita Dialysis at Baker Place

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

I encourage you to include coverage for renal multivitamins for people with kidney disease. I work with a special group of people with special health challenges. Many of the people I work with have very limited finances. A renal multivitamin helps replete nutrients that patients are unable to get on their restricted diets. They also provide additional quantities of vitamins that help with body functions that are compromised by the lack of kidney function, such as red blood cell formation. Please consider this request on behalf of the people who suffer from chronic kidney disease. Thank you.

Sincerely, Marianne G. Campbell, RD LD LMNT

Submitter : Dr. LLOYD TUCKER **Date & Time:** 10/04/2004 02:10:28

Organization : TUCKER PHARMACY, INC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

TUCKER PHARMACY, INC. HAS BEEN IN OPERATION SINCE 1937. WE FEEL THAT MEDICARE PART D IS A WONDERFUL BENEFIT, BUT WE HAVE SEVERAL CONCERNS.

1.) DISPENSING FEE IS THE TOTAL EXPENSE INVOLVED IN FILLING A RX. THIS FIGURE IS HIGHER THAN ON MOST REIMBURSEMENT FORMULA DISPENSING FEES BECAUSE THESE FORMULAS USE THE PRICE OF THE MEDICATION AND DIFFERENCE BETWEEN WHAT A PHARMACY CAN BUY THE DRUGS FOR AND WHAT THE COST FORMULA IS. IF THE FORMULA IS BASED ON THE DEAD NET COST THEN THE DISPENSING FEE MUST BE AT LEAST $7.50. NACDS COST TO DISPENSE WAS $7.27 IN 2003.
2.) PREFERRED PHARMACIES. WE FEEL THAT THIS IS A MEASURE THAT WILL WORK AGAINST EQUAL ACCESS TO ALL RETAIL PHARMACIES. ONE SINGLE FEE FOR ALL PHARMACIES IS FAIR TO EVERYONE, PATIENTS AND PHARMACIES ALIKE. MOST PATIENTS WHO SEE A LISTING OF "PREFERRED PHARMACIES" WILL THINK THAT THESE PHARMACIES ARE PROFESSSIONALLY SUPERIOR TO " NON-PREFERRED PHARMACIES."
3.) "ANY WILLING PROVIDER" SHOULD MEAN A LEVEL PLAYING FIELD. PATIENTS CAN USE A MAIL ORDER PHARMACY IF THEY CHOOSE BUT SHOULD NEVER BE REQUIRED TO USE MAIL ORDER. REBATES AND DISCOUNTS AVAILABLE FROM MANUFACTURERS SHOULD NOT BE USED EXCLUSIVELY TO SUPPORT MAIL ORDER OPERATIONS AND SPECIAL PBM'S WHO USE THESE REBATES AND "HIDE" THEM FROM THE DEAD NET COST TO PROVIDERS. IF A PATIENT WANTS A 90-DAY SUPPLY THEY SHOULD BE ABLE TO GET THAT QUANTITY FROM ANY PHARMACY.
3.) ELECTRONIC PRESCRIBING IS THE FUTURE OF PHARMACY. LET'S JUST MAKE SURE EVERYTHING IS COMPLIANT WITH STATE LAWS AND REGULATIONS.
4.) MEDICATION THERAPY MANAGEMENT. THIS IDEA NEEDS TO HAVE A DEFINED STANDARD OF SERVICE. THIS SHOULD BE AVAILABLE TO ALL PATIENTS AT ALL PHARMACIES. PHARMACISTS SHOULD HAVE TO SHOW THEY ARE QUAILFIED TO OFFER THE CONSELING. THIS IS ALSO THE FUTURE OF PHARMACY AND WE TOTALLY SUPPORT THE DEVELOPMENT OF THIS SERVICE AT THE PHARMACY LEVEL.

CMS-4068-P-882

Submitter : Dr. Jill Ryan **Date & Time:** 10/04/2004 02:10:45

Organization : Dr. Jill Ryan

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

At the moment, the card choices for seniors eligible for medicare drug benefits are too confusing. Patients are required to do much of the research on their own and usually this will not happen. The card system needs to be simplified and made more user friendly to those eligible.

CMS-4068-P-883

Submitter : Dr. Kristin Casper **Date & Time:** 10/04/2004 02:10:38

Organization : The Ohio State University/Kroger Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-4068-P-883-Attach-1.doc

October 4, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for taking the time to review this important document and consider suggestions and opinions from the public. I would like to offer my thoughts to CMS 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 service level, not the plan overall. If plans meet the standard on the local level, all beneficiaries will have convenient access to a local pharmacy and my patients can 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 the provider may lead to the choice of less qualified providers or even providers who are paid by the plan which would create a definite conflict of interest.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently work in a community retail pharmacy practice and where I offer wellness and screening services along with medication management services for patients with diabetes, high cholesterol, and general complications in their medication regimens. 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.

Sincerely,

Kristin A. Casper, Pharm.D.
Faculty Coordinator
Kroger Patient Care Center

Assistant Professor of Clinical Pharmacy
The Ohio State University
500 West 12th Ave.
Columbus, OH 43210
(614) 292-1712
casper.17@osu.edu

CMS-4068-P-884

Submitter : **Date & Time:** **10/04/2004 02:10:28**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense?s TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than ?on average? in a regional service area.
To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.
Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

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

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical pharmacists,? as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?

CMS-4068-P-885

Submitter : **Date & Time:** **10/04/2004 02:10:31**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

In subpart C, the pharmacy access standards should be revised fo meet the TRICARE requirements at the local level, not the regional or an average. This change will ensure that all beneficiaries have access to the local pharmacy of their choice. CMS must insure that Congress' intent to provide a fair business environment is followed and that plans should not favor mail order pharmacies by an unfair use of preferred networks.

In subpart D, all plans must include community pharmacists and their pharmacies in the delivery of MTM services to beneficiaries. Community pharmacists are the most convenient and easily accessible health care professionals to provide these services.

CMS-4068-P-886

Submitter : Ms. Melissa Rewinkel **Date & Time:** 10/04/2004 02:10:41

Organization : Coalition to Promote Choice for Seniors

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-886-Attach-1.doc

MedigapChoice.com
The Coalition to Promote Choice for Seniors

October 4, 2004

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

Re: Comments on Medicare Prescription Drug Benefit Proposed Rule – 42 CFR § 403.205 & Required Medigap Disclosure Notice

The Coalition to Promote Choice for Seniors (the Medigap Coalition) appreciates this opportunity to submit comments on the Medicare Prescription Drug Benefit Proposed Rule pursuant to the Medicare Modernization Act (MMA). The Medigap Coalition represents companies that provide Medicare supplemental insurance products to millions of Medicare beneficiaries. To that end, we provide the following comments on the rule to ensure smooth implementation and coordination of the new drug benefit with existing Medigap policies.

Part 403 – Subpart B (403.205):
Definition of Medicare Supplemental Policy

The proposed rule expands the definition of Medicare supplemental policy beyond what is appropriate and necessary. Beginning January 2006, it would include any insurance policies or riders that contain a drug benefit and are primarily designed for, or primarily marketed and sold to, Medicare beneficiaries as well as stand-alone limited health benefit plans. Additionally, any rider becomes an integral part of the policy and is subject to all requirements that apply to the base policy.

As you know, the Medicare Modernization Act (MMA) changes the definition of Medicare supplemental policy only insofar as it specifies that a Part D plan is not included within that definition. Further, we believe there is no indication that the legislative intent exists to warrant such a change. Not only is the proposed change outside the scope of the MMA, but it would also broaden the scope of federal regulation of Medicare supplemental products beyond what was contemplated by Congress under the original rules regarding Medicare supplemental policies. Section 1882(g)(1) of the Social Security Act (42 U.S.C § 1395ss(g)(1) defines a Medicare supplement policy as:

> A health insurance policy or other health benefit plan offered by a private entity…which provides reimbursement for expenses incurred for services and items for which payment may be made under this subchapter, but which are not reimbursable by reason of the applicability of deductibles, co-insurance amounts or other limitations imposed pursuant to this subchapter.

Congressional intent on this matter has been consistent with respect to state regulation of Medicare supplemental products. MMA directed the National Association of Insurance Commissioners (NAIC) - the organization of insurance regulators from all 50 states, the District of Columbia and four U.S. territories – to make the appropriate changes to its model Medicare supplement regulation. During the

process of revising the NAIC model, CMS proposed the definition change. The proposal was not approved by the NAIC Senior Issues Task Force, indicating a lack of support for such a change by state regulators, consumers and industry involved in the effort. Therefore, it is not clear what authority CMS would rely on for this proposed change.

Notwithstanding the above, we also believe that CMS' proposed definition of a Medicare supplemental policy is too broad to allow Medicare beneficiaries the choices and innovative products they deserve. Expanding the definition to include limited health benefit plans and policies could incorporate products such as disability income, long-term care, accidental injury, property and casualty, and hospital indemnity plans. It would be a disservice to seniors if the regulation of these types of products expanded and discouraged carriers from offering them widely.

The Coalition to Preserve Choice for Seniors was formed to ensure that, as Medicare is modernized and its benefits expanded, seniors continue to have access to Medicare Supplement (Medigap) coverage. Currently, one in four Medicare beneficiaries, nearly ten million seniors, rely on Medigap for protection against out-of-pocket costs not covered by Medicare. The Medigap Coalition believes that the proposed change to the definition of Medicare supplemental policy would damage this crucial senior product. Therefore, we recommend no changes be made to the definition of a Medicare supplemental policy.

<u>Required Medigap Disclosure Notice</u>

CMS provides a detailed disclosure notice in the preamble to meet the statutory requirements that Medigap issuers must inform policyholders of whether their policy provides "creditable coverage." Coalition members worked with the NAIC to develop a notice that fully meets all the MMA requirements in a manner that is beneficiary friendly and not burdensome on issuers. The CMS disclosure adds language to the notice developed by the NAIC stating that Part D coverage is a better value for the beneficiary than his or her current Medigap coverage. Because the comparative value of Part D versus Medigap will be determined by many factors, such as whether available plan formularies include a beneficiary's prescriptions, these statements detract from the statutorily mandated goal of accurately informing beneficiaries regarding their options. Therefore, we urge CMS to adopt the NAIC draft disclosure notice. Thank you for the opportunity to comment.

The Coalition to Promote Choice for Seniors

America's Health Insurance Plans (AHIP)
Blue Cross Blue Shield Association
Conseco
GenRe
Highmark Blue Cross Blue Shield
Monumental Life Insurance Company
Mutual of Omaha
National Association of Health Underwriters
Physicians Mutual Insurance Company
Torchmark Corporation
UnitedHealth Group
Universal American Finance Corporation
USAA
WellPoint

Submitter : Mr. Daniel Zatarski **Date & Time:** 10/04/2004 02:10:29

Organization : Ye Olde Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As an employee of Ye Olde Pharmacy, 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 expressed by pharmacists around the nation are being considered. All pharmacists want this program to work. Private sector health plans have far too often targeted pharmacies and pharmacy reimbursement in cost containment measures rather than working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow that path.

As a community pharmacist, I am concerned with three aspects of the Medicare part D proposed rules and recommend that CMS enable the following three policies:

Medicare recipients must be able to choose their own pharmacies
It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. The access standards should be applied at a level no broader than a county to ensure that recipients have ready access to the pharmacies in their community. Furthermore, plan sponsors should be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans have often used their market force to drive down pharmacy reimbursement below a pharmacy?s operational costs, thereby forcing the pharmacy providers to cost shift to other business sectors. Medicare must not allow this business practice to continue.

Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Recipients should not be economically coerced into using one pharmacy over another unless the plan sponsor for defined quality reasons prefers the preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

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

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

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

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacies must be allowed to participate equally and fully. And finally, pharmacy providers must receive

CMS-4068-P-887-Attach-1.doc

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As an employee of Ye Olde Pharmacy, 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 expressed by pharmacists around the nation are being considered. All pharmacists want this program to work. Private sector health plans have far too often targeted pharmacies and pharmacy reimbursement in cost containment measures rather than working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow that path.

As a community pharmacist, I am concerned with three aspects of the Medicare part D proposed rules and recommend that CMS enable the following three policies:

1 Medicare recipients must be able to choose their own pharmacies

It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. The access standards should be applied at a level no broader than a county to ensure that recipients have ready access to the pharmacies in their community. Furthermore, plan sponsors should be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans have often used their market force to drive down pharmacy reimbursement below a pharmacy's operational costs, thereby forcing the pharmacy providers to cost shift to other business sectors. Medicare must not allow this business practice to continue.

2 Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.

Recipients should not be economically coerced into using one pharmacy over another unless the plan sponsor for defined quality reasons prefers the preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

3 Plan sponsors should be required to establish specified MTM services.

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

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

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

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation's foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacies 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,

Daniel L. Zatarski, PharmD, RPh

CMS-4068-P-888

Submitter : Mrs. Debbie Rios **Date & Time:** 10/04/2004 02:10:38

Organization : National Multiple Sclerosis Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached Word Document

CMS-4068-P-888-Attach-1.doc

Comments of the PA Chapters of the National Multiple Sclerosis Society in re file code CMS-4068-P

Subpart A—General Provisions

The term "personal representative" needs to be defined. Under the proposed regulations, the term is used but not defined. This is of major importance because Subpart P [423.774(d)(1)] and Subpart S [423.904(d)(2)] require a personal representative to sign off on lower-income subsidy application forms under penalty of perjury. Construed broadly, advocates, social workers, and others who generously assist consumers in completing application forms will be severely limited in their ability and willingness to assist out of fear of liability. This will have a significant chilling effect on applications for lower-income subsidies.

Subpart B—Eligibility and Enrollment

The provision in Section 423.34(a) that PDPs are required to enroll all Part D eligible individuals who elect to enroll in the PDP is essential and must be maintained and enforced. Together with the prohibition on discrimination against any disability or group, this will protect people with disabilities.

The proposed regulations in Section 423.34 set forth the process for enrolling in a PDP but do not articulate a timeframe within which the PDP must make an enrollment decision and do not set forth any appeals process for consumers who are denied enrollment. Consumers must be provided a swift determination of whether a PDP will enroll them, especially where there is an annual coordinated enrollment period of only 6 weeks. The final regulations should establish a 14-day window for making an enrollment decision so that consumers have an opportunity to appeal or apply elsewhere. And, consumers must have an opportunity to appeal when they are denied enrollment, especially where there are factual disputes over whether they were eligible.

Allowing PDPs to disenroll consumers for disruptive behavior [423.44(b)(1)(ii)] and refuse them reenrollment [423.44(d)(2)(vi)] could be discriminatory to persons with certain disabilities or conditions. In addition, it could severely harm lower-income consumers and those in rural areas who may end up with no coverage for months at a time. We are very concerned that this provision [423.44(d)(2)(i) could be interpreted to allow PDPs to diseneroll consumers whose "disruptive behavior" may arise out of their illness/condition.

The ability of a PDP to disenroll for this reason will have a chilling effect on consumers' filing grievances or appeals. Consumers could be disenrolled for disruptive behavior and denied reenrollment into what might be the only PDP serving their area. Since dual eligibles are losing their right to access medication through Medicaid some people will be denied the very medication that allows them to control their behaviors under restrictive PDP formularies; without the medication, behavioral problems emerge; the consumer could then be disenrolled because his lack of coverage led to "disruptive behavior". **This provision must be removed from the regulations.**

The final regulations for Section 423.44 must set forth a process for appealing disenrollment decisions and denials of reenrollment.

Subpart C—Benefits and Beneficiary Protections

The MMA states that PDPs may cover clinically appropriate off-label uses of medications. The final regulations must require that plans allow off-label uses. In light of the pharmaceutical industry practice wherein FDA approval is initially sought for a drug and then never revisited, even after other clinically appropriate uses are identified, it is critical that off-label use of medications be accessible to consumers. At a minimum, off-label use must be accessible through a Part D plan's exceptions process for non-formulary drugs. Pennsylvania's SPAP allows off-label use when the off-label use appears in two of the compendia, which we believe is appropriate.

Excluding Medicare Part B drugs from coverage under Part D regardless of whether the consumer is enrolled in Part B is seriously detrimental to consumers who enroll in Part B but who cannot effectuate their enrollment for many months due to the Part B enrollment timeframes. Consumers without Part B coverage, but who intend to enroll in that program could enroll in Part D in April but would not be able to gain coverage for Part B covered drugs until 15 months later (enrollment in January effective in July). There must be an exception made for consumers in this predicament to allow their Part D plan to cover Part B drugs. This is especially important for the dual eligibles in this situation who would be unable to fall back on Medicaid to obtain coverage for their Part B medications. We recommend that Part D plans be required to cover Part B medications for a consumer for up to 15 months (the maximum amount of time it could take to effectuate an enrollment into Part B).

Sec. 423.104 Requirements related to qualified prescription drug coverage:

PDPs and MA-PDs must be required to offer a standard prescription drug coverage benefit (along with their alternative plans) so that consumers can actually compare plans across PDPs and MA-PD. This will also allow lower-income consumers to understand how their lower-income subsidies will work from plan to plan.

The provision at Section 423.104(e)(2)(ii) allowing for tiered co-payments must be restructured to limit the number of tiers and limit the amount of co-payments a Plan can require. No plan should be allowed to have more than three tiers, or the complexity of navigating their benefits will entirely overwhelm consumers. Co-payments must never be allowed to exceed 40% to the consumer. Lastly, CMS must closely review all formularies to ensure that the structure does not discriminate against individuals with certain disabilities by placing their core medications in the most expensive tiers.

In addition, current Medicaid regulations allow consumers to obtain medications even when they cannot pay the associated co-pay. However, there is no such protection in the proposed regulations for full dual eligibles. **Copayments must be nominal in all cases for dual eligibles, and all prescriptions offered by a plan must be available without charge to any dual eligible who cannot afford to pay.**

Sec. 423.120 Access to covered Part D drugs:

All plans should be required to have a P&T committee and those committees should be required to be involved in formulary development and review, as well as involvement in the development and review of tiering structures and prior authorization requirements. The proposed regulations in Section 423.120 (b)(1) only require plans to develop a P&T committee for purposes of developing and revising the formulary. Plans that choose to use an open formulary with tiered cost-sharing or use of prior authorization would not be required to have such a committee. The involvement of experts in the development and review of tiering structures is a critical consumer protection.

The P&T Committee's decisions regarding the initial development of a formulary and any subsequent revisions should be binding on the plans. The preamble states that CMS is interpreting the requirement that a plan's formulary be "developed and reviewed" by a P&T committee as requiring that committee's decision to be binding on the plan and we support that interpretation.

The composition of independent members on a plan's P&T Committee must be proportionate. Two independent members of a P&T Committee

comprised of 40 people are insignificant. We suggest one half representation by independent individuals. [Sec 423.120(b)(1)(ii)]

The final regulations in Section 423.120(b)(1)(ii) must require the Pharmaceutical and Therapeutics Committees to have specialists covering cross-disabilities practice areas. Requiring one "expert in the care of elderly and disabled individuals" is far too broad a requirement and is inadequate to address to vastly different needs of elderly and adults with differing disabilities. Several independent specialists must be part of the committee, including, at a minimum, a psychiatrist independent from the plan. Additionally, the P&T committee should be required to consult with independent specialists from areas that are not represented within the P&T committee.

The proposed regulations for Section 423.120(b)(5) regarding provision of notice regarding formulary changes need to be clarified and expanded in the final regulations. Website notice alone is inadequate; Many older people and those with disabilities do not have computers or use the Internet. US Mail service must be used and notice must be provided at least 30 days prior to effectuating the formulary change. Additionally, notice regarding changes in formularies should be made to beneficiaries in clear, understandable language and in alternative formats. If the notice of the change in formulary involves the addition of a medication, the notice should also explain how the medication will be classed, if the plan uses a tiered co-pay system or step therapy system. The notice should also indicate expected cost to the beneficiary. If a medication is being removed from the formulary, the notice should indicate what medication is available for individuals who were prescribed the medication being removed. Finally, the notice should include information about the exception process.

The final regulations should require that all formularies developed by Part D plans be reviewed by CMS. The preamble to Section 423.120 states that CMS will only review a plan's classification system when it differs from the US Pharmacopeia. However, CMS recognizes that a plan could adhere to the model guidelines in regard to classification system, but still design their formulary to discriminate against individuals with certain disabilities and encourage individuals with certain illness and conditions to not apply to that particular plan. At least at the beginning of the Part D program, CMS should review each plan's formulary to ensure that this is not happening. In addition, the regulations must establish criteria for the review process used to evaluate plan formularies and tiering structures.

In response to the request for comments on how to balance a plan's use of different strategies to produce cost-savings with the distinct and complex medication needs of consumers with certain diseases or conditions, we urge

the use of an open formulary for certain populations. The open formulary can employ cost-containment tools such as prior authorization. However, it is critical that the following populations have access to all FDA approved medication:

* full dual eligibles
* institutionalized individuals and those receiving HCBS services in lieu of institutionalizations
* individuals with life threatening conditions; and
* pharmaceutically complex individuals

Pharmaceutically complex individuals include but are not limited to those with behavioral health diagnoses and those taking multiple significant medications, including people with multiple sclerosis.

The final regulations for Section 423.128 should require that plans provide consumers with the complete information about the formulary a plan adopts. Specifically, the plan should make the following information available to the public: 1) the complete listing of all drugs included on the plan's formulary; 2) the drug price, 3) the co-payment amount/tier, 4) the prior authorization requirements, 5) other cost effective utilization controls associated with the medication (as in, an approval for use of this medication will be accompanied by MTMP). This information must be made public in a variety of media.

Subpart D- Cost control and Quality Improvement Requirements

There must be limits placed on the cost effective utilization programs so that they do not combine to create cumbersome obstacles or to wholly prevent access to needed medications. In order to institutionalize the prohibition on discrimination against populations or discrete disabilities, it is critical that PDPs and MA-PDs be prohibited from implementing quarterly or annual limits on drug use and other utilization barriers that make their plans unworkable for persons with chronic illness or disabilities that are costly to treat.

Cost savings tools should be used and developed under the direction and oversight of the P&T Committee. The preamble to Section 423.153 states that CMS is considering a requirement in the final rule that these cost savings tools should be under the direction and oversight of the P&T committee. We support this requirement, especially if requirements about the development and make-up of the P&T committee that we recommend in Subpart C are implemented. The P& T committee should monitor the use of these tools to help protect vulnerable consumers.

Subpart F—Submission of Bids

The preamble comments about Subpart F's prohibition on discriminating against certain Part D eligibles raise important concerns that are not included in the proposed regulations and must be. The comments note that cost-sharing variants and benefits structures should not have a discriminatory impact among Part D eligibles, but this topic is not adequately dealt with in the regulations themselves (appearing only in 423.272(b)(2)).

While we support the prohibition in Section 423.272 on plans designing their benefits in a way that they are "likely to substantially discourage enrollment by certain Part D eligible individuals under the plan," this section must be tighter. There is no description, definition, or example of what would amount to discouraging enrollment and there are no criteria spelled out for reviewing formularies for features that would discourage enrollment.

Subpart M - Grievance, Coverage, Reconsiderations, and Appeals

The proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution by failing to provide adequate notice and hearing when public benefits are being terminated.

Medicaid recipients whose prescription requests are denied currently receive a 72-hour supply of medications pending the initial coverage decision. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal of a reduction or denial of ongoing prescriptions if their request is denied and they file their appeal within a specified time frame (10 days in Pennsylvania). All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. **While we recognize that the most efficient means of protecting enrollees, amending MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review, and MUST take steps to prevent the eradication of the due process rights of dual eligibles.**

CMS must incorporate the fast-track, pre-termination review process adopted after the Grijalva v. Shalala case for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements. Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage

determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. CMS has failed to comply with the language of those provisions. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, adopted 42 C.F.R. 422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D.

- There is almost no deadline for review and decision that must be adhered to by the drug plan which can obtain an extension (even in expedited cases).
- There are no requirements as to who within the drug plan can make initial coverage determinations. At a minimum, the requirements regarding who can decide re-determinations should also be true for initial determinations. Pennsylvania's requirement that the reviewer be a physician of the same specialty as the prescribing physician is an appropriate protection.

What plan actions may be appealed must be broadened. The proposed regulations define "Appeals" as procedures that review coverage determinations. However, delays in providing or approving drug coverage are only subject to the appeals process"when a delay would adversely affect the health of the enrollee". This definition is too narrow and would require physicians to speculate about the future of their patients' health in a way they would be unwilling to do. Instead, the language should be changed to say " when a delay may adversely affect the health, etc"

Comments on specific regulatory sections:

The definition of authorized representative for purposes of appeals needs to clarify that a doctor or representative can act on behalf of an enrollee in exceptions and grievances. Sec. 423.560 defines appeal to exclude grievance and exceptions processes, and defines authorized representative as someone authorized by enrollee to deal only with appeals. This language is unclear.

The final regulations must tighten the rules as to when plans can extend deadlines on coverage determinations. In no case should plans be allowed to extend deadlines in an expedited appeal process. Allowing plans to extend almost any deadline for decisions directly contradicts the enrollees right to "timely" coverage determinations.

The statutory intent of giving consumers a right to an expedited process and a right to obtain exceptions is not clearly reflected in the proposed

regulations and must be established in the final regulations. Enrollees are given a right to request an expedited coverage determination (and re-determination) but not to have an expedited process. This language should be revised to reflect that consumers have the right to an expedited process if the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or their ability to regain or maintain maximum function. Likewise, enrollees are given a right to request an exception to the formulary or the tiered cost-sharing structure but not to be given an exception. A clear standard for when an exception to the tier structure and to the formulary must be provided by the plan should be articulated in the regulations. An enrollee's right to such exceptions should be added to this section.

Due process requires written decisions and an ability to appeal beyond the initial level both of which are absent from the proposed regulations. The Balanced Budget Act requirements for Medicaid Managed Care includes basic notice and due process requirements that should be adopted here. These include:

* A requirement that the plan issue a decision within 30 days of receiving a grievance;
* a requirement that the drug plan's grievance decision must be in writing.
* a requirement that there be provisions for further review beyond the initial decision.

Consumers must be able to obtain an expedited coverage determination even in those circumstances in which they have independently purchased or obtained the medication. This is especially critical for lower-income individuals and those with pharmaceutically complex situations. The proposed regulation allow for an enrollee to get an "expedited grievance" (a decision within 24 hours) only if the grievance is about a drug plan's decision to extend a coverage determination or re-determination, or about the drug plan's refusal to give an expedited coverage determination or re-determination, and the enrollee has not purchased or gotten the disputed drug. The regulations should not deny this expedited grievance option where the beneficiary has independently purchased or otherwise accessed the medication. Obtaining a swift coverage determination and, thus, reimbursement for money paid out, can mean the difference between food or no food on the table for lower-income individuals.

The definition should clarify that denials of enrollment in a Part D plan, involuntary disenrollment from a Part D plan, and the imposition of a late enrollment penalty are coverage determinations subject to the appeals process.

The final regulations must establish criteria for who must be involved in making an initial coverage determination. The regulations fail to provide any criteria for who can make a coverage determination. At a minimum, the criteria set out in §423.590 (f) should be incorporated into this section.

With regard to standard timeframe and notice requirements for coverage determinations, in Sec. 423.568, the plan should be required to provide oral notice to the enrollee as soon as it determines that it will extend the deadline, including notice of the right to request an expedited grievance. The oral notice should be followed-up in writing sent within 24 hours of the decision to extend the deadline and the written notice must spell out the right to request an expedited grievance. Section 423.568 should be revised accordingly.

The regulations should include a requirement that the prescriber also be sent a copy of the determination notice.

An authorized representative should be able to request expedited consideration just as the authorized representative may request a coverage determination. In many situations, enrollees may need or want someone else to act on their behalf.

All coverage determinations and appeals concerning drugs, including those in which the enrollee has paid for the drug, should be treated as requests for expedited review. Medications are vital to sustaining health status and most enrollees would suffer adverse consequences if required to wait for the longer time periods. Too many people will simply go without prescribed medications pending the outcome of the review. Doubling the time frames and disallowing expedited review in cases when enrollees pay for their drugs out of pocket could adversely affect the health of those who forego other necessities like food and heat in order to pay for their medicine.

Requests for exceptions should be automatically given expedited consideration. Where someone seeks expedited review of a request to continue a drug that has been removed from its formulary, the plan should be required to process the request in 24 hours pursuant to the provision that requires an expedited review to be completed as fast as the beneficiary's condition requires. The enrollee should be given a 72-hour interim supply of the medicine, which is automatically extended if the plan takes longer than 72 hours to decide.

The regulations should state that the doctor's certificate requesting expedited review and requesting an exception should be one and the same.

The standard for approving expedited requests should be amended to omit "seriously" and add "or maintain" after "regain". The proposed regulation requires a prescriber to state that applying the standard timeframe for making a determination may seriously jeopardize the enrollee's life or health or ability to regain maximum function. Jeopardy to an enrollee's health or life is serious enough to warrant expeditious review without forcing the prescriber to engage in a gradation exercise. Also, particularly for those with chronic conditions and disabilities, the maintenance of maximum function is just as important as regaining maximum function. This standard has worked well in Pennsylvania's HealthChoices program.

The final regulations should provide that the failure to provide timely notice of expedited determination operates as an approval, and must provide, at a minimum, that it is itself an adverse decision that can be appealed.

Overall, the exceptions process at 423.578 does not comply with the statutory requirements or meet the basic elements of due process.

The only notice requirement in the regulations is at 423.120 and these are inadequate. The proposed regulations do not explain how an enrollee will get notice about the exceptions process and/or that a drug is not included on the formulary. The only notice requirement is found in **423.120(b)**, which requires the plan sponsor to provide at least 30 days notice to CMS, affected enrollees, pharmacies, pharmacist and authorized prescribers before removing a drug or changing a drug's preferred or tiered status. Although the preamble talks about written, mailed notice (pg 46661), the regulatory language just says that notice must be given, and the statute requires posting on the Internet. **To meet basic due process requirements concerning termination of benefits, the notice of the change must be in writing and must include an explanation of how to use the exceptions process, including the requirements for a doctor's certificate, the right to a hearing, and reasons why a drug is not included on/removed from the formulary, or why the tier is changing, and the evidence required to establish an exception.**

The exception process section should include a subsection on notice that (1) refers to 423.120(b) and, (2) requires plan sponsors to develop a notice that explains the exceptions process, the situations in which someone may seek an exception, and the information that is required to support an exception request, which the pharmacy will give to an enrollee who requests coverage for a non-formulary drug or requests to be assessed a lower cost-sharing amount.

Section 423.578(a) (2) must be rewritten so that it meets the statutory requirement that the Secretary establish guidelines for an exception process.

There must be one uniform standard for medical necessity that plans must be required to employ in making exceptions decisions. The proposed regulations fail to establish a clear standard which, when met by the enrollee/their prescribing physician, entitles the enrollee to an approval of the exception request. This is critical for without such a standard the plan is given unbridled discretion to deny any request no matter what information the enrollee/their physician may provide. In addition, the standard would provide some certainty and clarity to enrollees/prescribers about when an exception is or is not likely to be approved. Finally, a uniform standard provides a level playing field among plans.

The final regulations need to correctly interpret the statutory provision on whether a preferred drug would not be as effective or would cause an adverse effect. The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory mandate that the doctor need only certify that the preferred drug would not be as effective or would cause adverse effects.

The final regulation should require that the lowest co-pay that applies is imposed on drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That's the whole point of this process – to infuse some equity upon a showing that none of the other medications covered are as effective or that they may cause harm. The preamble states that a PDPs exceptions process also would have to describe how a determination on an exception request would affect the enrollee's cost-sharing under the PDP's tiering structure.

The final rule should also include the following criteria, which were omitted:

- Rule permitting continued access to a drug at given price when there is a mid-year formulary change
- Requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis

In the regulations, the exceptions criteria for tiered cost-sharing structure should require plans to permit continued access to drugs at a given/unchanged price for the remainder of the year if the tiering structure changes mid-year. To do otherwise condones a "bait and switch" strategy by the plans, and allows them to take unfair advantage of the fact that members are locked in to the plan for the balance of the year, and may not react as reasonable consumers in the marketplace.

CMS must establish specific criteria for the review process used to evaluate plan formularies and tiering structures.

We support the proposed regulation providing that, if an exception is approved, the costs to the enrollee for the drug count toward meeting OOP threshold.

The definition of formulary must be revised to meet the statutory requirements. The proposed 423.578 fails to meet the statutory requirement that the Secretary establish guidelines for an exception process. The final regulation should clarify that formulary use includes not just dose restriction, but the format of the dosage (liquid vs capsule, et.) and packaging, such as bubble wraps for long-term care facility residents.

The criteria and process described in 423.578(b)(2) must be revised so that it can be possible to obtain an exception. As written, it will be impossible to get an exception. The process is not transparent, as is stated in the preamble (pg 46720), but is left totally to the discretion of each plan. CMS, and not each individual plan, must establish the criteria for evaluating the request. Without uniform criteria, enrollees in different plans have a different entitlement. And the need to tailor supporting certificates to the different requirements of each plan places an unreasonable burden upon prescribers.

The regulations need to establish fixed criteria for evaluating the prescribing doctor's determination that using all formulary drugs would not be as effective or would cause adverse consequences to the enrollee. To meet the statutory standard, the burden must be placed on the plan to show why the doctor's decision is not definitive.

- The amount and type of evidence proposed in the certificate would make it impossible to meet the standard. "Gold standard" clinical trials generally do not include older people, people with disabilities, and people with co-morbidities. While some such evidence exists, there is unlikely to be this level of evidence for all drugs and conditions. Moreover, the regulations may require the certificate to meet only the statutory standard (not as effective or adverse effects or both). The Secretary is not authorized to permit plans to require information as to why the "preferred drug" is not acceptable for the enrollee. The regulatory criteria must defer, as did Congress, to a physician's experience in evaluating the clinical impact of a given drug.
- For dosing exceptions, the regulation sets the standard as requiring a showing that the number of doses that is available

under a dose restriction for the prescription drug has been ineffective or based on both sound clinical evidence and medical and scientific evidence the drug regimen is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. The standard should include "or cause an adverse reaction or other harm to the enrollee".

The regulations must provide for the right to continuing drug coverage pending appeal for enrollees. The regulation provides for a one month supply of a drug, but only if the plan does not act timely on an exceptions determination. If the request for an exception is not given expedited treatment, the sponsor can take two weeks to issue a decision, meaning the enrollee would wait two weeks before getting the supply of medicine. Even if the exception is treated as a request for expedited review, the enrollee would still have to wait 72 hours (less if they could show the decision needed to be made more quickly because of the enrollee's condition.) Most people wait to the last day to refill a prescription, often because of drug plan and pharmacy restrictions. Continuing coverage should be a matter of procedural due process that is available to enrollees any time they are challenging the withdrawal of a medication, or any restriction on access to a medication, and have appealed in a timely fashion such that a final decision on the matter has not been rendered.

Plans should be required to make exception determinations and notify the enrollee in 24 hours as required under Medicaid for prior authorization determinations. 42 U.S.C. 1386r-8(d)(5)(A).

Drug plans should be required by the regulations to give at least a full month's coverage not "up to a month" at a time.

We strongly support the proposed regulation that requires if an exception is granted (to either the tiered structure or for a non-formulary drug), that approval must continue indefinitely and the plan can't make the enrollee request the exception for future refills. This requirement must remain in the final regulations for reasons of fairness and administrative ease.

The final regulations must establish a clear standard which, when met by the enrollee/their prescribing physician, entitles the enrollee to an approval of their exception request. This is critical for without such a standard the plan is given unbridled discretion to deny any request no matter what information the enrollee/their physician may provide. In addition, the standard would provide some certainty and clarity to enrollees/prescribers about when a drug is or is not likely to be approved. A uniform medical necessity standard is critical.

The regulations should allow enrollees to use the exceptions process to request a drug other than a covered Part D drug.

A prescribing physician or authorized representative should be allowed to request a re-determination, standard or expedited, and to request any necessary extensions. Currently, sections 423.580, 423.582 and 423.584 allow only the enrollee to seek re-determination of any coverage determination or an extension in asking for a re-determination, and permit only the enrollee or the prescribing physician to seek an expedited re-determination. Many enrollees need assistance to obtain their benefits and are not able to request re-determination on their own.

The plans should be required to provide a notice in writing in acknowledgement of the request for the re-determination. This notice should inform the enrollee or the party making the request for re-determination on behalf of the enrollee of the right to submit evidence orally, if the request for re-determination is made orally.

There is also a lack of detail about the notice responsibilities during the re-determination process that must be addressed. The final regulations should be very clear about what notices must contain during the re-determination process. **The plans should be required to send the enrollee, the prescribing physician and any authorized representative, a notice upon denial of a request for re-determination and any denial of a request for expediting re-determination. The notice should explain the reason for the denial, including the medical and scientific evidence relied upon, and the right to request review or expedited review, to the IRE, including time frames. Finally, enrollees should be notified in writing at least 15 days before the review/opportunity to present evidence occurs. These provisions have worked well to protect Medicaid recipients in the past.**

The proposed regulations are lacking other consumer due process protections in the re-determination process. **The regulations should be expanded to allow the enrollee or enrollee's physician to present evidence in person, by phone or in writing. Enrollees should also be given a right to appear in person or over the phone at the re-determination, with a representative. The plans should be required to accommodate enrollees in the scheduling and conducting of the re-determination. Enrollees and their representatives should have the right to review in advance all the information the plan had when making its initial coverage determination.** In other words, there need to be clear procedures for an in-person re-determination.

If a plan requests medical information in an expedited re-determination, the regulations should specify that the request must be made to the appropriate

prescribing physician/provider who has the information as well as to the enrollee.

Finally, the proposed regulations provide that when the issue is a denial of coverage based on medical necessity, a physician with expertise in the appropriate medical field must make the re-determination decision. However, the physician is not required to be of the same specialty as the prescribing physician. **This criteria for when a physician must make the coverage determination is too narrow, and should be expanded to include physician's decisions for any determination or re-determination where medical knowledge is relevant. In addition, the physician reviewer should be required to have the same or similar specialty as the prescribing physician, as has worked well in Pennsylvania's managed care system.**

The regulations must provide clear requirements for how the IRE process will work. The regulations should include a timeframe in which the IRE must make its decisions. We recommend that the IRE decision be made no later than 60 days from receiving the request for reconsideration. In addition, the regulations should provide that an enrollee can appeal to the ALJ if the IRE fails to issue a decision within the timeframe provided.

PDPs must be required to respond quickly to an ALJ appeal. The regulations should specify that if an ALJ appeal is filed with a PDP, the PDP must submit the file to the IRE within24 hours of receipt of the request and the IRE should transmit the file to the ALJ within 24 hours.

The timeline in 423.634 for effectuating all coverage re-determinations should be the same-- within 30 days

All IRE decisions should be effectuated within 72 hours.

All other coverage decisions should be effectuated within 30 days.

CMS-4068-P-889

Submitter : Mr. Ken Bartuka **Date & Time:** 10/04/2004 02:10:06

Organization : Maine Ryan White Title II Advisory Committee

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

The attached letter was written for the State of Maine Ryan White Title II Advisory Committee by Jean Lavigne and Ken Bartuka, both of whom are consumer members of the Committee.

CMS-4068-P-889-Attach-1.doc

September 30, 2004

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

File Code: CMS-4068-P

On behalf of the Maine Ryan White Title II Advisory Committee we are responding to the proposed rule, "Medicare Program; Medicare Prescription Drug Benefit," 69 FR46632. The Ryan White Title II Advisory Committee is a group of twenty members representing people living with HIV, AIDS service organizations providers, staff of the State of Maine affiliated programs, Title III providers, and medical providers throughout the State. We are very concerned that the current rule does not address the safety net necessary to provide for people living with HIV/AIDS through this benefit.

We urge CMS to designate people living with HIV/AIDS as a "special population" and ensure 1) they have access to an open formulary and 2) access to all medications at the preferred level of cost-sharing. By doing so HIV positive individuals would be assured of affordable access to all FDA approved antiretrovirals, in all approved formulations, as recommended by federal treatment guidelines.

The tremendous decline in HIV related morbidity and mortality will not be sustained unless people with HIV on Medicare and/or Medicaid have full access to medically necessary medications for them. As currently proposed, the new Medicare Rx plans will not be required to provide all FDA approved antiretroviral drugs. HIV mutates which challenges both long term survivors and people newly infected with virus that has already mutated. It is essential that all FDA approved drugs be available in the formulary.

Furthermore, for HIV positive people already on Medicare but dual eligible for state Medicaid or AIDS Drug Assistance Programs (ADAP), the proposed rule provides less coverage at a higher price than that already available. To remedy this situation, we recommend ADAP be recognized as a state pharmacy assistance program and allowed to wrap around Medicare Part D Drug Benefit. We also encourage you not deny medications for failure to pay copayments. Those Medicare beneficiaries with incomes between 135-150% of the federal poverty will be required to pay a 15% co-insurance for their drugs. With the high cost of HIV medications, this requirement will impose enormous financial burden on individuals who will not be able to pay. To be successful HIV medications require strict adherence. This requirement, leading to likely treatment interpretuptions, will jeopardize the success realized in HIV treatment.

In conclusion, the successes in the treatment of HIV/AIDS have been realized due to medication advancements and increased access to treatment. Do not use these CMS regulations or the proposed new "benefit" of the Medicare prescription drug benefit to turn back the clock on HIV/AIDS treatment.

Sincerely,

Ken Bartuka

Jean Lavigne, Ph.D.

CMS-4068-P-890

Submitter : Mr. Donald Belafsky **Date & Time:** 10/04/2004 02:10:55

Organization : Boyt Drug Store,Inc

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

I appreciate that CMS recognizes that the different benefiaries will require different MTM services such as a health asseccment, a medication treatment plan,monitoring and evaluating response to therapy,etc. I also
appreciate CMS's recognition that pharmacists will likely be the primary providers, but I am concerned that leacing that decision to the plans may allow(WILL)allow,to chose less qualified provders to provide MTM services
Pharmacist are the ideal health care professional to provide MTM services and determine which serevices each beneficiary needs. I currently provide full axcess prescription filling , drug compounding some surgical supplies and of course patient consulting.
Plans should be encourged to use my services-to let me help my patients make the best use of their medications. In conclusion ,I urge CMS to revise the regulaton to establish preferred provider networks, they decrease the patient, pharmacist interaction and make the system less safe esspially for the patients who are confused due to age and illness and those patients who need human interaction
Also do not let big discuount providers provide lower cost service resulting in unsafe and lower QUALITY heathcare

Submitter : Ms. Amy Belger **Date & Time:** 10/04/2004 02:10:22

Organization : Marshland Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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 expressed by pharmacists around the nation are being considered. All pharmacists want this program to work. Private sector health plans have far too often targeted pharmacies and pharmacy reimbursement in cost containment measures rather than working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow that path.

As a community pharmacist, I am concerned with three aspects of the Medicare part D proposed rules and recommend that CMS enable the following three policies:

Medicare recipients must be able to choose their own pharmacies

It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. The access standards should be applied at a level no broader than a county to ensure that recipients have ready access to the pharmacies in their community. Furthermore, plan sponsors should be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans have often used their market force to drive down pharmacy reimbursement below a pharmacy?s operational costs, thereby forcing the pharmacy providers to cost shift to other business sectors. Medicare must not allow this business practice to continue.

Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.

Recipients should not be economically coerced into using one pharmacy over another unless the plan sponsor for defined quality reasons prefers the preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

Plan sponsors should be required to establish specified MTM services.

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

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

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

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacies 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.
Amy Belger, PharmD, RPh

CMS-4068-P-892

Submitter : Mr. Mark de Bruin **Date & Time:** 10/04/2004 02:10:01

Organization : Rite Aid Corporation

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attached document

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

See attached document

BENEFITS AND BENEFICIARY PROTECTIONS

See attached document

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

See attached document

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

See attached document

ELIGIBILITY, ELECTION, AND ENROLLMENT

See attached document

GENERAL PROVISIONS

See attached document

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

See attached document

SUBMISSION OF BIDS, PREMIUMS AND RELATED INFORMATION, AND PLAN APPROVAL

See attached document

Issues 11-20

COLLECTION OF INFORMATION REQUIREMENTS

See attached document

FALLBACK PLANS

See attached document

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

See attached document

INTERMEDIATE SANCTIONS

See attached document

MEDICARE CONTRACT DETERMINATIONS AND APPEALS

See attached document

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

See attached document

REGULATORY IMPACT ANALYSIS

See attached document

SPECIAL RULES FOR STATES

See attached document

CMS-4068-P-892-Attach-1.doc

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October 4, 2004

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

Subject: Medicare Program; Medicare Prescription Drug Benefit, CMS 4068-P, RIN 0938-AN08

To Whom It May Concern:

Rite Aid Corporation is providing extensive written comments to the proposed regulation published August 3rd that would implement Title I of the Medicare Modernization Act (MMA) of 2003. This Title establishes the voluntary Medicare Part D prescription drug benefit program that will begin in 2006.

Rite Aid currently operates 3,369 pharmacies in twenty-eight (28) states and the District of Columbia. We are a major provider of pharmacy services to elderly and disabled Medicare beneficiaries, and will continue to do so under this new benefit program. We provide comments in each section in the order in which they appear in the regulation. In these comments, references made to Part D plans refer to Prescription Drug Plans (PDP) and Medicare Advantage – Prescription Drug Plans (MA-PD).

I. General Provisions (Includes Comments on Subparts A-J)

Section 423.30-423.50 - Issues Relating to Eligibility and Enrollment (Subpart A)

Sections 423.30-423.50 and 69 Fed. Reg. 46635-46646 describe proposed regulations relating to eligibility and enrollment of Medicare beneficiaries in Part D plans. Rite Aid generally agrees with the proposed rule's requirements regarding the type of information that beneficiaries have to receive both from CMS and individual Part D plans. However, we believe that it is important for beneficiaries to know the network status of all the pharmacies in the particular plans that they are considering so they can make an informed determination regarding which plan they may want to choose.

The network status of pharmacies can be very confusing to beneficiaries under the scheme that CMS has constructed. Pharmacies can be considered preferred, non-preferred or out of network. Plans must specify the status of specific pharmacy locations, not just note whether a particular chain is in the network. In addition, beneficiaries should know the exact cost sharing amounts involved with using particular pharmacies in the network. Plan materials should be carefully reviewed by CMS to assure that plan designs do not steer beneficiaries to mail order pharmacies.

Beneficiaries should also be told up front in both the CMS and individual plan educational materials that they have the option of using a preferred or non-preferred retail pharmacy in the network to obtain a maintenance supply of their medication. Plan educational materials should be reviewed carefully by CMS to assure that plans do not say or imply that maintenance medication can only be obtained through mail order. This requirement should extend to CMS education materials as well as plan specific educational materials. These materials should also provide general information about the types of medication therapy management (MTM) services being offered by the plans.

It is important that all beneficiaries that are enrolled in a PDP or MA-PD plan have a standard benefit card issued by a plan that the pharmacist can use through the online real-time claims adjudication system in the pharmacy to determine whether the beneficiaries are eligible for benefits under the plan. All information needs to be provided to the pharmacist through this system, such as if the person is eligible for benefits, if eligibility has expired, and the beneficiary's cost sharing status (i.e. whether the individual is in the donut hole, or exceeded out of pocket maximum, etc.) The pharmacist can not be held responsible for filling prescriptions for beneficiaries who are no longer enrolled in a plan if the information provided through the system indicates that the individual is eligible at that point in time. The pharmacist cannot be held responsible for delayed updates by the PDP or MA-PD sponsor regarding prescription claims for enrollees if eligibility has been voluntarily or involuntarily terminated.

RITE AID encourages CMS to recognize that many beneficiaries rely on pharmacists to help them understand how to most effectively use their prescription drug benefit plans. Moreover, it is common for individuals to talk with their pharmacist during "open enrollment" periods to help them determine which particular plan they should choose. CMS should consider preparing educational materials that will help pharmacists understand the benefit, and other material that they can use to educate Medicare beneficiaries. CMS should recognize that if a particular pharmacist assists a beneficiary in sorting through various drug plans that may be offered in an area, that and such help doesn't represent an "endorsement" of the plan. It simply represents an attempt by the pharmacist to help the beneficiary determine which particular PDP or MA-PD plan may be better for the beneficiary based on their drug use patterns, as well as particular needs.

RITE AID is particularly concerned about the impact of this Part D drug benefit on dual eligible Medicare beneficiaries who have traditionally received their drug coverage through the state Medicaid program. The Medicaid program in each state has traditionally offered a relatively uniform drug benefit, has not required mail order for maintenance medications, has

allowed freedom of choice of pharmacy, and has not subjected beneficiaries to strict formularies. Requiring beneficiaries to make these complex choices among Part D drug plans in their region may result in many not making a choice of drug plans during the early stages of the open enrollment period.

Many of these dual eligible enrollees will likely have to be automatically enrolled in the early part of 2006, but we are concerned that many dual eligibles will find themselves without prescription drug coverage on January 1, 2006. This can create serious health implications for Medicare dual eligible beneficiaries, and CMS should allow these dual eligible beneficiaries to have a transition period of no less than six months into 2006 to allow for a transition to this new drug benefit. We would urge that automatic enrollment of these individuals begin no later than December 1, 2005 so that we can be certain that these individuals will have drug coverage on January 1, 2006. We also urge CMS to include pharmacies in any educational efforts that may be started next spring to reach these dual eligible individuals. This will help assure that these dual eligible enrollees can both obtain the subsidies for which they might be eligible, as well as get enrolled in a Part D prescription drug program.

States should continue to receive FMAP during this transition period to assure that pharmacy service to this critical population is not disrupted. RITE AID is also seriously concerned about the potential disruptions in care that may result in 2006 by transitioning these low income individuals from drugs that they may have been receiving from their Medicaid program to drugs that are on their new PDP or MA-PD plan's formulary. This could involve hundreds of thousands of calls to physicians to obtain authority to switch drugs, further justifying some type of special transition period for dual eligible Medicare beneficiaries who are transitioning from the Medicaid program.

As an alternative, CMS should consider requiring Part D plans to pay for a continuation of a dual eligible's existing drug therapy through the first six months of 2006 or until the individual can select a plan that is appropriate for them in terms of the drugs covered on the formulary. This extended time will also allow for the pharmacist to work with the physician to execute any formulary switches that are necessary, and exhaust any appeals process that might be initiated. This will also allow for a gradual switching of medications in the most logical clinical order if the dual eligible has to be switched from several existing drug therapies to several new drug therapies.

Section 423.48 – Part D Information that CMS Provides to Beneficiaries

Continuation of Prescription Pricing Website: In its discussion of the information that CMS would propose to provide beneficiaries to make choices among Part D plans, CMS suggests that it will want to continue its prescription pricing website that it established for the Medicare-endorsed prescription drug discount program. The purpose of this website was to help beneficiaries select a Medicare-endorsed discount card by comparing negotiated prices that were being offered for covered drugs by the various card sponsors at various pharmacies.

CMS indicates that it proposes to "*build on our experience in implementing the drug discount card price comparison website as we develop requirements for the Part D price comparison,*

and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings." We agree that Medicare beneficiaries should take the most cost effective prescription medications.

Comparing the prices of medications is one way to help beneficiaries make Part D plan decisions, but there are many practical, administrative and operational issues that would make this interactive website unworkable and overly confusing for patients. Moreover, beneficiaries should be choosing plans based on other criteria as well, such as the pharmacy network (especially if they are snow birds), the scope and nature of medication therapy management services that are offered, out of network pharmacy policies, and other items. CMS should encourage beneficiaries to use prescription price as one factor in determining which Part D plan best fits their needs.

There are many significant challenges to creating a pricing website given that there are tens of thousands of prescription drugs with different dosage forms, strengths and package sizes. The retail prices of the medications change frequently due to manufacturer price increases. In addition, prices for the same dosage form and strength of drug may be lower if ordered in larger quantities, making it more difficult for beneficiaries to know exactly how much they might pay for a drug at our pharmacy. This is unfair to the beneficiary and unfair to the pharmacy. Given that Part D is a coverage program, beneficiaries will also have to know how to compute their out of pocket cost, given that cost sharing of some type – whether coinsurance or copayments – will apply.

It would be very costly and time-consuming for CMS to keep up with and maintain the changes on the website. Moreover, consumers may not understand that variations in prices, even across the same chain of pharmacies, may reflect different costs of doing business in particular parts of the country. Given the frequent changes in manufacturers' prices for drugs, CMS and beneficiaries cannot realistically expect that any posted price could remain the same for any significant period of time.

Another complication would be determining what price to post on the website. Pharmacy prices can vary from one pharmacy to another depending on the cost of doing business in a particular location versus another. Factoring these variables into a website would be costly and time-consuming. If CMS posts the "maximum price" that could be charged, then it may not provide the correct information to seniors because that price is usually the pharmacy's usual and customary cash price. This price probably will not reflect the actual price that would be paid at the counter which could be based on the negotiated price. Even if the price was accurate, beneficiaries may only be paying a cost sharing amount, which may have little or no impact on their out of pocket costs.

CMS needs to assure that any website includes pricing comparisons about generic drugs compared to their innovator brands, as well as generics compared to other brand name drugs in a similar therapeutic class. For example, there are now two generics available in the SSRI class of antidepressants. Individuals going to the pricing website should be able to find this information. This will encourage the use of generics in therapeutic categories where one or two such versions might be available.

In addition, unlike the current Medicare approved discount card website, CMS must post the prices on the website of pharmacies that offer maintenance supplies of medications. This will assure that beneficiaries will know by consulting the website that they can also obtain maintenance quantities of medications from their Rite Aid pharmacy.

Posting the actual contracted prices could be problematic for pharmacies and plans because it could reveal confidential proprietary information about plans' negotiations with pharmacies regarding prices. Similar to how specific rebate and discount information from manufacturers to plans is protected from disclosure, and can only be reported in the aggregate, CMS will be creating a double standard for the revelation of proprietary contracting and pricing information if it creates a website that discloses this proprietary information from pharmacies. If the posted prices for a particular plan were to include negotiated price concessions from manufacturers as well (which is allowed under the regulation, since plans can pass these through in the form of lower prices), it could be a back door way of revealing drug specific manufacturer discounts that are not supposed to be revealed under the statute. Moreover, posting of such prices including these discounts would indicate that a plan had lower prices for certain drugs, but then a beneficiary would have to determine whether those prices, combined with the premium charged, was better on balance than another plan that had higher posted prices, but lower premiums.

Section 423. 100 - Definition of Covered Part D Drugs

In Section 423.100, the proposed regulation defines covered Part D outpatient drugs. RITE AID supports the definition of covered outpatient drugs specified with statue and the regulation. We understand that the definition will allow for the coverage of oral medications, self administered injectable drugs, infusion drugs that may be delivered through equipment such as a drip apparatus, vaccines, and insulin (as well as related injection supplies).

We are concerned that the benzodiazepine category of drugs may be excluded by Part D plans. The MMA law and regulation consider these drugs to be "excludable". Many Medicare beneficiaries take these medications because they are safe and cost effective to treat such conditions as insomnia and anxiety. It is not clear what physicians might substitute for these drugs. Beneficiaries can obtain these medications if they pay for them or if they purchase (or are offered through an employer or state-based program) a supplemental Part D plan or wrap around that covers these drugs. We interpret the regulation as allowing state Medicaid programs to pay for these medications and collect Federal matching funds to help defray the cost.

Medically accepted indications of Part D drugs will be covered as well, consistent with these indications appearing in the listed published compendia. We are concerned however with the ability of the pharmacist to know from the prescription that the physician is writing the prescription for an off label or medically accepted indication. We are concerned that retrospective review of the use of a drug may indicate that it was not used for a medically accepted indication. In that case, the pharmacist should not be penalized for dispensing a prescription for a covered drug used for an indication that is not medically accepted.

Our pharmacists cannot be expected to be in a position to contact each physician for each prescription in question to determine whether the drug has been prescribed for such an indication. Physicians are often reluctant to put any indication on the prescription for various reasons, including patient privacy concerns. CMS should require physicians to obtain a special code from the Part D or MA-PD plans that can be communicated to the pharmacist when the prescription is filled to indicate that the plan has approved the medically accepted use of that drug. This would be especially important for certain classes of drugs, such as cancer drugs antipsychotic, antiepileptics, and pain medications.

RITE AID encourages plans to put a hard stop or edit in their system to avoid Medicare Part D plans paying for Part B covered drugs for beneficiaries that are eligible for payment of their Part B drugs under that part of the program. We would assume that if a beneficiary had both Part B and Part D coverage that Part D could not pay for the 20 percent cost sharing that might be payable for a Part B drug. (That is, Part D would not provide the wrap around, although we encourage CMS to address this issue.) We are also concerned that the fragmentation of Part B and Part D coverage could compromise quality of care for Medicare beneficiaries.

The systems used to fill Part B drugs (i.e. DMERC carriers) and the systems used to fill Part D drugs (i.e. PBMs, health insurance) may not communicate with each other. This makes it difficult for our pharmacists to check for drugs interaction or other medication use problems. Thus, beneficiaries taking Part B drugs should be encouraged to use one Pharmacy for all their Part B and Part D drugs.

Options for Dispensing Fees: In its discussion of covered outpatient drugs at 69 Fed. Reg. 46647-48, the proposed regulation presents different options for payment of dispensing fees for covered Part D drugs. RITE AID expects that Part D and MA-PD plans will pay us a reasonable dispensing fee for providing these medications. The statute and regulation clearly envisions that such a fee will be paid by plans. However, the regulation's background is clearly concerned about plans paying appropriate dispensing fees to long term care pharmacies, but doesn't engage in the same discussion regarding the adequacy of dispensing fees paid to retail pharmacies. We encourage CMS to monitor the scope and nature of dispensing fees paid by plans to pharmacies to assure that there is appropriate community-based access for Medicare beneficiaries to pharmacy services.

We believe that the plan should pay the basic dispensing fee to cover our routine cost of dispensing, as well as overhead. We also believe that plans should consider the use of differential fees to encourage the use of generic drugs. Some recent studies regarding the cost of dispensing illustrate that a reasonable fee would be in the following range:

- Texas, Myers and Stauffer, August 2002: Myers and Stauffer (M&S) determined the weighted median (i.e., the midpoint) cost of dispensing in Texas to be $5.95. The weighted mean (i.e., the "average") was $6.16. The unweighted mean was $6.96. M&S notes generally higher costs in urban areas, primarily due to labor-related costs.

- California, Myers and Stauffer, June 2002: Myers and Stauffer (M&S) determined the weighted median (i.e., the midpoint) cost of dispensing in California to be $6.95. The weighted mean (i.e., the "average") was $7.21. The unweighted mean was $7.87. These figures are much lower than the dispensing fee paid by Medi-Cal at the time, which was $4.05. M&S indicates that the cost of dispensing in California is higher than observed in other states, primarily due to higher pharmacist salaries.

- Kentucky, Myers and Stauffer, October 2003: Myers and Stauffer (M&S) determined the weighted median (i.e., the midpoint) cost of dispensing in Kentucky to be $5.72; they also provide an adjusted figure that supposedly takes into account response bias (over-sampling of chain and institutional pharmacies), which is $5.76. The weighted mean (i.e., the "average") was $5.86. The unweighted mean was $6.40. M&S notes generally higher costs for institutional pharmacies, chain pharmacies (partly due to higher labor costs for employee pharmacists), and pharmacies in urban areas. M&S note that labor costs from increasing pharmacist salaries, particularly in chains, were putting inflationary pressure on the cost of dispensing. They attribute the rising labor costs to a perceived pharmacist shortage.

While these are recent cost of dispensing studies, an analysis conducted by the University of Texas at Austin Center for Pharmacoeconomic Studies found that these studies have generally understated the cost of dispensing. That is because they did not account for other important overhead factors, such as corporate chain overhead costs, advertising expenses, costs of professional licensure maintenance for practicing pharmacists, owners compensation costs allocation, and others. Therefore, to assure beneficiary access to retail pharmacies and well as institutional pharmacies, we urge that you monitor the adequacy of the dispensing fees paid by Part D plans.

For the purpose of defining a dispensing fee for Part D drugs, RITE AID believes that Option 1 of the proposed rule's definition of dispensing fee should be adopted. This includes, according to the preamble, charges associated with mixing the drugs, delivery and overhead.

Third party payers in almost all circumstances reimburse us for the cost of the product as well as dispensing the prescription. Because pharmacists in the retail setting generally do not "administer" drugs to beneficiaries, the act of providing patients prescription drugs in generally defined as "dispensing" the drugs. We agree that the definition of dispensing fee as envisioned in the statute and the regulation would not normally include the costs of professional services, such as medication therapy management services. However, the dispensing fee should include the costs of counseling provided by our pharmacists to the patient, if requested under state law. The simple act of transferring the prescription to the patient is an important part of dispensing, but a basic component of transferring that prescription involves helping the beneficiary take the medication correctly. This occurs through the basic counseling requirements that are included in almost all pharmacy practice acts, if the patient agrees to such counseling by our pharmacist.

Moreover, there are some drugs that do require certain supplies or items for effective or appropriate administration (e.g., nebulizer, spacer chamber) that are usually also paid as part of

a drug plan. These are usually considered to be a separate item, for which the patient pays an additional cost sharing or may pay the entire cost of the prescription.

We do believe however, that a general dispensing fee as defined in Option 1 should require plans to provide various levels of dispensing fees depending upon the complexity of the preparation required to dispense the prescription. For example, beyond a fee paid for dispensing, a plan may also establish another additional fee for compounding a prescription. CMS appears to envision such a payment when it refers to the act of "mixing" a drug as part of its definition of dispensing fee in Option 1. ("Compounding" should be distinguished from the process known as "reconstitution", which simply requires our pharmacist to add sterile water to a powder preparation. Compounding can involve several complex steps regarding the weighing and mixing of multiple ingredients.)

Another additional dispensing fee could be established for infusion drugs, such as antibiotics, covered under Part D. These drugs are usually prepared as "admixtures", which can involve additional costs, such as the use of a laminar flow hood. Finally, many drugs need to be prepared in special packaging, such as blister packs or bingo cards, that help enhance medication compliance. While payment for these services is envisioned under the medication therapy management section, this type of packaging may be required for individuals that do not qualify for MTM services. Therefore, plans should consider payment for this special packaging to enhance medication compliance by beneficiaries. Thus, CMS should require plans to develop dispensing fee schedules depending on the complexity of tasks required to deliver or dispense the drug to the patient.

We also believe that plans must reimburse us for value added or professional services relating to dispensing the prescription. CMS should understand that many of the formulary management and drug utilization techniques that will be used by potential Part D plans are performed by our pharmacists. As such, plans should indicate as part of their bid submission how they intend to compensate pharmacists for performing these valuable cost management and quality improvement functions. This compensation must be in addition to the product reimbursement and dispensing fees that have to be paid to us. CMS envisions that we would be paid for these functions (i.e. formulary compliance and generic drug substitution) because they are described as part of "performance based measures" under the definition of "insurance risk". These professional intervention service payments should be consistent with the time needed to perform them and should be updated each year to account for increasing costs to Rite Aid.

Because the new Part D benefit appears to include coverage for self injectable drugs and other self-administered infusion drugs, there is a need to reimburse for the services and setups required for the safe and effective use of these medications.

Section 423.104 – Requirements Relating to Qualified Prescription Drug Coverage

Availability of 340B Pricing to PDP Plans: At 69 Fed. Reg. 46651, CMS asks for comments about how to maximize savings for people in need of HIV/AIDS medications under the 340B program. In particular, CMS wants to know whether it is feasible for ADAP programs to participate with prescription drug plans so that drugs offered to individuals with HIV/AIDS can

be offered at 340B pricing. CMS also solicits comments regarding the coordination of ADAP and Medicare Part D benefits. RITE AID supports the ability of individual with HIV/AIDS to continue to obtain their necessary medications. Successful treatment of HIV/AIDS requires patient-specific combination of select drugs, which need to be taken regularly in order to treat the condition.

We are not sure what CMS is considering when it asks whether 340B pricing can continue to be offered to these individuals. If PDP and MA-PD plans are administering these programs, and all pharmaceutical price negotiations must occur between these entities and manufacturers, then it is not clear how 340B pricing would be made available.

If CMS wants pharmacies to charge ADAP beneficiaries lower prices equal to 340B prices, and thus lower any cost sharing that these individuals might have, then manufacturers of 340B drugs dispensed to ADAP individuals must provide rebates back to plans equal to 340B pricing, and pass those rebates through to the pharmacies. Rite Aid will not keep separate sets of inventory for different groups of patients (i.e. 340B drugs), so any plan that would allow ADAP beneficiaries to access these prices at retail pharmacies must be done through some real time reconciliation process that does not require keeping of separate inventory by pharmacies. Moreover, if ADAP programs want to "wrap around" the Part D benefit and provide supplemental coverage for drugs not covered on a Part D formulary, or provide cost sharing, we assume that these expenses are not counted toward the TROOP. However, the Part D plan needs to establish a process – similar to those established for other plans that wrap around – that would allow the pharmacy to know in real time at the point of care the amounts that should be collected from the ADAP beneficiary for the covered Part D drugs, if any.

Access to Negotiated Prices: At Section 423.104(h), the proposed regulation defines "negotiated prices" (also found at 69 Fed. Reg. 46654-5). PDP and MA-PD plans are required to provide enrollees with access to negotiated prices used for payment for covered outpatient drugs during the periods when benefits are not provided for these drugs, such as after the first coverage limit is reached ($2,250 in total spending for 2006). These prices are also to be passed through on a drug that is within a tier in a plan's formulary for which no benefits may be payable. Beneficiaries are responsible for 100 percent of these costs, but would be charged only the "negotiated price."

The proposed regulation indicates that "negotiated prices", shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remuneration, and shall include dispensing fees. Negotiated prices are essentially the contract rate that the plan will pay the pharmacy for a prescription drug. We consider the requirement that we pass through negotiated prices during the coverage gaps and for non-covered formulary drugs to be price controls on retail pharmacies. We should not have to shoulder the burden of these discounts when the regulation fails to spell out whether and how manufacturers price concessions and reductions are also to be passed through in these cases.

PDP and MA-PD sponsors should be required to pass through all, and not just "take into account", these manufacturer and pharmacy price concessions and rebates when determining the negotiated rate. These include formulary placement fee discounts, market share movement

discounts, and any administrative fees paid by the manufacturer to the PBM. The pass through of these amounts will lower the overall cost of the drug benefit for Medicare and potentially reduce the amount of cost sharing that a Medicare beneficiary would have to pay. It will also help lower beneficiaries' out of pocket costs and reduce the rate at which beneficiaries will reach the initial plan limit. It is consistent with the intent of this prescription drug program that discounts and rebates from both pharmacies and manufacturers be passed through.

PDP and MA-PD sponsors should not be able to keep any pharmacy spreads on prescriptions provided for brands and generic drugs. For example, plans should be prohibited from paying the pharmacy a lower rate than they are charging the plan for filling the prescription, thus retaining some of the pharmacy spread. This spread should be passed through in full to the beneficiary. CMS should require plans to report the extent to which they retain any spread on pharmacy reimbursement.

PDP and MA-PD plans are required to provide aggregate information to the Secretary on negotiated price concessions that they receive and pass through in the form of lower premiums, lower subsidies and lower prescription drug prices. Reporting should include formulary placement incentives, market share movement incentives, administrative fees that are paid to the plan, and other direct and indirect forms of remuneration.

We are responsible for passing through of manufacturer price concessions at the point of service. We should expect that the PDP or MA-PD plans will reimburse us for any manufacturer price concessions that are passed through by us in a timely manner, but no later than one week after submission of the claim. We cannot be expected to "float" for the PDP or MA-PD a significant amount of reimbursable costs for product inventory.

Section 423.120- Access to Covered Part D Drugs

Section 423.120(a)(1)-(5) - Issues Relating to Access to Pharmacies

The standards for Medicare beneficiary access to pharmacies are being implemented in a manner that is inconsistent with Congressional intent, and will significantly reduce Medicare beneficiary access to and interaction with their local community pharmacy. We believe that it was Congress' intent to protect and enhance, rather than jeopardize the health of Medicare beneficiaries by creating access standards to retail pharmacies.

To do this, Congress required plans to comply, at a minimum, with the DOD TriCare access standards, as well required plans to establish access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906-03-R) by the Department of Defense on March 13, 2003, for the purposes of TriCare retail pharmacy programs.

These standards, known as the Department of Defense's TriCare pharmacy access standards, require on average that 90 percent of Medicare beneficiaries in urban areas have access to a pharmacy within 2 miles; 90 percent in suburban areas have access to a pharmacy within 5 miles; and 70 percent in rural areas have access to a pharmacy within 15 miles**.** This

solicitation requires that a "contractor shall maintain a pharmacy network which minimizes the number of eligible beneficiaries who will have to change pharmacies…".

Averaging Access Standards: The TriCare access standards were the minimum standards that plans were to meet. However, under the proposed regulation, each PDP and MA-PD plan is required to apply each of these TriCare standards (i.e., urban, suburban, rural), on average, across each region of the plan's service area. We believe that each plan should be required to meet these standards in each state in each region in which they operate. While the proposed regulation does not specify the service areas, the fact is that using an "average" could allow plans to permit much greater access for beneficiaries in certain urban areas of the region, while reducing access in other urban areas of the region. The same is true for the suburban and rural areas of the region. Here are some examples of how such "averaging" affects beneficiary access to pharmacies:

- Using an "averaging" approach, a PDP plan could allow for greater than 90 percent access by offering a program in New York state with 90 percent urban pharmacy access in New York City and Albany, but much less access in Syracuse, Buffalo, and Rochester. On average, across all the urban areas in this service area, this PDP might meet the 90 urban access requirements, but would not have done so in each urban area. The same averaging could apply to suburban and rural areas.

- Similarly, a PDP offering a plan in contiguous New England states such as Vermont, Massachusetts, Maine, and New Hampshire could meet the card sponsor pharmacy access requirements, on average, by exceeding the 90 percent urban standard in certain cities of these states, but falling short of that requirement in other urban areas. Thus, Medicare beneficiaries in Boston could have an over abundance of pharmacies from which to choose, while those in Manchester, Burlington, and Portland might have a difficult time finding a retail pharmacy that is in the network. In addition to creating uneven access, this would obviously create an incentive for card enrollees to use mail order pharmacies, disadvantaging enrollees who want to continue to use their local retail pharmacies.

Creating "Preferred Pharmacy" Network: The proposed regulation also allows plans to totally circumvent the TriCare standards by creating "preferred pharmacies" and "non-preferred" pharmacies. Thus, a PDP or MA-PD plan could include the minimum number of pharmacies in its overall network to meet the TriCare access standards, and then create a defacto smaller network by allowing some of the pharmacies in the general TriCare network to offer lower cost sharing to beneficiaries than the non-preferred pharmacies. The proposed regulation does not specify how many pharmacies would be able to offer such lower cost sharing or the extent to which the cost sharing might differ.

While such reduction in cost sharing might be helpful to beneficiaries, it creates a smaller network than TriCare that was simply not envisioned by the statute. In effect, it renders the TriCare standards meaningless because it allows plans to create much smaller networks than is allowed by the statute. Note that the DOD TriCare program uses only an "in-network" pharmacy and non network pharmacy program. The in network pharmacy meets the TriCare

access standards, and has uniform cost sharing for all these in network pharmacies. DOD has not created a smaller "exclusive provider organization" type network as created by CMS under these proposed rules. Thus, CMS application of the TriCare pharmacy access standards is inconsistent with DOD's application of the standards, and the application of the TriCare standards by CMS establishes rules that are less favorable than those required under the March 13, 2003 statement of work solicitation. This is inconsistent with Congressional intent.

The report language accompanying the statute (see pp. 451-452 of Conference Report to H.R. 1, Report 108-391) makes it clear that plans cannot create "smaller networks" than the TriCare access standards. It indicates that the "…minimum in network pharmacy for each plan offered by a PDP or MA in a geographic area must provide access to pharmacies that is not less restrictive than the TriCare access standards." The report language further states that "plan sponsors cannot create any pharmacy networks that are more restrictive than the TriCare access standards." CMS basically ignores this intent of Congress with how it is implementing the program.

CMS basically admits to the negative impact of such a network by saying that:

> *"We recognize the possibility that plans could effectively limit access in portions of their service areas by using the flexibility provided in…of our proposed rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a plan could establish a differential between cost sharing at preferred pharmacies versus non preferred pharmacies – while still meeting the access standards in our proposed rule – that is so significant as to discourage enrollees in certain areas (rural or inner cities, for example), from enrolling in that plan. Our intent is to use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process described in § 423.272 of our proposed rule, the design of proposed prescription drug plan and MA–PD plan designs to ensure that they are not likely to substantially discourage enrollment by certain part D eligible individuals. Such a review would preclude the approval of bids submitted by plans that attempt to use strategies such as that outlined above to limit enrollment in portions of their service areas that are more difficult or costly to serve."*

Thus, CMS itself indicates that it is creating "in networks" of pharmacies that will be more restrictive than TriCare, directly contravening Congressional intent. Moreover, implementation of the TriCare access standards established in the solicitation of work create much more access to retail pharmacies than the way that CMS is implementing these standards, which is also contrary to Congressional intent.

We believe that for each plan being offered in each state in each region, PDPs and MA-PDs must establish the same cost sharing requirements for all TriCare pharmacies, and cannot create lower or different cost sharing requirements among "in network" TriCare pharmacies. Lower or different cost sharing amounts for some preferred pharmacies in the TriCare network would only be accessible by some Medicare beneficiaries, creating a defacto smaller pharmacy network.

The proposed regulation also fails to indicate that, in determining distances to pharmacies required under the TriCare standards, plans must apply the standards using "commercially traveled routes". These are the actual travel distances for beneficiaries to these pharmacies, not just the distances between the beneficiary and the pharmacy. For example, a beneficiary may only be geographically two miles from a pharmacy, but because of the way that the road system is structured, the beneficiary has to travel or drive 5 miles to reach that pharmacy. The actual driving distance should be used to determine whether the TriCare access standards are being met.

Taken together, all these loopholes mean that millions of Medicare beneficiaries will not be able to obtain their needed medications from their local Rite Aid pharmacy at the best cost sharing rates possible. For example, a Medicare beneficiary living in an urban area may be within 2 miles of a Rite Aid pharmacy, (the pharmacy that she has been using for multiple years). However, because it is a non-preferred pharmacy, the beneficiary may find that she has to pay $10 rather than $5 for her medications, and cannot afford to do so. The nearest preferred pharmacy may be in an urban area many miles away, because this plan's urban access average includes more pharmacies in another urban area rather than this beneficiary's urban area.

In another example, a Medicare beneficiary in a different urban area in the same region may be 4 miles from the nearest network pharmacy. This beneficiary still meets the TriCare access standards because of the "averaging" allowed for the urban areas in this region. However, this Rite Aid pharmacy is not a preferred pharmacy, but the nearest preferred pharmacy is 6 miles away. This beneficiary is also disadvantaged from using her Rite Aid pharmacy because of the incorrect interpretation of the statute regarding the TriCare access standards.

CMS indicates that it will waive the pharmacy access standards under certain conditions. This includes MA-PD plans that provides access through pharmacies owned and operated by the MA organization that operates the plan. RITE AID believes that such a waiver should only apply to staff model HMO plans that are also MA-PD providers. These types of plans typically own their own buildings, including pharmacies, where health care services are delivered. However, a MA-PD plan that is a regional or local PPO should not be allowed to own one pharmacy to evade the pharmacy access requirements. We encourage CMS to only allow this waiver to be applicable to HMO staff model MA-PD plans

Definition of Pharmacy: The regulation indicates that PDP and MA-PD plans can only consider in their networks retail pharmacies that are "licensed pharmacies from which covered part D enrollees could purchase a covered Part D drug without being required to receive medical services related to that particular covered Part D drug from a provider or institution affiliated with that pharmacy." In our view, PDP and MA-PD plans can only count traditional community retail pharmacies that are accessible to the general public when determining whether they meet the TriCare access standards. That means that only those pharmacies licensed in the state where any individual can take a prescription in that state in order for that prescription to be filled should count toward the TriCare standards. As such, plans cannot count mail order or central fill pharmacies, closed door pharmacies (such as nursing home or institutional pharmacies), PHS clinics or IHS pharmacies, state's border pharmacies (unless in

the region), hospital outpatient pharmacies, dispensing physicians, infusion pharmacies or other pharmacies that are not accessible to the general public.

Moreover, plans can include home infusion pharmacies in their networks, but these should not count toward the TriCare access standards because these pharmacies typically provide special types of drugs and supplies (i.e. intravenous antibiotics, TPN, etc), that are not found in traditional retail pharmacies. Only patients eligible to receive drugs from Indian Health Service pharmacies should receive drugs from such pharmacies under this program if the pharmacies are included to meet access requirements. In its definition of long-term care pharmacy, CMS should recognize that some long term care pharmacies may be subsidiaries of corporations that own both a LTC and retail pharmacy establishment. CMS cannot count retail pharmacy in a plan's retail pharmacy network but the LTC pharmacy is in the LTC network established by the same plan.

We believe that plans should contract with pharmacies outside their service area (who would then become network pharmacies) to provide pharmacy services to beneficiaries that travel (i.e. snow birds). However, as the proposed regulation indicates, these pharmacies cannot count toward the TriCare access standards for that region, unless the pharmacies are in the same region.

In summary, the final rule must not allow plans to average access requirements across urban, suburban, or rural areas in each region. The final rule must specify that each PDP and MA-PD plan must meet the TriCare access standards in each state in each region in which they offer such plans. Plans cannot create any networks that are smaller than TriCare. The final rule must specify that only traditional retail pharmacy should be counted by plans toward meeting the pharmacy access requirements. To achieve access to pharmacies consistent with Congressional intent, the final rule must specify that the TriCare access standards can only be met by counting "preferred pharmacies" not "non preferred pharmacies." The final rule should require that "commercially traveled" routes be used by plans to determine whether the TriCare access standards are being met.

Standard Pharmacy Contract: The background to the proposed regulation asks whether CMS should require plans to make available to all pharmacies a standard contract for participation in their plan's networks. CMS indicates that such a contract could be varied with terms and conditions that would only have to be made available to a subset of pharmacies. We believe that such a model contract should be made available by plans to any pharmacy willing to participate in the plan's network. In addition, in order to avoid any issues regarding whether a pharmacy is still in operation and actually participating in a PDP or MA-PD network, CMS should require that all pharmacy contracts be done by plans through an "active" process rather than a "passive process."

In other words, plans should not use "all products" clauses in existing third party contracts to assume that a pharmacy will also be in the plan's network. This situation occurred in the process by which plans contracted with pharmacies to form their discount card networks. As was the case, some of these networks included pharmacies that were no longer in operation, or had not "actively" accepted a contract to participate in the discount card sponsor's network.

PDP or MA-PD plans should be required to demonstrate that they have negotiated separate contracts with these pharmacies specifically related to participation in these networks.

We believe that these contracts should, among other items, specify the terms and conditions of payment. Contracts between pharmacies and PDP sponsors should clearly define terminology and descriptive criteria associated with the terms used in the agreement, as well as operational processes and procedures to assure efficient administration of the program. These would include the following:

- *Real Time Adjudication:* All information regarding the adjudication of the prescription claim, including eligibility information, copays, formulary coverage status, other liable payers, and claims payment status must be provided by the plan to the pharmacy through an online, real-time claims system.
- *Average Wholesale Price (AWP):* The contract should indicate the source of the AWP, how often the plan's AWP files are updated, what AWP is used, what "current" AWP means, and designate the package size on which the AWP is based.
- *Brand Name Drug:* Because both single and multi source products have brand names, the term brand name either needs definition or should not be used. If brand name means single source, then the contract should say single source. If brand name also refers to multi source products with brand names, then the contract should so state.
- *Generic Drug:* All drugs, both single source and multi-source drug products, have a generic name. If the contract is referring to a product available and marketed from multiple sources, then it should be referred to as a multi source drug.
- *Compensation:* The contract should identify the compensation formula for paying pharmacies for prescriptions, as well as any payments for other services, and incentives for performance. The other services and incentives, and the requirements for pharmacies to receive compensation, should also be defined.
- *Maintenance Supply of Medications:* The contract should specify that a network pharmacy can provide a maintenance quantity of medication, and the specific differences in prices, if any, that a beneficiary would have to pay at the retail pharmacy. The contract should also allow the pharmacy, at its option, to accept the mail order reimbursement (i.e. negotiated rate) for the medication if it is lower than the negotiated rate for the retail pharmacy.
- *No Acceptance of Risk:* As required under law, pharmacies cannot be required to accept risk. This should be stated in the contract. The contract should also preclude other forms of potential risk transfer, such as terms that would institute fixed fee amounts for drugs that are prescribed in specific drug classifications, fixed amounts of reimbursement per patients or capitated payment amounts, delayed reimbursement, or other forms of financial hardships because of the inability of plans to control costs.
- *Co-Payments:* Often patients' co-pay differs depending on the drug prescribed or "tier" in which the drug is located. All contracts should carefully describe the various co-payments and tiers, as well as how and when they apply.
- *Covered Services:* The contract should describe covered services, restrictions and exclusions.

- *Eligibility and Identification Cards:* Contracts should identify the criteria for coverage, and specify that the PDP's identification card meet the NCPDP standards for identification cards. There should not be a multitude of dissimilar looking cards containing varying and inconsistent information.
- *Maximum Allowable Cost:* A MAC schedule is often a component of the pharmacy compensation methodology. It is important that the source and the method that the sponsor uses to determine MAC be identified in the contract, and that processes are in place to assure that MACs are adjusted in a timely manner to reflect changes in the market place.
- *Policy and Procedures:* The contract and plan material provided to pharmacies should completely define the processes and procedures to be used when submitting claims, for seeking prior authorization, for responding to electronic communications from the processor etc.
- *Payment for Services:* Contracts should specify who pays the pharmacy and when. Since claims are to be submitted electronically, payers should be able to make payment to pharmacies within 7-10 days. Pharmacies should not be subjected to bearing large and costly receivables and having their cash flow jeopardized because of payers' delayed payments.
- *Late or Non-payment:* The contract should address the processes and procedures that pharmacies are to follow should a plan be delinquent in payment, or unable to meet its financial obligations.
- *Patients' Records:* It should be made clear that patient information and prescription records are the property of the pharmacy and payers and sponsors can not use that data for other than processing and paying claims. The pharmacy will allow records to be copied for meeting regulatory requirements.
- *Retroactive Recoupments:* Plans must be prohibited from requiring pharmacies to retroactively recoup from other third party payors that were determined to be liable for all or part of the prescription claim (after the prescription claim was adjudicated).
- *Auditing and Record Reviews:* Contracts should include a description of the processes used for audits, including what can be audited, how an audit is conducted, providing prior notification, appeals processes, etc.
- *No Passive Contracting Changes:* Any and all changes to a contract between a plan and a pharmacy should be required to be negotiated. Plans should not be able to make material changes to a contract by simply indicating in the contract that pharmacies agree to any and all changes made in the plan's provider manual. Plans often seek to circumvent the need to negotiate significant benefit design or plan participation requirements with pharmacies by simply indicating that the pharmacy agrees to any change made by the plan in the provider manual. We do not believe that CMS should allow any plan to make material changes in this manner, given that it may affect the ability of plans to maintain networks.
- *Usual and Customary Price:* RITE AID supports CMS' definition of "usual and customary" price as the price the pharmacy charges a customer who does not have any form of prescription drug coverage. That is, this is the price for a prescription that would be paid by a cash-paying customer. This is an industry standard, and should be included in the standard model contract developed by plans.

- *Termination of Contract:* The plan must give pharmacies 90 days notice that it intends to terminate its contract with CMS, and assure that payment for all prescription claims filled during the remainder of the contract period are paid within one week after the contract date ends.

Issues Relating to Low Income Individuals: Plans are prohibited from creating different deductible or cost sharing requirements other than those established by law for Medicare beneficiaries below 150 percent of poverty (i.e. $1 generic/$3 brand for those up to 135 percent of poverty; $2 generics/$5 brands for those up to 150 percent of poverty). That is, plans are prohibited from creating actuarially equivalent benefit plans for these individuals. For that reason, because there cannot be differential cost sharing or "actuarially equivalent" plans for these individuals, any pharmacy (in network or out of network) that wants to provide prescription services for these individuals should be able to do so, as long as they meet the other terms and conditions of the contract.

Allowing dual eligible Medicare beneficiaries to obtain their prescription drugs from any pharmacy in the network will help assure appropriate pharmacy care for these individuals, many of whom do not have the means to travel long distances to "in network" retail pharmacies to obtain their prescription medications and pharmacy services.

Plans should be discouraged from using mail order pharmacies for these low-income populations, and should be prohibited from varying the cost sharing amounts for these individuals to encourage the use of mail order pharmacy over retail pharmacy. There should be no additional payment required from these individuals to obtain the same benefits (same quantity of medication) from retail pharmacy as through mail. That is because co-payment amounts for these populations – as well as any future year increases – are fixed by law.

Essential Rural Provider: The proposed regulation asks for comments on how beneficiaries that reside in rural areas might be assured of access to a retail pharmacy. The TriCare access standards require that 70 percent of beneficiaries in rural areas live within 15 miles of a network retail pharmacy. CMS has interpreted this as allowing plans to "average" this access requirement among all the rural areas in this region. This could mean that a beneficiary could have to travel more than 15 miles before they find a preferred pharmacy in the plan's network. This would create uneven access for Medicare beneficiaries to retail pharmacies and create unfair incentives for them to use mail. Such a result would essentially nullify an important policy component of the Medicare law; that is, giving beneficiaries the choice of obtaining pharmacy services from the provider of their choice if they are in the network.

There are likely to be rural communities where there is only one pharmacy for many miles, making it the only location within reasonable traveling distances for many beneficiaries. CMS should assure that these pharmacies are included as preferred pharmacies in the plan's network, at the lower cost sharing amounts that are established. While we strongly oppose the concept of preferred pharmacies and non preferred pharmacies, rural beneficiaries may have to travel much longer distances than 15 miles to find a preferred pharmacy. CMS should create a similar concept as an "essential rural provider" designation for rural pharmacies that are clearly critical to providing community-based pharmacy services to Medicare beneficiaries.

Section 423.120(a)(4) – Contracting Terms with Pharmacies and Prohibition on Transferring of Insurance Risk

Section 423.120(a)(4) describes pharmacy network contracting requirements for PDP and MA-PD plans. Under these requirements, plans cannot require pharmacies to accept insurance risk as a condition of participating in these plans. The proposed regulation defines "insurance risk" as risk that is commonly assumed only by insurers licensed by a state, and does not include payment variations designed to reflect performance-based measures within the control of the pharmacy, such as formulary compliance and generic drug substitution, nor does it include elements potentially in control of the pharmacy for example labor costs and productivity. While these types of performance-based programs do exist in the market today, payments for these performance-based measures are generally made in addition to, not instead of, payment for dispensing the prescription. They represent additional payments for meeting certain incentive measures.

Consistent with the legislative intent, the final regulations should prohibit plans from forcing us to accept any contractual terms that require us to accept lower payment rates as a result of plan cost overruns. These terms would include fixed fee amounts for drugs that are prescribed in specific drug classifications, fixed amounts of reimbursement per patients or capitated payment amounts, delayed reimbursement, or other forms of financial hardships because of the inability of plans to control costs. These unexpected cost increases can result from, among other factors, unexpected cost overruns for drug spending under the plan resulting from insufficient premium bids, the introduction of costly new drugs, insufficient incentives to use lower-cost generics, overuse of brand name drugs in mail order, or other cost increase factors not under the our control as specifically defined by the contract.

PDP and MA-PD plans should be required to clearly identify for CMS as well as pharmacies the pricing source that they will use as the basis of paying for covered outpatient drugs provided under their program. For example, plans should indicate whether they are using First DataBank, Medi-Span, or another pricing source, and indicate how often this will be updated. Changes in data sources should be prohibited contractually until the contract between the pharmacy and the Part D or MA-PD plan expires. Plans should also be required to publish their Maximum Allowable Cost (MAC) list for generic drugs, update the list frequently, and use the list to reimburse both for retail prescriptions and mail order prescriptions. Plans should also indicate how and when they will add new generics to their MAC list.

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

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

amount, scope, and duration of covered outpatient drugs and medication therapy management services at any community retail pharmacy that is in the plan's pharmacy network (which include those that are in the preferred network and non preferred network) as they offer through mail order pharmacies.

That is, the 90-day supply quantity mentioned in the law is only an example of the type of benefits that PDP or MA-PD sponsors have to allow retail pharmacies to provide to Medicare beneficiaries if they are also provided through mail order pharmacies, and we believe that the proposed regulation agrees with that interpretation. Entities that are administering the Part D prescription drug coverage programs should do all they can to make any cost differences between mail order and retail pharmacy minimal for the beneficiary.

Based on legislative history and Congressional intent, plans cannot create artificial cost sharing structures to create incentives for beneficiaries to use a particular source to obtain their covered outpatient drugs. That is, plans cannot create differential cost sharing requirements to shift beneficiaries to mail order. The only difference in cost between a retail and mail order prescription for a beneficiary should be the net cost, if any, of the difference between negotiated prices as explained below. In fact, a colloquy between Senator Enzi, the provision's sponsor regarding retail and mail order equity, and Senate Finance Chairman Grassley, provide clear Congressional intent regarding how this provision should be implemented:

> ***Senator Enzi:*** *"My intent in offering this amendment was to prohibit plans from implementing restrictions that would steer consumers to mail order pharmacies…My concern is that any differences in charges between mail order and retail be reasonable differences, based on the actual cost of delivering the service. I would be concerned if differences in charges were used as a method of steering seniors and disabled to mail order pharmacies."*
>
> ***Senator Grassley:*** *"I say to my colleague from Wyoming that Medicare drug plans and Medicare Advantage organizations should not force seniors or the disabled to choose a mail order house when they would prefer to patronize their local community pharmacy…it is my expectation that any differential in charge be reasonable and based on the actual cost of providing the service in or through the setting in which it is provided. I would also expect that the Secretary of Health and Human Services would disapprove of any plan that would impose a differential charge that was intended primarily to steer Medicare beneficiaries to mail order pharmacies versus retail pharmacies"* [1]

In a February 10, 2004 appearance before the House Ways and Mean Committee, Secretary Thompson said the following in response to a question raised by Congressman Phil Crane:

> ***Congressman Crane:*** *…It was clearly the intent of Congress to improve seniors' choices by creating a level playing field between local pharmacies and mail order. I hope that when HHS implements the drug coverage portion of this law, that you'll work to make sure that drug plans do nothing to intentionally discourage seniors from choosing a 90-day*

[1] Congressional Record, Senate, November 24, 2003, p. S15744

supply of drugs from their local pharmacies. I am especially concerned that drug plans may attempt to steer seniors to their mail order businesses by requiring higher copays or other cost sharing just for choosing to obtain a 90-day supplement from their neighborhood pharmacy. That was not the intent of this Committee, and I urge you to be vigilant in preventing plans from doing this. And do you have any specific plans for preventing this from occurring?

HHS Secretary Tommy Thompson: *We're going to be very vigilant as you have admonished us to be Congressman Crane, and we are going to use procedures to make sure that does not happen, we have very aggressive in making sure that seniors are treated properly and correctly and we want to make sure that we carry out the will of the Congress and will and intent of this Medicare Modernization Act and we will do everything we possibly can to prevent any kind of scamming that may possibly be considered.*

In a March 8, 2004 letter to Secretary Thompson, Congressman Joe Barton (R-TX), Chairman of the Committee on Energy and Commerce of the House of Representatives, indicated, regarding this provision, that:

> "…the provision indicates that any differential in charge between mail order prescriptions and prescriptions filled by community pharmacies will be paid by enrollees. To ensure a level playing field between mail order and retail pharmacies any such additional charges should be reasonable, and should not exceed the additional direct costs associated with dispensing the drugs through a community pharmacy. To permit large differences in charges would have the undesired effect of steering enrollees away from community pharmacies and toward mail order pharmacies."

Under the law, Medicare beneficiaries are required to pay any difference in charge for obtaining their covered outpatient drugs through retail pharmacy rather than mail order. The proposed regulation interprets the phrase "difference in charge" by indicating that the enrollee pays for any "differential in the negotiated price for the covered Part D drug at the network retail pharmacy and mail order pharmacy". "Negotiated prices" according to the regulation, should take into account "price concessions, such as discounts, direct or indirect subsidies, and direct or indirect remunerations, for any covered Part D drugs, and include any such dispensing fees for such drugs."

Consistent with this definition, the "negotiated price" should only reflect the net direct cost to the PDP or MA-PD plan, net of rebates, discounts or other price concessions, for the same quantity of medication dispensed to the patient. That means, the cost difference to the senior should only reflect the net cost to the plan of paying for the prescription through retail versus mail, net of any manufacturer rebates, discounts, or price concessions paid to the plan for a similar quantity of the drug dispensed through retail versus mail order, with those various price concessions applied directly to reducing the cost of the retail or mail order prescription. Plans should not be allowed to use rebates that are provided to them for prescription drugs that are dispensed through retail pharmacies to artificially lower the cost of providing mail order prescriptions. This makes it appear that mail order is less expensive, so they can make higher profits and dispense larger quantities of prescription drugs by steering beneficiaries to mail.

Moreover, to make an "apples to apples" comparison, plans must use the same AWP basis to determine the reimbursement rate for mail order and retail, and not use artificially-inflated or repackaged product AWPs for mail order which generally overstate the AWPs as compared to retail package AWPs. Moreover, reimbursement rates for generic drugs should be the same whether provided through retail or mail. That is, if a plan uses an AWP discount rate to reimburse mail order for generics, it should use the same method for retail. Similarly, if the plan uses a MAC (maximum allowable cost) for generic reimbursement for retail, it should use the same for mail order. Moreover, plans should pass along any spread between the rate they pay to pharmacies and the rate they charge the beneficiary. Plans should not be allowed to keep the spread (and thus make the retail price higher) by passing along the spread on the mail order side, but retaining it and charging the higher price on the retail side.

Given that subsidy-eligible low income individuals cannot have any difference in copayment amounts for their medications (i.e. $1 for generic; $3 for a brand) these individuals should be able to obtain larger quantities of medications from their local retail pharmacies – whether preferred or non preferred - without having to pay any difference in price for their prescriptions.

In conclusion, we believe that the final rule must specify that plans cannot use differential cost sharing to steer beneficiaries to mail order pharmacies. The final rule must specify that, in calculating the difference between the negotiated price for the same quantity of prescription dispensed through retail vs. mail, that the price in each case reflects the rebates or discounts earned for that particular drug by the PBM in each channel in which they are earned. The final rule should specify that any differential in price paid by the enrollee for a prescription obtained from a retail pharmacy versus a mail order pharmacy, or vice versa, should be considered an "incurred cost", and count toward the beneficiary's out of pocket spending thresholds.

Section 423.120(b) - Drug Formulary Requirements

Rite Aid works with millions of patients each day to help provide them their prescription medications consistent with their plan's drug formularies. Formulary "enforcement" generally occurs at our pharmacy counter and often involves significant administrative hassles for the patient and pharmacist with little or no compensation. In fact, often times the rebate credits are earned by the PBM or health insurance plan for a formulary-based drug switch that was executed by our pharmacist.

The MMA allows plans to use drug formularies and allows plans to create tiers within their formularies. Given that this new Part D program will affect the prescription patterns of millions of elderly individuals- including millions of low income Medicaid recipients – the potential for tens of thousands of drug switches to comply with new Part D drug formularies is possible, especially in the early months of 2006. This will create significant administrative hassles for our pharmacists and beneficiaries, since almost all of these switches will likely require physician approval.

As part of its review process of a plan's formulary, CMS has indicated that it will also examine other utilization management strategies that are tied to appropriate drug use, such as tiered cost sharing, step therapy and prior authorization. All these mechanisms are integral to formulary use, and in almost all cases, they are implemented through the our pharmacists. We agree that CMS should review these mechanisms in conjunction with the plan's formulary, as well as the extent to which the plan is using tiered cost sharing to encourage the use of certain medications. RITE AID believes that drug formularies developed by Part D plans (PDP and MA-PD plans) should include covered Part D drugs that reflect contemporary medical practice. Having said that, we believe that beneficiaries should be started on the most cost effective drug that is available on the formulary to treat their medical condition, and that plans and formularies should encourage the use of generic or lower cost multiple-source drugs where possible. Beneficiaries should be able to obtain specific brands when necessary, but we are concerned that direct to consumer advertising of prescription drugs may result in excessive brand drug usage where more cost effective generics might be available.

With respect to the specific issues raised regarding formulary implementation, we would recommend the following:

- **Impact of Drug Switching**: Given that this new Part D program will affect the prescription patterns of millions of elderly individuals- including millions of low income Medicaid recipients – the potential for tens of thousands of drug switches to comply with new Part D drug formularies is possible, especially in the early months of 2006. This will create significant administrative burdens for our pharmacists and beneficiaries, since almost all of these switches will likely require physician approval. There could be extensive pharmacist time and cost involved in explaining denials to patients, contacting physicians to switch drugs, and executing claims transactions back and forth before a particular drug is approved for dispensing by the plan.

  We are also concerned about the potential number of drug switches involved with a particular Medicare beneficiary. For example, a beneficiary may be taking multiple drugs, some of which may be prescribed by different physicians, and some of them may have to be switched to accommodate the plan's formulary. It may not be advisable to switch all the drugs at once, especially for drugs that have narrow therapeutic ranges, or potential side effects. These switches should occur over time consistent with good patient care and sound medical practice, and not just to accommodate a plan's formulary.

- **Generics Preferred**: Drug formularies should be structured so that a generic drug is the preferred agent in as many classes as possible (where available) unless the physician has indicated that a specific brand is medically necessary. Plans may want to consider requirements for physician approval of certain brand name drugs in therapeutic classes where generic drugs are available.

- **Physician Obtains Prior Approval:** RITE AID agrees that prior approval and step therapy programs can help plans reduce drug spending and improve overall quality of care. However, any prior approval program or step therapy program should require the

physician to contact the plan and obtain approval. The plan's approval to dispense a particular drug should be communicated to our pharmacists through the online, real time claims adjudication system. Our pharmacists should not be responsible for obtaining all the authorizations necessary from the plans to dispense a drug requiring "prior approval", or those drugs in a "step therapy" program.

- **Over the Counter Drugs:** The MMA allows plans to exclude over the counter medications from coverage. However, it may be the case that plans will cover OTC medications in their formulary and attempt to have these "counted" as one of the two drugs that are required to be covered per each class or category. This is particularly likely in classes where there is a former prescription product that has been switched to OTC status. For example, there have been recent switches in the PPI class (i.e. omeprazole), and in the non-sedating antihistamine class (i.e. loratadine), and future potential switches are possible, such as lovastatin, which is a cholesterol-lowering drug.

  After these switches, many commercial managed care plans have stopped coverage for or limited coverage of (i.e. shifted to a higher tier) prescription versions of these products. This has shifted the entire cost or most of the cost to the patient, even though these OTC drugs may not have the same indications as the prescription drug, or be considered to be bioequivalent by the FDA's Orange Book. We urge CMS to determine whether plans are limiting availability of certain prescription medications in classes where equivalent or substitutable OTCs might not be available.

- **Pharmacy and Therapeutics Committee:** Pharmacy and Therapeutics Committees (P&T) should be involved in the development of clinical programs for PDP and MA-PD plans, such as formulary development, prior authorization, medication management, and step therapy, but only if the majority of P&T committee members are free of conflict of interest. It makes no sense to vest more authority and control in a P&T Committee if there are significant conflicts of interest that compromise appropriate and cost effective drug use for that plan's beneficiaries. State Medicaid programs often use their Medicaid P&T Committees to, among other activities, develop formularies, preferred drug lists, prior authorization procedures, and monitor clinical programs, such as medication therapy management or disease management.

  Thus, using these Committees for these purposes makes sense, as long as the group consists of individuals whose goals are to assure the most appropriate, cost effective prescribing. Because cost management and clinical programs of these types are implemented at the pharmacy level, P&T Committees should include representatives of chain corporate offices since many of the procedures that might be put in place are likely to be implemented, in part, at the corporate chain level.

- **Off Label Usage:** Physicians who prescribe drugs for an off label use should indicate the diagnosis on the prescription or through the electronic prescription communication so our pharmacist knows that is being used for such a use. Our pharmacists cannot be placed in a position of "policing" off label use of prescription medications for the plan. The regulation indicates that prescribers are "encouraged" to "clearly document" and

justify off label use in Part D enrollees "clinical records". We strongly urge that such information also be noted on the prescription provided to our pharmacist so our pharmacist can properly conduct drug utilization review.

- **Appeals Process:** It is the responsibility of the beneficiary and the physician to navigate the formulary appeals process. Our pharmacists can provide the beneficiary with general information about the process but cannot and should not be placed in the middle of the process. Our pharmacists should be told of the ultimate decision of the appeals process through the online real time claims adjudication system regarding the approval of (or disapproval of) coverage of certain drugs.

  Moreover, we are concerned with the complex appeals process that is put in place for beneficiaries and physicians to "appeal" a formulary decision. There are appeals processes both at the PDP level and the Medicare level. In addition, the length of time to make a decision on an appeal depends on many factors, including whether the beneficiary is paying or not paying for the drug on appeal. It is not clear how our pharmacists will know the status of these appeals, or how a decision on an appeal will be communicated. The status of these appeals must be communicated to our pharmacists through the real time electronic prescription processing system. Our pharmacists cannot be placed in the middle of these determinations processes, but must be aware of the status of the appeals to help the beneficiary know the status of their prescription drug coverage.

  We believe that CMS should assure that plans develop an appeals process that is minimally burdensome to beneficiaries, physicians and pharmacists. CMS should require plans to document the process they will use, as well as involve pharmacy providers that are in their networks in the design and implementation of this process to assure it is minimally burdensome on pharmacies.

  CMS may want to consider creating a standard dispensing procedure for a drug that is not on the formulary, or on appeal, especially if our pharmacist is unable to contact the physician. This might happen, for example, over a weekend when a beneficiary might have to fill a prescription for a necessary antibiotic or pain medication. We again refer to the Medicaid program which requires the dispensing of a 72-hour supply of medication in an emergency situation. It will be very difficult for pharmacists and beneficiaries to know how to handle emergency situations at our pharmacies regarding a physician's order for a non-formulary drug. There should be some standard procedure incorporated into the system. Moreover, we need to be paid for the dispensing of the emergency supply of the medication as well as the dispensing of the remaining quantity of the medication should the original prescription be approved under the appeals process or the physician prescribes another formulary drug.

- **Same Formularies Between Retail and Mail Order:** CMS should assure that all formulary drugs are available to Medicare beneficiaries through both retail and mail pharmacies. Part D and MA-PD plans cannot structure formularies to only make certain drugs available through mail order rather than retail pharmacies. All covered outpatient

drugs should be available to beneficiaries through retail pharmacies as they are made available through mail order pharmacies. Also, consistent with congressional intent, plans cannot use differential cost sharing to steer beneficiaries to mail order pharmacies and create different cost sharing tiers for retail pharmacies versus mail order pharmacies.

- **Communication of Formulary Changes**: It is particularly important to communicate formulary changes to beneficiaries, pharmacists and physicians as soon as possible. Formulary changes are likely when new drugs come to market (or are removed from the market), generics are added, or new off label uses are defined. RITE AID suggests that plans change formularies as infrequently as possible. Our pharmacists and patients often only become aware of formulary changes when a beneficiary comes into fill and/or refill a prescription.

  We agree that a beneficiary should be able to obtain a prescription fill or refill for a formulary drug at the same cost share for 30 days after the plan formulary notifies enrollees about a change in the drugs status on the formulary. The formulary change should be communicated to our corporate headquarters so that any appropriate changes can be made in our pharmacy system.

  The key is for the plan to communicate all information to us in real time through the online claims adjudication system at the time the prescription is presented. We need to have at least 30 days notice of any prepared formulary status changes. We believe that plans should use a standard formulary change form, and that CMS should develop standard policies and procedures for how these changes are communicated to beneficiaries, pharmacists, and physicians. Mass mailings should not be the only method by which these changes are communicated. The best way to communicate these changes to pharmacies is through the online claims adjudication system.

Payment Incentives to Pharmacies: CMS should understand that many of the formulary management and drug utilization techniques described here are performed by our pharmacists. As such, plans should indicate as part of their bid submission how they intend to compensate pharmacists for performing these valuable cost management and quality improvement functions. This compensation must be in addition to the product reimbursement and dispensing fees that have to be paid to the pharmacist. CMS envisions that pharmacies would be paid for these functions (i.e. formulary compliance and generic drug substitution) because they are described as part of "performance based measures" under the definition of "insurance risk". These professional intervention service payments should be consistent with the time needed to perform them and should be updated each year to account for increasing costs to Rite Aid Corporation.

Section 423.120 (c)- Use of Standard Technology (Standard Benefit Card)

We agree with the provision that indicates that CMS will base its card standards on the elements of the NCPDP "Pharmacy ID Card Standard", which have been developed and agreed upon by industry consensus. These are the elements that all payers require, at a minimum, to

process a claim for pharmacy benefits. Additionally, these elements are required to properly route a pharmacy benefit claim to the correct entity for claims processing. We urge CMS to adopt NCPDP's "Pharmacy ID Card Standard" as the format for Medicare Part D benefit card. Any deviation from the NCPDP standard would cause unnecessary confusion for our pharmacists and lead to unnecessary delays in the delivery of medications and services to part D beneficiaries. CMS should approve any and all cards issued by plans to assure that they comply with the NCPDP standards.

A standard card for all pharmacy benefit payers would save our pharmacies time and effort; all necessary claims reimbursement information would be provided, and it would be provided in a widely-accepted format that is easy to read. Dealing with the administrative burdens created by inconsistent and confusing prescription benefit cards creates unnecessary barriers to our pharmacists providing care to their patients.

Section 423.124 – Special Rules for Access to Covered Part D Drugs at Out of Network Pharmacies

The proposed regulation requires that plans allow Medicare beneficiaries to obtain covered outpatient drugs at out of network pharmacies under certain conditions and establishes requirements for plans relating to how such drugs could be obtained at such pharmacies. This assumes that these pharmacies are neither preferred pharmacies nor non preferred pharmacies, and simply do not have a contract with the PDP or MA-PD to participate in that particular plan.

RITE AID is concerned that the requirements specified in the rule's background regarding out of network pharmacies are impractical and inconsistent with current industry practice. Plans traditionally do not establish certain "out of network" pharmacies. While this proposed rule establishes "preferred" and "non-preferred" networks, it does not appear to be the intent of this rule to have the plans contract with select out of network pharmacies. Indeed, the very definition of out of network pharmacies in the rule indicates that the plan does not have a contract with a PDP or MA-PD sponsor. Therefore, any pharmacy not under contract in the network is an out of network pharmacy.

If a beneficiary has to use an out of network pharmacy to obtain covered outpatient drugs, then all the out of network pharmacy can do is fill the prescription for the beneficiary and charge the beneficiary the pharmacy's full usual and customary price for the medication. The pharmacy can provide the beneficiary with a receipt for the prescription, and the beneficiary will then have to reconcile with the plan any copayments, plan allowances, formulary status issues and application of the amount paid to the out of pocket maximums, after the prescription is filled. The very fact that the pharmacy is not in the plan's network means that the pharmacy cannot determine many important plan components that are necessary to fill the prescription if the beneficiary was enrolled in the plan.

For example, out of network pharmacies cannot be in a position to determine that the prescription was or was not medically necessary, or an emergency. A beneficiary filling a 90-day prescription for a needed blood pressure medication may be an emergency, but depending on the circumstances would not need a full 90-day supply from the pharmacy. A limited supply

would probably suffice. However, the pharmacy would have to retain the original prescription (even if the beneficiary only wanted a limited supply) and the beneficiary would have to obtain another prescription from the physician or have the physician contact the regular network pharmacy that the beneficiary uses.

Plans and beneficiaries should not be allowed to seek any cash or payment recovery from the pharmacy subsequent to providing the prescription if the prescription was not urgently needed or the pharmacist filled the prescription for a quantity greater than allowed by the plan, or the drug was not on formulary. CMS may want to consider establishing a consistent emergency supply definition and consistent procedures from plan to plan. For example, Medicaid allows for the dispensing of a 72-hour supply of medication if prior authorization cannot be obtained within 24 hours. In some cases, the out of network pharmacy may be provided a short-term emergency supply, while in other cases, it might be provided a longer-term supply.

Pharmacies that are not under contract to a plan cannot know a beneficiary's formulary status through the electronic claims processing system. That is because the pharmacy cannot access the important information necessary to adjudicate the claim real time because it does not have a contract with that pharmacy to access that information. Therefore, pharmacies cannot determine the formulary status of a particular prescribed drug (i.e. tier, on formulary, etc.) unless the pharmacy has access to the online system.

The proposed regulation recognizes the impracticality of the pharmacy enforcing any formulary provision for a prescription filled at an out of network pharmacy in its section by waiving the public disclosure relating to pharmaceutical prices (i.e. lower cost generics) for these pharmacies. The explanation says that such a requirement is impractical because "by definition, out of network pharmacies are not under contract with a PDP sponsor or an MA organization, complying with such disclosure would be impracticable."

Establishment of plan allowance amounts and copays due from a beneficiary for providing a Part D covered drug at an out of network pharmacy must be reconciled between the beneficiary and the plan after the prescription has been filled. We are unsure whether the plan allowance will be the amount that a plan reimburses a preferred pharmacy or a non preferred pharmacy, and how CMS will require plans to calculate that amount. While this should not affect pharmacies, we simply point out that such a definition is unclear.

Finally, pharmacies do not set their "usual and customary" prices based on the potential that a Medicare beneficiary will seek to have a prescription filled at an out of network pharmacy. "Usual and customary prices" are set by the private marketplace consistent with the highly competitive nature of the retail pharmacy marketplace. Pharmacies do not differentiate these prices based on the type of cash-paying customers.

Beneficiaries should be told up front that they should only use out of network pharmacies in true emergencies. That is because out of network pharmacies will have a difficult time providing prescription services if they don't have information regarding the plan's allowance, or information necessary to perform DUR. Pharmacies will not know if the person is even covered. Pharmacies will not know what the emergency access Rx limits are if they differ by

plan, and the beneficiary cannot be relied upon to tell them. Thus, uniform emergency access standards may have to be developed to reduce the confusion to the pharmacist and the beneficiary from inconsistent and conflicting out of network standards.

Plans should also not use the out of network requirements to force beneficiaries that live in another service area part of the year (i.e. snow birds) to use mail order. The proposed rule indicates that plans can "require the use of mail order pharmacies as appropriate for extended out of network travel." This could mean that beneficiaries that live in another location for part of the year could be forced to obtain their maintenance medications through the mail, even though the statute requires that beneficiaries be able to obtain such quantities from retail pharmacies. Plans must make adequate accommodations for enrollees to obtain such quantities from out of network retail pharmacies in the same manner that they make such quantities available through mail order pharmacies.

Section 423.128 – Dissemination of Plan Information

Content of Plan Description: As stated in a previous section, RITE AID generally agrees with the proposed rules requirement regarding the type of information that beneficiaries have to receive both from CMS and individual Part D plans. However, we believe that it is important for beneficiaries to know the network status of all the pharmacies in the particular plans that they are considering so they can make an informed determination regarding which plan they may want to choose. The network status of pharmacies can be very confusing to beneficiaries under the scheme that CMS has constructed. Pharmacies can be considered preferred, non-preferred or out of network. Plans must specify the status of specific pharmacy locations, not just note whether a particular pharmacy chain is in the network. In addition, beneficiaries should know the exact cost sharing amounts involved with using particular pharmacies in the network. Material should be carefully reviewed by CMS to assure that plan designs do not steer beneficiaries to mail order pharmacies.

Beneficiaries should also be told up front in both the CMS and plan educational materials that they have the option of using a retail pharmacy in the network to obtain a maintenance supply of their medication from a network or non-network pharmacy. Plan educational materials should be reviewed carefully by CMS to assure that plans do not say or imply that maintenance medication can only be obtained through mail order. This requirement should extend to CMS education materials as well as plan specific educational materials. Beneficiaries should also be told that appeals and grievances must be resolved through the plan, and that the pharmacist is not responsible for making decisions regarding formulary coverage.

Provision of Specific Information: We agree that PDP and MA-PD plans should maintain 7-day a week, 24 hour a day support centers for beneficiaries. A separate technical support center should also be maintained for pharmacies that should operate all the time. Many pharmacies are now open 24 hours a day. Pharmacies that may need to contact a plan for information necessary to fill a prescription should have a separate support center and adequate phone lines for pharmacists to call.

Claims Information: Section 423.128(e)(1)(5) of the proposed regulation require that Part D plans provide monthly summary statements to beneficiaries require an explanation of their prescription drug benefits. It is suggested that, with regard to such statements "if technically feasible, a PDP sponsor or MA organization could also provide the notice of benefits at the point of sale…". This could imply that such a statement could be provided by the pharmacist. Many pharmacies have the technological capability to provide summary statements to patients for prescription usage for such purposes as filing income taxes.

The scope, nature and type of information envisioned being provided under this provision, however, would be far beyond what our pharmacies would have on file, and would be technologically infeasible at this time. We would have to purchase a separate printer to produce these forms, assuming their systems were even capable of receiving information from plans that would be used to provide this information. In addition, it would add another significant administrative task for our pharmacies for millions of beneficiaries each year. This summary statement should be sent by the plan to the beneficiary by mail or be sent electronically to them if the beneficiary has that capability.

Section 423.132 - Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

This section requires that plans require our pharmacists dispensing a covered Part D drug to inform a plan enrollee of any differential between the price of the drug and the price of the lowest-price generic drug available at that pharmacy, unless the particular Part D drug being purchased is the lowest price version of that drug available at that pharmacy. In almost cases, our pharmacist will be dispensing the product that is stocked in the pharmacy when a prescription is written for a multiple source drug.

Therefore, in reality, this basically only requires our pharmacist to tell the patient if they are dispensing a higher cost version of a generic that they stock in the pharmacy rather than the lowest cost version that they stock. The use of the term "lowest" can imply that three or more versions of generics are available at a pharmacy. This is rarely the case. We only stock one supplier of each generic drug dosage form and strength, making that product the defacto "lowest" cost generic at each pharmacy.

There may be cases where the product that our pharmacist is dispensing is an innovator multiple source drug whose price is equal to or less than the generic competitors. We would urge that the regulation only require that our pharmacist inform the patient of the price difference if they are dispensing a higher cost version of a multiple source drug that is available at that pharmacy. In many cases, these off-patent innovator brands – which are part of the multiple sources of supply – are less costly than their generic counterparts. Without making this technical correction, these drugs may not be considered by some plans to be "generics", triggering the requirement that the pharmacist inform the beneficiary that the drug they are dispensing is not the lowest cost "generic", but is the lowest cost version of that "multiple source drug" stocked at that pharmacy.

Retail pharmacies are required to provide this information at the point of sale. Mail order pharmacies are only required to inform Medicare beneficiaries at the time of delivery of the

drug, after the prescription is filled. The Secretary can waive the requirements relating to the timing of the notice in circumstances specified by the Secretary. We believe that this should be interpreted and implemented so that the same requirements related to timing of the notice are placed on mail order pharmacy as are placed on retail pharmacy.

Mail order pharmacies should be required to contact the Medicare beneficiary before the prescription is filled and delivered to the beneficiary's home to indicate that a generic is available. This is especially important since mail order pharmacies have lower generic dispensing rates than retail pharmacies, including for maintenance medications.

Section 423.153 Cost and Utilization Management, quality assurance, medication therapy management, and programs to control fraud, waste, and abuse Control and Quality Improvement Programs

Section 423.153(b) - Cost Effective Drug Utilization Management

RITE AID supports the use of programs to encourage the use of the most cost-effective medications. Our pharmacists can be critical to making these programs work, since they are the health professionals that are interacting directly with the beneficiary and the physician regarding their prescription.

One such item proposed in the regulation is establishing differential dispensing fees for generic drugs or multiple source drugs. We believe that such a differential, combined with a reduction or elimination in cost sharing for generics, could help increase the use of generics. This should not be interpreted as our supporting higher generic dispensing fees and lower brand name drug dispensing fees, but rather, an additional bonus payment for pharmacists to increase generic substitution and dispensing rates. Our pharmacies have fixed cost to dispense prescriptions whether brand or generic. In fact, because of the higher carrying cost for more expensive brands, it costs us more to stock and dispense a brand name drug.

However, encouraging the use of generics also requires that plans use reasonable programs to reimburse us for generic drug products. CMS should assure that plans are not using aggressive Maximum Allowable Cost (MAC) programs to reimburse for generics. While these programs are commonly used in third party programs, they should be developed so that there are appropriate incentives to dispense these drugs. Also, these MAC lists should be regularly updated to keep pace with rapidly-changing generic drug pricing and market conditions. CMS should actively monitor whether plans are using different generic reimbursement mechanisms for their retail pharmacies versus their mail order facilities. That is, plans often reimburse themselves more for the same quantity of generic dispensed through their own mail order facilities than they do to retail pharmacies.

We also believe that the legislative history of the law precludes plans from using differential cost sharing to encourage beneficiaries to use mail order as compared to retail pharmacies. Evidence suggests that encouraging individuals to use mail order really offers little if no savings, and actually encourage wastage of higher-priced brand name drugs. While plans can use different cost sharing to encourage the use of preferred pharmacies versus non preferred

pharmacies, the legislative history described above makes clear that Congress did not intend plans to steer beneficiaries to mail order. Evidence suggests that "conflicts of interest" exist when plans own and operate their own mail order pharmacies. This conflict ultimately results in higher costs to beneficiaries and ultimately to Medicare.

Section 423.153(b) - Quality Assurance Programs

The preamble to the regulation engages in an extensive discussion about quality assurance programs that plans should have in place. The discussion asks whether OBRA 90 standards adopted for the delivery of pharmacy services for Medicaid beneficiaries should be considered the industry standard that should be applied to the Medicare population. Medicaid consists of a program of prospective utilization review (ProDUR), retrospective review (RetroDUR), and educational interventions for prescribers and physicians.

In terms of ProDUR, Rite Aid Corporation has a system in place to help assure the quality of prescription drug dispensing which is applied before the prescription is provided. This system detects potential medication related problems such as over utilization and under utilization of prescription drugs, therapeutic duplications, and inappropriate drug use.

Included in these ProDUR standards is an OBRA-90 mandated requirement that pharmacists offer to counsel Medicaid beneficiaries on their prescription use. These requirements have been adopted by almost all Boards of Pharmacy as part of their practice acts, and have become the standard for the practice of pharmacy. We believe that requirements relating to counseling Medicare beneficiaries on their prescription medications should be consistent with the state's pharmacy practice act. All states address the issue of how pharmacists are to offer to counsel individuals on their prescription use. State practice acts specify whether the offer to counsel must be made on refills as well as new prescriptions, who is to make the offer, and method of documentation. We do not believe that Federal law should create a new standard for pharmacy practice, which has traditionally and appropriately been regulated by state boards of pharmacy.

Likewise, quality assurance programs for pharmacies are required by many states. State practice acts and regulations specify the legal protections afforded the programs, the types of policies and procedures required, and the level of flexibility the pharmacies have in developing their own quality assurance programs.

RITE AID is supportive of quality assurance programs and we believe that focusing on lessons learned from quality assurance programs will benefit both the beneficiary and pharmacy practice. We suggest, however, that rather than requiring PDPs to develop their own quality assurance program that providers would have to utilize (which may conflict with a program they are currently using for all their patients) that PDPs have systems and measures in place to ensure providers have a quality assurance program in place, and are complying with the program.

It is noted in the preamble that, in the future, quality reporting may be required that includes error rates which would be used for enrollees to compare and choose individual plans. We feel strongly that this would be counter productive to an effective quality assurance program. The

Institute of Medicine (IOM) Report *To Err is Human: Building a Safer Health System* released in 1999 recognized that for any quality improvement program to be effective, those who report errors must feel safe to report in a confidential, non-punitive environment with all of the necessary legal protections.

The use of bar codes on prescription products can help improve the quality of pharmacy dispensing and overall pharmacy operations. Bar codes can help identify potential medication related issues before the product is dispensed, such as whether the wrong drug or wrong dose is being dispensed, potential drug interactions or therapeutic duplications, or other issues.

We urge that Medicare have a more in depth discussion with stakeholders about a potential medication error reduction and reporting program. While we are clearly supportive of programs that would reduce such errors, we need to be sure about what constitutes such an error, and how such errors would be reported to plans and how they would be reported to beneficiaries.

Most plans have policies regarding early refill of medication. Such policies should be implemented through the online real-time claims adjudication system in which the plan would indicate that a refill has been obtained too early. Beneficiaries should be fully informed of their policy and our pharmacists should be able to obtain this information through the online system.

Section 423.153(d) - Medication Therapy Management

Section 423.153(d) requires PDP and MA-PD plans to include programs of medication therapy management in their plan offerings. RITE AID supports the inclusion of MTM services in the Part D plans, but we are concerned with CMS's interpretation of the law through the proposed rule. Our comments relating to specific components of the proposed rule are detailed below.

Unlike DUR programs, which tend to be focused on "populations', we believe that MTM programs are supposed to be focused on improving medication use in specific individuals. We believe that MTM programs should be structured with the clear goal of improving quality, reducing overall health care costs, and demonstrating improved health care and quality outcomes for specific beneficiaries by optimizing their use of prescription medications. Our pharmacists are extremely well qualified to provide MTM services and Rite Aid Corporation has developed these types of programs to a significant extent. The inclusion of MTM services under Medicare Part D will accelerate the development of this capability.

Medicare enrollees are more likely than other population groups to have multiple chronic illnesses that require treatment from multiple physicians. According to CMS data, 20 percent of Medicare beneficiaries have five or more chronic conditions. The average Medicare beneficiary sees seven different physicians and fills upwards of 20 prescriptions per year. Problems relating to care fragmentation and insufficient provider communication often lead to avoidable complications for Medicare beneficiaries. Medication therapy management represents a positive step in ensuring that Medicare beneficiaries are placed on optimal drug therapy regimens and experience better health outcomes.

Program Structure and Incentives: Both PDPs and MA-PDs are required to provide medication therapy management services under Part D. We support the inclusion of MTM on both the managed care and fee-for-service side of the Medicare program.

However, we would point out that financial incentives for the two types of plans, are likely to be different as they relate to MTM programs. MA-PDs are at risk for all of the health care utilization of their enrollees (including pharmacy, hospital, and physician services). PDPs, on the other hand, will only be placed at risk for prescription drug expenditures. This may give these plans a financial disincentive to promote comprehensive MTM programs. Based on experience from other disease management programs for the chronically ill, for example in state Medicaid programs, MTM services are likely to increase drug utilization while decreasing the utilization of hospital and emergency room services. For MA-PDs which are at risk for each of these service types, higher costs on the prescription drug side could be seen as an investment in lower health care utilization overall. However, for PDPs, MTM may represent only an added administrative expense that actually decreases their ability to manage their risk.

For a PDP that is seeking to lower its administrative costs and increase its ability to manage its risk, there are currently a number of potential loopholes in the proposed rule that would allow them to narrow the scope of the MTM program, especially with regard to program services, providers, and provider payments. CMS should be aware of these loopholes, and provide enough guidance in the final rules to prevent these potential service reductions.

CMS should be aware of these conflicting incentives and should ensure that the MTM programs that are offered to beneficiaries, both on the managed care and the fee-for-service side, are as comprehensive as they need to be in order to optimize medication therapy. This is especially true since, at least historically, sicker beneficiaries with higher numbers of chronic conditions have often chosen to remain in the fee-for-service program. While this trend may shift in the future, we still remain somewhat concerned about how PDPs serving the fee-for-service side of the program might choose to structure their MTM programs.

Under Part D, PDPs can seek accreditation from a national accreditation organization, and part of that process will include a review of the plans' MTM programs. While we are aware that CMS would prefer to allow fairly broad flexibility to the private plans in determining the structure of these programs, we would encourage CMS to specify in the final rule some of the specific requirements for meeting accreditation standards, including the primary use of community pharmacists in performing MTM services. Plans should also be required to demonstrate that they are offering a specific package of MTM services, and indicate how they will pay providers, including pharmacists, for these services.

MTM Program Development: As mentioned above, CMS has expressed a clear preference to allow the private sector prescription drug plans to design and develop their own MTM programs and allow competition in the private market help determine the structure of these programs. The proposed rule also indicates that there are likely to be a broad range of services – ranging from simple to complex – that will be offered to enrollees, as well as a range of providers who may supply MTM services. We believe it is essential to give community pharmacists and physicians a significant role in the design of these programs. Both the

Medicare law and the proposed rule specify that pharmacists and physicians will be given a role in helping to design the MTM programs, both for MA-PDs and PDPs.

We support this provision and would emphasize the importance of including practicing *community* pharmacy providers, rather than those that are employed by the private plans, in assisting with this effort. We also believe that executives from chain corporate headquarters (i.e., pharmacy practice, pharmacy operations), should be involved in the design and implementation of these programs since the programs will have to be integrated into the existing workflow of the pharmacy and the pharmacist. We believe that involving Pharmacy and Therapeutics (P+T) committees (whose members are free of conflicts of interest) in helping to structure these programs could help assure that they are suited to meet the needs of Medicare beneficiaries.

MTM Services: We agree with CMS' conclusion in the proposed rule that the MTM services offered to beneficiaries should vary depending on the needs of the individual. Some cases are more complex than others, and there will be varying need for medication therapy management services. We also agree that enrollees should not be charged copays for the services offered through MTMs. Imposition of copays could likely discourage the use of MTM services. We do believe, however, that PDP and MA-PD plans should be required to offer a basic package of services which may be provided to beneficiary at the pharmacist's discretion (or within a certain approved protocol) and billed by the pharmacy to the plan.

That is because we are concerned that unlike the case with the "standard drug benefit" defined under the statute (which may be an actuarially- equivalent offering), there will be significant variability among plans – even within the same region – regarding the nature and scope of MTM services that might be provided. Given that these services remain undefined in the minds of many beneficiaries, it will be important to define a basic package of services that beneficiaries that are eligible and enrolled in these programs might expect from the plan. While the competitive marketplace might be able to decide this, it is unlikely that a Medicare beneficiary will be able to distinguish among the types of services that might be offered by a plan.

To accomplish this, pharmacy providers recently gathered to discuss what services should be included under the rubric of medication therapy management. These providers generated a consensus document that provides a comprehensive list of services. We believe that private plans offering MTM programs under Medicare Part D should draw from the core set of MTM services included in that consensus document.

For example, we believe that Medicare beneficiaries newly-enrolled in the MTM program should be provided an initial face-to-face consultation by the pharmacy provider in the community retail pharmacy setting to assess their medication therapy management needs. This activity, which would be of appropriate length to achieve its objective, would involve an assessment of the prescription and non-prescription medications being taken by the Medicare beneficiary (medication history review). The pharmacist should have available information on all the medications that the beneficiary is taking, including those that might have been provided

by mail order pharmacies. The pharmacist would also assess the ability of the Medicare beneficiary to coordinate the appropriate use of their medications.

Next, the pharmacist would develop a treatment plan which would include:

- Avoiding adverse drug reactions and duplicate therapy with other prescription and non-prescription medications;
- Helping the beneficiary remember to take all the current prescription and non-prescription medications, and interacting with the beneficiary's physician to discuss modifying various treatment options, including use of generic drugs and long-action (one/day) dosage forms, if needed;
- Developing interventions to help beneficiaries take their medication appropriately, such as:
    - Special medication treatment cards or reminders;
    - Special packaging, such as blister cards which include the beneficiary's daily medication dosages;
    - Written refill reminders or telephone calls to the beneficiary to determine if they have taken their medications.

The MTM program should allow beneficiaries to have at least monthly consultations with the pharmacy provider to provide continuity of care, positive reinforcement, and an assessment of the interventions used. The need for monthly consultations would be made consistent with the assessment of the pharmacist of the progress being made by the beneficiary in managing their medications.

The purpose of these consultations is to assess the impact of the MTM program on optimizing therapeutic outcomes, and to reduce the risk of adverse events in the beneficiary. This will also allow the pharmacist to assess the educational activities and interventions being provided to the beneficiary under the MTM program, and make appropriate modifications.

After these basic services are provided, then a next level of services can be provided for individuals that have more complex conditions or require a different level of services. Thus, we would support a "step" approach to MTM services in the final regulation that would specify how plans would have to implement these programs.

Defining MTM Eligibility Criteria: Beneficiaries eligible for MTM services could be identified either by the plan itself or the beneficiary's pharmacy provider. We agree with the proposed rule, which states that MTM services should be targeted to specific beneficiaries, rather than population groups. Under MMA, eligibility for MTM services is to be based on three criteria. The Medicare enrollee must (1) have multiple chronic illnesses; (2) be taking multiple covered Part D drugs; and (3) have high estimated annual drug costs.

CMS has indicated that it would prefer to have the private drug plans set their own eligibility criteria to the greatest extent possible, rather than establishing federal guidelines. However, CMS has asked for comment on further defining these criteria. We believe that determination of the need for these services cannot solely be based on objective criteria; there are also

subjective criteria that need to be considered. For example, we believe that patients that have two or more chronic medical conditions (i.e. diabetes, CHF, hypertension), taking two or more prescription medications (i.e. antihypertensives, antidiabetic medications, cholesterol-lowering medications), should be identified as potential candidates for this MTM program. Some of these individuals may have the capability of managing their drug therapy, and may not be in need of MTM services.

For example, we do not necessarily believe, however, that a patient taking a medication for chronic glaucoma as well as chronic medication for a toe nail fungal infection would necessarily meet the criteria on a subjective basis, even though they might meet it on an objective basis. We also believe that the beneficiary's full range of drug therapies should be considered – not just covered Part D drugs – when considering eligibility for the MTM program. For example, a beneficiary may be taking several non covered Part D drugs, such as benzodiazepines or barbiturates, and some Part B drugs, such as immunosuppressives or oral cancer drugs. To ignore the other drugs the beneficiary might be taking when determining eligibility for MTM could exclude certain beneficiaries from the program who would clearly benefit from MTM services.

However, we believe that criteria should require plans to, working with the pharmacist, assess the need for MTM for plan enrollees that are taking two or more drugs for two or more chronic conditions. We also suggest that, instead of setting a specific targeted expenditure threshold to identify beneficiaries that are candidates for MTM, that the plans analyze beneficiaries in certain top percentile ranges of drug spending for the plan (i.e., top 10 %, top 20%). In general, the highest drug spenders will likely be taking the most drugs, making them the most likely candidates for MTM.

Using a percentage amount, rather than a specific dollar amount, would reduce the influence of regional variation in drug prices and drug use patterns in determining which individuals should be candidates for MTM. We also believe that plans should consider that some beneficiaries could be taking multiple medications, all (or many of which) are generic, potentially disqualifying them from the spending threshold, even though they may need MTM. Moreover, if an individual's drug spending falls below a threshold (or percentage), it should not be assumed that they can be eliminated them from the program. That is because the services being provided through the MTM program may be the only reason that they are taking their medications appropriately and reducing the need for other medications.

We believe that pharmacists can play a role in identifying which patients should be receiving MTM services. This input from pharmacists could be gathered at either the program development stage, or over time as pharmacists encounter Medicare patients. Given that medication therapy management is still fairly new, there will probably be a learning curve over time regarding which Medicare beneficiaries should be receiving MTM services. Plans might want to develop a system to assure that pharmacists can contact plans to encourage enrollment of certain Medicare beneficiaries in these MTM programs, such as through a "prior approval" process before the pharmacist could provide these MTM services. CMS should structure the program so that the expertise of community pharmacists is taken into account as this experience is gained. If a pharmacist's recommendation is not taken regarding enrollment of a

beneficiary in a MTM program, the pharmacist should receive a written response from the plan describing the reasons why that beneficiary was not accepted into the program.

We believe that once beneficiaries are enrolled in the MTM program, whether such enrollment is initiated by the plan, or through a joint agreement between the plan and the pharmacy, then the beneficiary should receive a more complete description from the plan about the nature and scope of the MTM services that should be provided. While we believe that an explanation of these services should be included in the marketing and plan description materials that are provided to beneficiaries before and after enrollment, a more complete description of the program should be provided to the beneficiary upon MTM enrollment. This would include the purpose of the program (i.e., improving their health); the services that the beneficiary should expect under the program (i.e. initial consultation with the pharmacist, periodic meetings with the pharmacist to review progress); the fact that the beneficiary can obtain their MTM services from any pharmacy in the network – preferred or non preferred; and, that there are no copayments for the services. We encourage CMS to develop and test a model form that plans would have to distribute to beneficiaries enrolled in MTM programs.

Eligible Providers Under MTM: More than 85 percent of all outpatient prescriptions are dispensed in community retail pharmacy settings, and we believe that MTM services should be provided primarily in these settings. Pharmacists working in these settings are often the only health professionals that know that the beneficiary is taking multiple medications, often times from multiple physicians, or is having trouble managing the task of taking medications appropriately.

Our pharmacists are highly-trained health care professionals and are experts in managing the medication needs of patients, including Medicare beneficiaries. Our pharmacists are trained in pharmacology, therapeutics, disease management, and clinical assessment, and have either five or six years of professional training. They are licensed by the state boards of pharmacy in the states in which they practice. As such, these professionals are appropriately trained and qualified to provide MTM services. For all practical purposes, the lawful defined "scope of practice" for a health professional should determine the extent to which they are eligible to participate as providers in this program. Health professionals that are not trained as experts in medication therapy management or do not have this activity as part of their scope of practice should be precluded from providing services under this program.

In the proposed rule, CMS writes that MMA "specifically states that a pharmacist may furnish MTM services. While we believe that pharmacists will be the primary providers of these services, MTM services could also include other qualified health care professionals as providers of services." We agree that pharmacists should be the primary provider of these services and that there may be cases where it is appropriate for other qualified health care professionals to perform MTM services. The type of provider most appropriate to provide these services should be based on the complexity of the patient's condition. Because MTMs will be directed to patients who, by definition, have multiple chronic illnesses and are taking multiple different drugs, the vast majority of MTM participants will be complex cases. Given this degree of complexity, we believe that community pharmacists are uniquely qualified to perform the majority of medication therapy management services that will be needed.

We would also emphasize the importance of having face-to-face patient encounters, rather than relying on phone-based services. The proposed rule makes reference to programs that rely on "impersonal telephone services" and we agree that developing and maintaining on-going beneficiary-provider relationships is key to the success of the MTMs. We have established or are establishing special consultation areas in our pharmacies where we can provide these MTM services. This will help provide a comfortable and professional environment for our pharmacists to provide these important face-to-face services.

Provider Payments Under MTM: Both the MMA legislation and the proposed rule indicate that private plans offering prescription drug coverage should take into account the time and resources required to offer MTM services in determining payment rates for those services. We would add that since these costs increase over time, payment rates should be updated frequently to reflect price changes. We also support CMS' conclusion that payment for MTM services should be separate from the payment of a dispensing fee.

Because medication therapy management is a relatively new service, pharmacies will need some time to gather experience and information about resource utilization in providing these services. We prefer to be reimbursed on an hourly basis (or fraction thereof), rather than a "per member per month" (PMPM) basis, at least initially. The hourly rate will allow payments to vary along with the complexity of the services offered. Once more experience is gained with the program, we may consider offering a PMPM rate.

In addition, we support the development of a standardized billing process for MTM services. Billing for these services should occur through the same online, real time electronic process that is used to provide prescription services. We encourage CMS to include in the final rule a provision that would incorporate this standardized billing process.

The Pharmacist Services Technical Advisory Coalition (PSTAC) has created specific CPT billing codes for MTM services that will be reviewed by the American Medical Association (AMA) for inclusion in its Current Procedural Terminology (CPT) book. These codes could be used by pharmacies to bill for MTM services because they take into account the "time and resources" expended by pharmacists to provide MTM services. RITE AID is interested in learning what codes CMS will require for the billing of pharmacy professional services. RITE AID is also interested in learning if CMS will require submission of MTM payment claims, including the appropriate CPT codes, in the HIPAA 837 batch Health Care Claim or if it plans to allow community pharmacies to submit payment claims like it does to virtually all other third party payors, in the real-time HIPAA 5.1 Pharmacy Payment Claim Standard.

We support CMS's requirement that PDPs and MA-PDs disclose to CMS the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTM services. These terms should be included in the standard contract that CMS suggests should be developed to anchor the negotiations betweens plans and pharmacies. However, we have some concerns about CMS' preliminary decision that it will not adjudicate any specific disputes between PDP sponsors or MA organizations and pharmacists or other providers regarding the

specific fees due for MTMP services. We believe that CMS should provide some mechanism by which such disputes can be resolved.

MTM Outcomes Assessment: Our pharmacies can provide information to the PDP or MA-PD sponsors that will help assess outcomes from MTM programs. However, the program should contain provisions for the PDP and MA-PD plans to provide relevant information to our pharmacies about the impact of MTM services on clinical outcomes for the beneficiary. To the extent possible, the impact of the MTM program should be assessed against changes or improvements in clinical outcomes, economic impact, and quality of life improvements for the beneficiary. Assessment of cost outcomes should reflect total health care spending, including spending under Medicare Parts A and B, and not just drug spending alone.

Coordinating MTM and CCI: As CMS indicates in the proposed rule, there may be some overlap between the Chronic Care Improvement (CCI) program and MTM program. CMS goal is to avoid duplication in the delivery of MTM services, which will likely be a component of the CCI program. The overlap is mitigated by the fact that CCI only applies to about 300,000 fee-for-service Medicare enrollees, and applies to only a limited number of conditions, primarily congestive heart failure and complex diabetes. The CCI program will begin sooner than the MTM program, and the CCI program is likely to arrange for the delivery of covered Part D medications to CCI enrollees. This makes sense given that medications are critical to the treatment of the CCI program targeted conditions.

If the CCI program is in fact providing medications as part of its program, then one question that will have to be answered is what happens to beneficiaries when Part D becomes available in 2006. If CCI enrollees are not receiving medications through the CCI program, then they will likely enroll in Part D when it becomes available. CMS should be able to share with Part D plans those individuals enrolled in the CCI program so they can identify individuals enrolled in both programs. Part D plans should work with the CCI contractors to determine the extent to which their CCI programs are already providing the MTM services that would be offered by that Part D plan.

We believe that our pharmacists should be kept informed when a Medicare beneficiary is also receiving services through the CCI program. This will assist our pharmacists in providing an appropriate level of services for their patients.

Model MTM Programs: In the proposed rule, CMS requested information on current MTM best practices. As mentioned above, medication therapy management is a new area and there is limited experience with it to date. However, one pharmacy-based program that provides MTM services for the chronically ill is in Ashville, North Carolina. The program provides community-based pharmaceutical care services for patients with diabetes enrolled in self-insured employer health plans. A study published in the Journal of the American Pharmaceutical Association in March/April 2003 found that patients receiving those services showed significant improvement in A1c values and lipid levels, as well as a decrease in direct medical costs of $1,200 per enrollee on average.

The provision of a community retail pharmacy-based medication therapy management program for select Medicare beneficiaries, as required under the new Medicare Part D drug benefit, will enhance the use of medications in this population, reduce the chance for adverse reactions, and improve overall health and quality of life. Rite Aid pharmacists have a key role in identifying individual beneficiaries who are candidates for this program and developing specific interventions that will help them manage their medications. Our pharmacists are also in a key position to assess the impact of these beneficiary interventions and make necessary modifications.

Section 423.153(e) – Program to Control Fraud and Abuse

Section 423.153(e) would require plans to implement programs to control fraud and abuse. RITE AID strongly supports this requirement. It is important for CMS to provide more details regarding the necessary components of an acceptable fraud and abuse program. Otherwise, any fraud and abuse program, no matter how lax, would appear to satisfy this requirement.

In particular, CMS should strictly limit the potential for fraud and abuse surrounding drug substitution programs, commonly referred to as "switch programs." CMS specifically requests comments on fraud and abuse issues surrounding switch programs. *See* 69 Fed. Reg. at 46670.

It is often entirely appropriate for a pharmacist to recommend that a patient take an alternative medication instead of the prescribed medication. For example, switching from a brand name drug to a generic drug may save the patient and the plan money. Similarly, switching from one drug product to another therapeutically equivalent product may reduce adverse reactions or provide other advantages (e.g., increased ease of use in switching from a pill to a liquid, or from a daily pill to a weekly pill). For these reasons, switch programs should not be eliminated.

But the potential for fraud and abuse associated with switch programs does make it important for CMS to limit switch programs operated by the PBMs that work for plans. PBM switch programs have raised many fraud and abuse concerns, and have resulted in a great deal of litigation.

One of the largest investigations into PBM switch programs lead the Attorneys General of twenty states and the federal government to file a complaint against Medco Health Solutions, Inc. ("Medco"), the nation's largest PBM, for alleged violations of various consumer protection and unfair trade practice statutes. The complaint claimed that Medco had a "conflicted interest" because it's drug switching programs were improperly influenced by its desire to receive rebates from drug manufacturers, not by a desire to save clients money. According to the complaint, Medco failed to pass on savings to patients or their health care plans, and failed to disclose to prescribers or patients that the proposed drug switches would increase rebate payments from drug manufacturers to Medco. Medco's drug switches also allegedly resulted in increased costs to health plans and patients, including additional costs for follow-up doctor visits and tests.

The complaint against Medco was settled in a Consent Order on April 26, 2004. RITE AID recommends that CMS require plans to implement fraud and abuse programs that are consistent with the Medco Consent Order.

The Consent Order carves out four specific instances in which Medco may not make drug switch solicitations to physicians and prescribers:

- The cost of the proposed drug exceeds that of the current drug;
- The current drug has generic equivalents, but the proposed drug does not have generic equivalents (except in situations in which the proposed drug is cheaper than all generic equivalents of the initially prescribed drug);
- The patent for the current drug expires within six months, or the proposed drug switch would have the effect of avoiding competition from future generic equivalents; and
- Within the past two years, a patient has either already switched a drug in the same therapeutic class in response to Medco's solicitations, or subsequently reversed such a switch.

Medco must disclose certain information to prescribers when it requests a drug switch. For example, Medco must disclose:

- The annual minimum or actual cost savings of the proposed drug switch, as well as the effect of the proposed drug switch on patients' co-payments;
- Whether and under what circumstances the patient's health plan will continue to cover the current drug;
- Whether Medco receives any payments from manufacturers for promoting drug switches; and
- Any material differences in side effects between the initial and the proposed drugs.

The Order expressly allows patients to reject the proposed drug switches by Medco. If the patient declines the proposed drug switch, the Order requires Medco to honor such requests and provide the initially prescribed drug. If switching drugs causes the patient to incur additional medical costs (e.g., costs associated with additional medical tests or physician visits), the Consent Order requires Medco to reimburse those costs.

The Consent Order also requires Medco to disclose important information to health plans, such as information regarding rebates received from drug manufacturers. Finally the Consent Order requires Medco to adopt the code of ethics of the American Pharmacists Association.

RITE AID recommends that the requirements of the Medco Consent Order should be incorporated into CMS's guidance regarding what constitutes an adequate fraud and abuse program. We encourage CMS to provide specific guidance for plans and their PBMs, in order to avoid future fraud and abuse problems.

CMS also requests comments on the possibility that "plans could develop and utilize methods such as data analysis, record audit of PBMs, pharmacies, physicians, and other providers, ... and methods used to consider and resolve disputes related to pharmacies, physicians', and other provider's dissatisfaction to ensure the integrity of all entities (government, beneficiary,

PDP sponsor, PBMs, pharmacies, physicians, and other providers)." 69 Fed. Reg. at 46670. We certainly agree that plan sponsors must guard against fraud, abuse and waste.

However, we are concerned that audits of our pharmacies may be misused to deny reimbursement that is properly due. Experience shows that PBMs sometimes abuse the audit process by conducting invalid "extrapolation" audits, and by hiring "bounty hunters" to deny valid pharmacy reimbursement claims.

"Extrapolation" audits involve auditing a sample of reimbursement claims and then extrapolating from that the results of that audit to deny reimbursement claims that were not in the sample. For example, a PBM may audit 100 of the claims submitted by a pharmacy for dispensing drug, allege that 5 of these claims are somehow improper, and then extrapolate from that audit to deny reimbursement for five percent of the tens of thousands of drugs dispensed by that pharmacy. PBMs have been known to abuse extrapolation audits by using samples that are too small, and by cherry picking particular types of claims to be included in the sample and then extrapolating the results to all of a pharmacy's claims. Therefore, we do not believe that extrapolation is an appropriate method for plans or their PBMs to audit pharmacies.

At the very least, CMS should require plans and their PBMs to avoid extrapolation audits based on samples that are too small or otherwise unrepresentative of all the reimbursement claims. In describing it's own procedures for audits of plans, CMS wrote that "the program audit process would require at least a statistically valid random sample of all Part D drug claims." Id. at 46687. If plans and PBMs are allowed to conduct extrapolation audits of pharmacies, these same standards should apply.

"Bounty hunters" are independent auditors that plans and their PBMs pay based on the number of pharmacy reimbursement claims they reject. These bounty hunters have an obvious conflict of interest, because they are not paid based on an objective analysis of reimbursement claims, they are paid based on denial of reimbursement claims. We ask CMS to warn plans and their PBMs against using bounty hunters to audit claims.

In general, we ask CMS to discourage plans and PBMs from abusing the audit process. In discussing its own audits of plans, CMS noted that "our goal would be to determine the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight." Id. at 46686. That same standard should be applied to plans' oversight of pharmacies.

Section 423.159 - Electronic Prescription Programs

RITE AID supports electronic prescribing because of the efficiencies it provides and its significant potential to improve patient health and reduce medication errors. RITE AID participates with SureScripts, an electronic prescription gateway for pharmacies.

Currently, of community pharmacies that have electronic prescription connectivity with prescribers, the vast majority use the NCPDP SCRIPT standard. We know of no competing standard, and we are not aware of any serious flaws in this standard. We believe that there is

adequate industry experience with this standard for CMS to move forward with notice and comment on using NCPDP SCRIPT as a foundation standard for communication between prescribers and community pharmacies for new prescriptions, prescription renewals, cancellations and changes. Also, we agree with NCVHS' recommendation that CMS conduct pilot tests of NCPDP SCRIPT with respect to fill status notification.[2] Fill status notification is a feature of SCRIPT that has not been used much in the industry.

With respect to CMS' request for additional steps to spur adoption of electronic prescribing, RITE AID believes that the proposed differential payments are a very appropriate incentive to increase the number of prescribers who engage in electronic prescribing. Unfortunately, most prescribers have been resistant to the adoption of this technology; it has been difficult to convince them of the benefits of investing time and money in changing their prescribing processes. Because of this challenge, RITE AID believes that the differential payments, at the MA organization's discretion, should take into consideration the cost to the prescriber of implementing an electronic prescribing program. The cost consideration should include both actual technology costs and costs that may be more difficult to quantify, such as training and temporary workflow disruption.

From a practical point of view, we urge CMS to move forward on NCVHS' recommendation of supporting NCPDP's efforts to create a guidance document to map the information on the NCPDP Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271.[3] One barrier to electronic prescribing is that prescribers have limited access to a patient's pharmacy benefit information. The NCPDP Pharmacy ID Card Standard provides information on a patient's pharmacy benefit. ASC X12N 270/271 is the HIPAA-named standard for prescribers to perform eligibility and benefits verification. Coordination between these two standards would better facilitate prescriber communication with payers about a patient's eligibility for pharmacy benefits and formulary information.

We agree with NCVHS' assessment that the deployment of electronic prescribing may involve workflow or policy issues that are outside the scope of standards but are important related issues.[4] One such workflow issue concerns the flow of patient medication and medical histories among prescribers, pharmacies and payers. In its recommendations, NCVHS states that "HHS should actively participate in support and rapid development of an NCPDP standard for medication history message for communication from a payer/PBM to a prescriber, using the RxHub protocol as a basis."[5] However, we disagree with NCVHS' recommendation on this point. To allow the pharmacist to assist the prescriber in drug product selection, any patient medical and prescription history from payers/PBMs should be routed through the pharmacy, and then to the prescriber. Pharmacies have information that patients provide specifically during patient counseling, such as potential allergies, sensitivities, and other adverse reactions. Only pharmacies have patient records for anything that the patient paid for out-of-pocket, such as prescriptions not covered by a payer, and a vast array of nonprescription items including

[2] Letter from John Lumpkin, Chairman, NCVHS, to Tommy G. Thompson, Secretary, Department of Health and Human Services (September 2, 2004), Page 6.
[3] Ibid. at 7-8.
[4] Ibid. at 5.
[5] Ibid. at 9.

herbal and nutritional supplements. A more complete patient medication history can be achieved by combining the records of the payer/PBM with that of the pharmacy.

Being the medication experts, pharmacist collaboration with prescribers reduces the likelihood of medical errors and adverse drug reactions. Reducing medical errors and adverse drug reactions are not only laudable goals, but also they are goals of the MMA. We believe it is only logical that electronic prescribing programs and pilots recognize the value of prescriber-pharmacist collaboration, encourage such collaboration, and do not create standards or procedures that would disrupt such collaboration.

In this age of managed care and shrinking reimbursements, harried prescribers are searching for efficiencies. Many have realized that pharmacists are able allies ready to assist. Any electronic prescribing technology should not reverse the trend of prescribers' relying more upon pharmacists. However, the RxHub model has pushed some of pharmacists' traditional duties upon already overworked prescribers, this includes such activities as drug utilization review (DUR) and checking for other medication-related concerns. We believe this model acts as a barrier to prescriber adoption of electronic prescribing. Because of this, we believe that CMS should reject NCVHS' recommendation to adopt and foster the RxHub model. The pharmacist may assist the prescriber in drug product selection, at the prescriber's request, based upon information available from the payer, and provided by the prescriber to the pharmacist at the prescriber's discretion. This can be accomplished if payer information related to patient medical and medication history is routed through the pharmacy.

Similar to the grants authorized for prescribers, CMS should spur more widespread adoption of electronic prescribing by providing financial incentives to pharmacies. Community pharmacies have been the early adopters of electronic prescribing technology. Not only have they had to pay for software modifications necessary to engage in electronic prescribing, but also they are the only entities that are required to pay an electronic prescribing transaction fee. Surely, these early adopters and payers of transaction fees should be rewarded for their efforts at least as much as the more resistant parties.

While we fully support the further adoption and expansion of electronic prescribing, we are concerned about the inherent potential for abuse that exists with this new technology. NCVHS has also expressed concern to HHS about this. Specifically, NCVHS has stated to HHS that electronic prescribing messages should be free from commercial bias.[6] We believe that CMS must incorporate additional standards in regulation to prevent commercial entities from exercising undue influence on prescribers' choices of medications and patients' choices of pharmacies. We recommend that CMS adopt a broad definition of commercial messaging to include any non-clinical messaging from any outside entity that would influence a prescriber's choice of medication or a patient's choice of pharmacy. For the sake of patient care, the professional, autonomous relationship between health care providers (prescribers, pharmacists) and patients must be preserved. CMS must prohibit commercial messaging at the point of prescribing. Only such prohibition could prevent outside parties from unduly influencing a prescriber's choice of medication or patient's choice of pharmacy.

[6] Ibid. at 14.

Moreover, the prohibition on commercial messaging must include messaging that might occur prior or post the actual medication selection by the prescriber. There should not be pre-emptive messaging that seeks to influence a prescriber's choice because of a prescriber's indication that he or she is interested in a particular type of drug or class of drugs. Similarly, there should not be messaging that seeks to make the prescriber's choice difficult to finalize or to otherwise change a choice already made.

Another way that outside entities may seek to unduly influence the prescribing process is by affecting the way information is presented to the prescriber. CMS should require that formulary information and pharmacy information be communicated in a single, neutral consolidated list. All medication information should be equally legible and readable; the same should apply to pharmacy choices. Prescribers should not be forced to click through numerous screens to access non-preferred or non-formulary medications, or to access traditional brick-and-mortar pharmacies.

Electronic prescribing offers much promise to health care providers and patients to improve the delivery of medication and medical care. However, we must be sure that regulation of electronic prescribing is carefully crafted to take full advantage of the benefits of electronic prescribing and that it is not used only to benefit the commercial interests of payers, PBMs and technology vendors.

Section 423.162 - Quality Improvement Organizations

QIO Activities Under Medicare Part D: Section 423.162 of the proposed rule under MMA would expand the work of Medicare Quality Improvement Organizations (QIOs) to include Parts C and D. QIOs have a long history of advancing care quality under Parts A and B of the program, and we support their involvement in providing quality assurance to Medicare drug beneficiaries under Part D.

Under the draft 8th Scope of Work, QIOs will be directed to offer quality improvement assistance to Medicare Advantage Drug Plans (MA-PDs), Prescription Drug Plan (PDP) sponsors, and medical providers (including physician practices and pharmacies). Quality improvement initiatives will center on improving disease-specific treatment (i.e., therapeutic monitoring), reducing adverse drug interactions, increasing generic use, addressing problems with polypharmacy, and improving medication therapy management (MTM) programs. These are all areas where opportunities for quality improvement will be exist for Medicare beneficiaries.

Interaction with Other Quality Improvement Initiatives: To some extent, the quality improvement work of the QIOs under Part D is likely to overlap with other activities initiated in the Medicare reform law relating to PDP and MA-PD requirements. These initiatives include drug use review (DUR) programs that will likely be established by plans, other internal quality assurance programs that might be established by pharmacy providers, and the required medication therapy management programs.

Drug use review programs generally include a program of prospective drug use review (ProDUR), retrospective drug use review (DUR), and educational interventions for physicians and pharmacists. These activities can be designed as population-based measures, or for individual patients. However, they are designed specifically to identify and correct some of the very issues tasked to the QIOs, such as reducing adverse reactions, therapeutic duplications, and polypharmacy, as well as increasing the cost effective use of drugs, such as increasing generic use.

Each MA-PD and PDP will be required to have in place a medication therapy management program which, in addition to increasing enrollee knowledge about, and adherence to, medication regimens, will be aimed at reducing adverse drug events and decreasing over- and under-utilization of recommended drug therapies. These programs will be directed to beneficiaries with multiple chronic illnesses, whereas the activities of the QIOs will be directed to all beneficiaries, but to some extent the work of the QIOs will likely mirror that of existing MTM programs.

We believe that the QIOs can serve an important function in assessing the MTM programs initiated by the drug plans and making recommendations for improvement. Comprehensive MTM programs, while potentially increasing drug spending among Medicare beneficiaries, will lower overall Medicare spending by reducing hospitalizations and emergency room use. We are particularly concerned, however, that the final regulation will not provide sufficient specificity to plans in how to develop and conduct their MTM programs. We believe that there is potential for wide variability in the nature and scope of services that might be offered by plans; a potential that each plan will have a different set of criteria regarding Medicare beneficiary eligibility for MTM services; and the potential that plans will restrict the ability of beneficiaries to use their local community pharmacy provider for these MTM services. QIOs can help plans assess their MTM programs and modify them if necessary to assure that these programs are truly meeting the needs of Medicare beneficiaries.

PDP sponsors serving the fee-for-service population may have a financial incentive to initiate more modest MTM programs, perhaps relying less on face-to-face interactions with pharmacists and more on impersonal phone conversations with nurses who have limited expertise regarding prescription medications. We believe the QIOs can help in providing oversight and ensuring that the MTM programs offered by plan sponsors are robust.

MMA will also launch the Voluntary Chronic Care Improvement Program (CCIP), which will focus on improving care processes for chronically ill enrollees in the Medicare fee-for-service program. During its 3-year pilot phase, CCIP will be limited to enrollees with one of three chronic illnesses and a total of 150,000-300,000 beneficiaries. However, given that this population includes many beneficiaries that are high-utilizers of health care services, a number of these enrollees may also be targeted by the QIO. QIOs can help assure appropriate coordination of activities between MTM programs and CCI programs.

CMS indicated in the proposed rule for Part D that it intends to issue guidance on how QIOs can coordinate their activities with the other quality related initiatives. We would advise CMS

to be aware of these potential overlaps and to clarify the relationships between these various quality improvement programs in the QIO Scope of Work.

Interactions with Multiple QIOs: Rite Aid Corporation serves broad regions of the country and operates in multiple states. We have already instituted quality improvement initiatives at the corporate level, and have implemented them system-wide. However, because each QIO will be serving only one state, we are likely to interact with multiple QIOs, each with different requirements in their quality improvement standards. This poses a significant administrative and operational challenge for us and our quality assurance programs. The same challenge exists for PDP plans, since they are likely to be serving regions that consist of multiple states.

We encourage CMS to consider this issue as it proceeds forward with more clearly defining the relationship between pharmacies, plans, and QIOs. Given that our quality assurance programs are developed at the corporate level it is important for QIOs to interact with our corporate personnel when providing feedback. It is even more important to establish greater standardization among the QIOs that will be serving the Part D populations. Rather than having each QIO interact with each pharmacy chain that operates in the state, an alternative approach would be to designate one or two QIOs with certain expertise in prescription drug quality improvement areas to work with pharmacies on quality-related initiatives.

QIO Data Review: In the proposed rule under Part D, CMS indicates that QIOs will be given access to pharmacy claims data resulting from transactions between pharmacies and the private drug plans. This data is to include a number of specific elements, including NDC, dose, days supply, ingredient cost, dispensing fee, pharmacy identifiers, and prescriber identifiers. CMS says that, "potentially" the information will be aggregated before it is distributed to QIOs.

We support the role of the QIO in reviewing these data and identifying areas where quality improvements can be made. We also support CMS' suggestion that it will aggregate the data prior to releasing it. It will be important to identify trends in treatment patterns that are not meeting recommended standards of care and we welcome the opportunity to identify some of those improvement areas, both for the prescribers and the pharmacies.

The rule states that CMS has been consulting with pharmacy benefit managers, managed care organizations, programs that have monitored drug utilization, and others who have utilized pharmacy claims data. We recommend that CMS also consult with pharmacy chain representatives to receive their views regarding the use of these data.

Issues Regarding Confidentiality: We support CMS' assertion that any information collected by the QIOs would be subject to confidentiality requirements in Part 480 of our regulations. Part 480 specifies that "each QIO must instruct its officers and employees and health care institutions participating in QIO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of QIO information." We also ask for clarification that the confidentiality provisions of 42 USCA Section 1320 c-9 would apply as well.

CMS has indicated that, for the purposes of these confidentiality requirements, PDPs and MA-PDs will fall within the definition of health care facilities. The rule does not specify how pharmacies under contract with these private plan sponsors will be regarded. We recommend that CMS incorporate into the final Part D rules language specifying that pharmacy providers under contract with PDPs and MA-PDs are also entitled to the same confidentiality provisions including the disclosure prohibitions of 42 USCA Section 1320c-9. In order to ensure that service improvements are made through the QIO process, our pharmacies should be shielded from potential legal actions resulting from possible information disclosure. In addition, we should receive assurances that any information disclosures that we make to the QIOs do not violate patient privacy rules contained under the Health Insurance Portability and Accountability Act of 1996.

Section 423.165 – Compliance Deemed on the Basis of Accreditation

RITE AID is concerned about the ability of Part D PDP plans to circumvent several of the access and quality assurance requirements in the program by seeking accreditation for its plans from an outside accredited entity. The actual proposed regulation, as well as the background, does not provide the reader with a good description of how such programs would operate.

Moreover, it is not clear (but could be assumed) that plans would not be required to obtain this accreditation to be able to contract as a Part D plan. It appears that the accreditation is voluntary. We strongly urge that CMS engage stakeholders in a more deliberate and detailed process of how such a process should work, and more fully delineate the criteria that would be used to "accredit" the accrediting organizations.

Submission of Bids and Monthly Beneficiary Premium - Determining Actuarial Valuation

This section describes the process by which CMS will review bids from Part D plans to determine whether they meet necessary standards to provide qualified prescription drug coverage. In reviewing the bids, RITE AID asks that CMS pay particular attention to reviewing the following sections of the plan's bid:

*Pharmacy Networks***:** The plan should submit complete information to indicate that all the pharmacies in its network are currently under contract with the PDP and the pharmacy has positively indicated that it intends to participate in the Part D plan's network. CMS should not rely on plan attestations, but should review actual signed contracts from pharmacies to indicate that a pharmacy has agreed to participate in a plan's network.

To prevent discrimination against Medicare beneficiaries in fairly choosing a pharmacy provider, we believe that CMS should only approve those pharmacy networks whose *preferred* networks meet the TriCare access standards in each state in each region that the plan operates. That is, CMS should give preference to plan designs that include more preferred pharmacies in their networks. This is, in our view, the intent of the MMA in how plans should be structuring their pharmacy networks.

CMS should examine the number of pharmacies in the plan's preferred network in relation to the number of total pharmacies in the network, and then determine the resulting net beneficiary access to preferred pharmacies by applying the TriCare access standards. For example, if beneficiaries in certain urban areas in the region are within 3 miles of a network pharmacy (because of the ability to average the 2 mile urban standard across all urban areas), but the average distance to a preferred pharmacy is really 5 or 6 miles, this would appear to be discriminatory against many Medicare beneficiaries in an area who would not have realistic access to the lower cost sharing of preferred pharmacies. Using this approach, plans could designate pharmacies for non preferred status in certain areas of the region where there is high maintenance medication use to encourage the use of mail order. This would be discriminatory against beneficiaries.

CMS should require plans to indicate their estimate of the total number of Medicare beneficiaries and prescriptions they expect to use preferred pharmacies in the network. There are real concerns that too few preferred pharmacies will be in a network, but because these networks have lower cost sharing, that these pharmacies will have to fill a disproportionate share of prescriptions for Medicare beneficiaries in that plan's region. In addition to the frustration of traveling longer distances than they should have, some beneficiaries might have longer waits to obtain their prescriptions because pharmacies may have excess volume. These factors combined help to encourage beneficiaries to use alternative prescription sources, such as mail, which we believe is inconsistent with the intent of Congress and the spirit of the TriCare standards.

*Cost Sharing***:** CMS should examine the extent of the differences that exist in cost sharing between preferred pharmacies and non preferred pharmacies. Any significant difference in cost sharing would be discriminatory against those beneficiaries that did not live within a reasonable driving or traveling distance of these preferred pharmacies. Moreover, CMS should require plans to submit information on the cost sharing amounts that would apply to all beneficiaries in the plan if a "preferred" vs. "non preferrerd" scheme was not used. In other words, the ability of a few beneficiaries to obtain lower cost sharing could increase the cost sharing for a larger percentage of beneficiaries than if the cost sharing had been uniform across all the pharmacies in the Tricare network, not just the preferred pharmacies.

CMS should also review plan bids to assure that plans are not charging differential cost sharing to encourage beneficiaries to use mail order over retail pharmacy providers. CMS should also assure that plans are not creating different tiers of formulary coverage so that certain drugs are only available through mail order rather than retail pharmacies, and that plans are not using artificial limits on the amount scope and duration of drugs that might be obtained through a retail pharmacy rather than a mail order pharmacy.

Section 423.401 - Organizational Compliance with State Law and Preemption by Federal Law

Proposed section 423.440(a) would implement sections 1860D-12(g) and 1856(b)(3) of the Social Security Act, which provide that the Medicare Part D rules will preempt "any state law or regulation" with respect to PDPs, except for "state licensing laws or state laws relating to

plan solvency." RITE AID supports CMS' conclusion that Executive Order 13132 on Federalism requires CMS "to construe preemption statutes narrowly." 69 Fed. Reg. at 46696. Unfortunately, that policy of narrow construction is not reflected in the proposed rule.

CMS should state in the final rule that it does not intend to "occupy the field" by preempting all state health care standards that apply to plans. Instead, CMS should clarify that a state law or regulation will be preempted only to the extent it directly conflicts with a specific provision of the Medicare Part D rules. A state standard should not be preempted if it is possible for a PDP sponsor to comply with both the state standard and the Medicare Part D rules.

At the very least, the Medicare Part D rules should not preempt state laws and regulations to the extent that the state standards apply to the non-Medicare operations of plan sponsors and their business partners, such as PBMs. In other words, if a plan sponsor offers both a Medicare plan and a private plan, CMS should clarify that state standards (i.e. any willing provider laws) should continue to apply to the private plan even if those state standards are preempted by the Medicare Part D rules with respect to the Medicare plan. Congress was careful to limit preemption only to Medicare PDP plans that operate under Part D, not to all operations of plan sponsors.[7]

In particular, CMS should expressly state that the Medicare Part D rules will not preempt state pharmacy practice acts. The regulation of pharmacy practice is traditionally a matter of state law. In enacting the Medicare Part D drug benefit, Congress never express an intention to preempt state standards regarding the practice of pharmacy. Preemption of state pharmacy practice acts would be contrary to a narrow interpretation of the preemption authority enacted by Congress.

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

Overview: RITE AID has focused its comments in this section on the two major tasks that we believe CMS must accomplish to reach its self–defined goals of maximizing the efficiency and effectiveness of a Coordination of Benefits (COB) system that can provide information to pharmacies in real time regarding a beneficiary's "true out of pocket costs," also know as TrOOP. CMS has indicated that it wants to have this system in place by January 1, 2006. The two major tasks that we believe CMS must accomplish are:

- Creating an online real time COB–TrOOP system that expands CMS' Option 2 by including community retail pharmacies in its single point of contact system thereby considerably increasing the efficiency and effectiveness of CMS' Option 2. RITE AID proposes that CMS implement the Single Point Of Contact System (SPOCS) as described immediately below; and,

[7] Section 1856(b)(3) of the Social Security Act, as amended by section 232(a) of the MMA, provides that "the standards established under this part" preempt state law "with respect to MA plans which are offered by MA organizations under this part." Section 1860D-12(g) of the Social Security Act provides that section 1856(b)(3) "shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C."

- Streamlining current COB policies and procedures so they can be accommodated in the new COB–TrOOP system. RITE AID comments on these policies under the appropriate preamble subsections below.

We propose a Single Point of Contact System (SPOCS) for COB and TrOOP. This SPOCS proposal has two major advantages over CMS' proposed Option 2 on F.R. page 46706. Those advantages are that both providers and Medicare beneficiaries also have the advantages of a single point of contact system, not only payers. This increase in functionality maximizes the efficiency and effectiveness of a COB–TrOOP real time system.

We offer this SPOCS Proposal to assist CMS in its efforts to establish, before July 1, 2005, procedures and requirements that will promote the effective COB between a Part D plan and a State Pharmaceutical Assistance Program (SPAP), Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage CMS may specify at in the future. In addition, SPOCS can be operational by the MMA deadline of January 1, 2006. Most importantly, Medicare beneficiaries will find SPOCS to be the easiest system to understand and the most convenient system to obtain their prescription medication and supply services.

Proposed Single Point of Contact System for Medicare Part D COB and TrOOP Calculations:

Overview of the Proposed COB–TrOOP Process

- Medicare beneficiary presents Medicare standard benefit prescription card and prescription(s) at the pharmacy;
- Pharmacy submits all Medicare beneficiary's prescription claims (e.g., SPAP, Medicaid, group health plan, FEHBP, TRICARE) to the "SPOCS";
- SPOCS has all of the Medicare beneficiary's insurance eligibility information and the correct billing order in its electronic files;
- SPOCS, after receiving a prescription medication or supply payment claim from the pharmacy, identifies the Medicare beneficiary in its electronic file and sends the payment claim to that Medicare beneficiary's primary payer. The primary payer responds back to the SPOCS with the necessary COB and TrOOP information and the SPOCS repeats the process with the Medicare beneficiary's secondary payer, etc. until all of the responsible payers are billed;
- SPOCS sends the claim with a "separate response payment segment" for each payer back to the pharmacy so the pharmacy knows what each payer has paid and who to expect payment from;
- SPOCS receives the final TrOOP calculation for that claim and sends this information to the appropriate parties.

Advantages of Suggested Process:

- Medicare beneficiary only needs to present Medicare card at the pharmacy. No other insurance cards are necessary because of the single point of contact with the SPOCS;
- Medicare beneficiary's claims will go through the SPOCS and can be accessed for Medicare eligibility determination, TrOOP management, physician-billed Part B claims updates, claims reversal communications, and inquires by appropriate parties about the TrOOP;
- CMS will only need to work with the SPOCS for eligibility and TROOP management;
- Pharmacy knows where to send ALL of the Medicare beneficiary's prescription claims reducing dispensing time so that the Medicare beneficiary obtains prescription medications and supplies more quickly than she/he otherwise would if the pharmacy was required to make eligibility inquires or to try to determine the correct billing order of the Medicare beneficiary's payers;
- A prescription ID card is not required to be sent to Medicare beneficiary. The Medicare beneficiary's standard prescription benefit card is all that is necessary;
- SPOCS will be able to manage all* payment claims real-time, including Medicare Complementary Cross Over Claims;
- SPOCS is an independent entity that acts as a switch for real–time COB and TrOOP information that does not have a potential conflict of interest managing patient identifiable health care information and pharmacies' confidential payment rates;
- Separate response payment segments from the SPOCS will eliminate the current confusion in those cases when the DMERCs do not let the pharmacy know the secondary payer information on Medicare Complimentary Billings;
- Each payer is responsible for its own payments, which are reflected in the SPOCS's separate response payment segments back to the pharmacy.

*ALL – Need to have pharmacy Medicare Part B claims process online, real-time. See below.

SPOCS' System Requirements:

- Claims processing at PBMs must have a separate and enforced Bin Number for all Medicare claims processing at their site to assure that claims go through the SPOCS with the proper routing;
- All Medicare beneficiaries' billing information and billing order must be on file at SPOCS and continually updated;
- Must have separate "response payment segments" for each payer billed through the SPOCS;
- To process COB claims, the processors would need to follow one of the NCPDP COB billing standards. The processor would elect to process the payment information by electing to use the 5.1 COB segment and accepting the "Other Payer Amount Paid", or, not use the 5.1 COB segments but use the 5.1 pricing segment and accept the "Copay Billing" which would be populated with the gross amount due;
- SPOCS treats all pharmacy claims and information as proprietary and confidential;
- Pharmacy maintains ownership of submitted claims data to dissuade the unauthorized uses and further disclosures of patient identifiable health care information as prohibited by the HIPAA privacy regulations;

- Pharmacies and payers would need to make appropriate software changes that would allow them to: interact with SPOCS as the central point of contact for Medicare billed claims, receive multiple payment response segments, and receive TrOOP accumulator information. These changes for the Medicare beneficiaries' claims would allow the SPOCS system to identify the eligible Medicare beneficiary, bill their claims to responsible payers in the proper billing order, send the information back to the pharmacy in an identifiable payment reconciliation format, and communicate the TrOOP back to the appropriate parties. The system should also allow for easy update of physician billed Part B claims;
- Medicare Part B pharmacy claims must process on-line, real time through SPOCS. This is required to allow for proper and accurate TrOOP calculation for the Medicare beneficiary. It is necessary to know the Medicare Part B paid amount (which by today's use of paper claims can takes weeks to obtain) to do any wrap around or additional COB billings and obtain a real-time calculation of Medicare beneficiary's TrOOP;
- Medicare Part B claims processing requirements would need slight modifications to make them as streamlined as pharmacy commercial payment claims and Part B would need to move to NCPDP 5.1 online, real time claims management;
- COB claims submission process would need to be accomplished within the industry standard claims submission time–out window of approximately 12 seconds;
- Preferable that all Medicare Prescription Plans use the Medicare beneficiary's Medicare ID number (or one ID number designated by CMS) as the Medicare beneficiary's ID number for all the various prescription programs the Medicare beneficiary may be enrolled. If not, the SPOCS would need to maintain the alternate ID billing numbers for the Medicare beneficiary to cross reference and COB bill;
- Work towards using common claim identifier values for physicians (NPI) and for drugs (NDC numbers).

Summary:

This proposed COB–TrOOP single point of contact system is the most effective and efficient system that can be designed. Although the SPOCS utilizes current industry capabilities, CMS must recognize that there would be significant programming requirements by pharmacy to make the SPOCS work. However, of the preamble alternatives set out by CMS, the SPOCS model is clearly the best because it does the following:

- Is easy and convenient for the Medicare beneficiary;
- Does not require additional insurance program ID cards;
- Facilitates pharmacies' correct billing of COB plans in the proper order;
- Provides a central entity to collect, manage, and resolve TrOOP questions, for Medicare beneficiaries, CMS, claims processors, and pharmacies. The result would be a simpler process, less people hours to manage the process, better service to all, and satisfied Medicare beneficiaries;
- Provides online real time TrOOP calculation;
- Increases the efficiency of pharmacy claims reconciliation;
- Maintains the confidentiality of Medicare beneficiaries' personally identifiable health care information.

It is only fair that the Federal government fund the development and implementation of CMS' COB system, because it receives the largest amount of financial savings as a result of its use. In addition to the savings the Federal government will accrue from the use of the COB e–highway, this e–highway will be part of the National Health Information Infrastructure (NHII), which CMS is promoting.

Community pharmacies should not be charged a "User Fee" or any other charge for using CMS' COB system. Because community pharmacies will expend substantial resources, both financial and human, to connect to this federal COB e–highway, it is not reasonable to expect them to pay to use that highway. For this reason, user fees must not be charged, nor allowed to be charged, to community pharmacies for using the federal COB e–highway.

The Federal government should fund both the increased claims transaction fees and the fees for re–routing post adjudication claims, which will both frequently occur if CMS does not implement SPOCS. If community pharmacies are not allowed to share information real time with the single point of contact as the router to and from the multiple payers, the number of pharmacy transactions will increase substantially causing administrative costs to rise significantly. An even larger increase in administrative costs will occur when pharmacies are required to re–direct post adjudication claims for COB and TrOOP because that information was not updated when the claim arrived at the pharmacy.

By not implementing SPOCS, CMS will be shifting huge administrative costs to pharmacies and will also increase the time of dispensing while pharmacists wait for the necessary COB and TrOOP information to correctly bill the Medicare beneficiary. More importantly, Medicare beneficiaries' wait time will be unnecessarily increased as a result of a much less efficient and effective COB–TrOOP system proposed by CMS.

Coordination with State Pharmaceutical Assistance Programs (SPAPs)

At 69-CFR-46701-2, the proposed regulation discusses the coordination between Medicare Part D and SPAPs. This coordination must be efficient and effective because SPAPs payments will count toward TrOOP expenditures for Part D enrollees (Medicaid and Pharmacy Plus 1115 waiver programs do not). Medicare pays first and the SPAPs are the secondary payers. SPAPs could pay the Part D premiums on behalf of enrollees and/or develop a claim–specific wrap–around benefit, which would complicate the necessary coordination between Medicare Part D and SPAPs.

Part D enrollees' TrOOP is required to be calculated by payers. After paying a claim and updating the TrOOP, the payer could then send that updated TrOOP real time to the single point of contact's database, where that single point of contact could include it as part of the claim response back to the pharmacy where the Part D enrollee is waiting. The SPOCS proposal allows this real time sharing of information that will meet Part D enrollees' expectations that their TrOOP will be correct and delivered real time to their pharmacy.

In those situations where SPAPs create a wrap around benefit, the SPAP information would be included in the SPOCS' database so that when a pharmacy submits a Part D enrollee's claim to the SPOCS, it would know to first route that claim for payment to the Part D plan as the primary payer. The Part D plan would then send a claim response back to the SPOCS including the updated TrOOP, which would then send the remaining claim to the SPAP as the secondary payer. The SPAP would then send a claim response back to the SPOCS including the updated TrOOP, which would be sent by the SPOCS to the pharmacy on a claims response indicating what each payer has paid and the updated TrOOP. The SPOCS would then send an information only claim to the primary payer to update the TrOOP so their system would be able to accurately calculate subsequent claims against the TrOOP. Real time information feedback loops will be essential in determining an accurate TrOOP.

The SPOCS is action oriented. It actually routes claims, unlike the COB system described on page 46702 of the prepared regulation, which merely passes information to the pharmacy so the pharmacy will know where to submit both the initial claim and the resulting secondary claim. The SPOCS is much more efficient than the system described by CMS in the preamble.

The Part D enrollment card is not the most efficient way for pharmacies to obtain necessary COB information. The proposed SPOCS only requires the Part D enrollee to present his or her standard prescription drug benefit card. No other cards are necessary so the costs for those other cards are thereby eliminated. This card provides sufficient information for the pharmacy to submit the payment claim to the SPOCS for routing to the appropriate payers in the proper billing order.

Coordination with Other Prescription Drug Coverage

At 69-CFR-46702,Rite Aid is offering CMS the SPOCS proposal because its use will allow Part D enrollees to receive their prescription medications and/or supply services more quickly**.** SPOCS will provide the most efficient and most effective coordination between Medicare Part D and other plans providing prescription drug coverage, including: (1) Medicaid programs (including a State plan operated under a waiver under section 1115 of the Act); (2) Group health plans; (3) FEHBP; (4) Military Coverage (including TRICARE); and (5) other prescription drug coverage that CMS may specify.

Although RITE AID understands that there is a relatively limited applicability of COB between Part D plans and state Medicaid programs, the SPOCS would still need to provide the updated TrOOP real time to pharmacies so that Part D enrollees waiting at those pharmacies would know how much they are required to pay for their prescription medications and/or supply services.

Coordination of Benefits (COB)

In regard to the discussion at 69-CFR-46702-4, the SPOCS could manage all of the information described in the following paragraph. SPOCS would use this information when a pharmacy submits a Part D enrollee's real time claim to the SPOCS for the SPOCS to route to the appropriate payers in the correct billing order.

RITE AID understands from the preamble that the:

- MMA requires that CMS, by July 1, 2005, establish requirements for COB between Part D and the SPAPs;
- Elements that are to be coordinated must include: Enrollment file sharing; claims processing and payment; payment of premiums for both basic and supplemental drug benefits; third-party reimbursement of out-of-pocket costs; application of the protection against high out-of-pocket expenditures (by tracking TrOOP and the annual out-of-pocket threshold); and other administrative processes and requirements that CMS may specify;
- Enrollment file sharing might include information such as beneficiary name, date of birth, health insurance claim number, sex, name and address of benefit administrator, insured's identification number, electronic transaction routing information (RxBin, RxPCN, RxGRP), group number, patient relationship, and coverage effective dates; and
- Claims processing information might include collecting information similar in nature to that currently contained in a Medicare provider Remittance Advice statement. Information must be sufficient to successfully link with enrollment files and in order to allow Part D plans to make a correct determination of TrOOP expenditures on the part of beneficiaries.

The SPOCS proposal would provide a solution to CMS' technical communications concerns and assure that CMS' stated goals would be accomplished. CMS correctly stated in the preamble that the COB at the pharmacy point of sale is a technical communications challenge and that this challenge must be over come if CMS is to attain its stated goal:

> *"… the goal is that the beneficiary pays the correct coinsurance or co-payment at the point of sale and that the pharmacy is subsequently reimbursed the correct amount from the other source or sources. [See page 46702]*

CMS also realizes the need for a "reliable feedback loop", which is an essential component of the SPOCS solution that is the real time organized system that CMS describes immediately below:

> *"coordination of benefits for beneficiaries enrolled in Part D plans must include a reliable feedback loop of paid claims data from the employer, union or other insurer back to the Part D plan for purposes of tracking TrOOP. Additionally, given the real-time claims environment for pharmacy benefits, the feedback would ideally be in real-time so that beneficiary liability (if any) can be known at the point of sale, the correct insurer pays the correct share of the total drug cost, and the TrOOP calculation can be updated as quickly and accurately as possible. This suggests the need for an organized system to share, update, and push data back and forth between pharmacy benefit managers and pharmacies…." [F.R. page 46702] [Emphasis added.]*

Medicare Part B must be managed by SPOCS to maximize the efficiency of COB and TrOOP calculation. Pharmacy–dispensed drugs covered by Part B include medical equipment and

supplies including durable medical equipment (DME), certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and oral anti-cancer drugs, and such other items as the Secretary may determine.

RITE AID understands that community pharmacies will not be paid by Part D in those situations when "payment is available" for an individual who could have been enrolled under Part A and/or Part B. RITE AID also understands that there are a number of complex plan design situations that determine whether or not "payment is available" under either Part A and/or Part B, including the fact that Part B coverage varies depending on the region of the country the individual resides.

The SPOCS proposal would eliminate the need for 50,000 pharmacy computer system to be modified to incorporate the intricacies of Medicare's Part A, Part B, and Part D payment policies and benefit designs.

CMS' statement in the preamble clearly supports a system such as the SPOCS Proposal:

> *"We would wish to ensure that Part D coverage coordination works seamlessly for beneficiaries with Parts A and B of Medicare, and that beneficiaries do not lose Medicare coverage otherwise available to them due to unforeseen difficulties encountered in the coordination process. This is a critical consideration for effective and efficient coordination between the original Medicare program and the new coverage provided under Part D." [Page 46703] [Emphasis added.]*

Certainly, CMS would have to agree that the chances for "unforeseen difficulties encountered in the coordination process" would be much more likely if Part D enrollees were required to go to community pharmacies for Medicare payment and benefit information rather than one single source.

Seamless COB between Part A, Part B, and Part D has benefits for providers, beneficiaries, and for Medicare as the payer. Described below are four examples that demonstrate problems that could occur if SPOCS is not implemented:

- **Example One:** Beneficiaries with Part B and Part D potentially will have prescription products coverage in both Part B and Part D. The Part B coverage is typically targeted toward treatment for specific diseases or disease states (i.e., organ transplants–auto—immune suppressants, cancer—anti-neoplastic products and anti-emetics, lung disease––inhalation therapy as well as blood glucose monitoring—diabetes testing equipment and supplies). A number of these products are treatment options for multiple disease states and only a small number of these disease states may qualify in Part B exclusively. A good example is methotrexate. This drug has a common use in treating some forms of cancer therefore qualifying for Part B coverage and also for arthritic conditions, which is not covered in Part B but is in Part D. If proper coordination of coverage does not exist, coverage in two distinct Parts of Medicare could be costly to the Provider, Medicare, and the beneficiary.

- **Example Two**: The provider could be negatively impacted by incurring additional administrative costs. Medicare Part B has significantly more and different documentation requirements than Part D. If a provider prepares the documentation for a Part B claim, submits the claim to Part B, only to have the claim denied, then all that time spent in obtaining that documentation was wasted and added significant costs to the process. Additionally, if a provider submits a claim initially to Part D, which is rejected because it is covered in Part B, the provider must then spend substantial time pursuing the required Part B supporting documentation. After spending considerable time pursuing these required supporting documents, the provider may not receive full payment because of not complying with the timely filing requirements of Medicare.

- **Example Three:** Improper coordination of co-insurance and deductible requirements between Part B and Part D can have a negative impact on the beneficiary. A claim submitted to the wrong Part can cause the beneficiary to pay a deductible or co-insurance amount beyond their actual requirement. Though providers will promptly refund the overpayment, the beneficiary potentially could be ill-prepared to be out of pocket for these funds. Additionally, customer co-insurance obligations associated with claims submitted to the wrong Part can potentially skew the customers TrOOP and create situations where a refund is due to the beneficiary, again creating an out of pocket situation many seniors cannot afford.

- **Example Four:** Medicare could be negatively impacted because of the potential for duplicate payments. Without coordination between Part B and Part D, Medicare could potentially pay for a service in Part B, and then duplicate that payment in Part D. This duplication could occur through clerical billing errors.

Just as importantly, the SPOCS proposal would allow CMS to meet the Part D enrollees' expectations of knowing what they owe when they pick up their prescriptions at the pharmacy. To meet these expectations, the SPOCS will provide the necessary billing information real time so that Part D enrollees' TrOOPs can be accurately applied and updated by payers before being communicated by the SPOCS pharmacy. Meeting Part D enrollees' expectations will be key for a successful implementation of the Part D program in January 2006.

CMS' following preamble example of the Part B and Part D double coverage illustrates how complex it would be for community pharmacies to determine whether or not they will be paid by Part D without the implementation of SPOCS:

> *"This means, for example, that if a form of administration of a drug is covered under Part B in a region when injected incident to a physician office visit, that drug administered in that manner in that setting cannot meet the definition of a covered Part D drug. However, that same drug can be covered under Part D when picked up at a retail pharmacy to be self-administered by the patient." [Page 46702–03]*

CMS provides another coverage problem also illustrating how difficult it would be for community pharmacies, without the implementation of SPOCS, to determine whether or not they will be paid by Part B:

"…under local medical review policies, a drug that might be covered under Part B for an individual in one area of the country may not be covered under Part B in another area of the country. Thus, what is covered "under Part B for that individual" may be different in different geographic regions." [F.R. page 46703]

Medicare's payment policies and plan designs must become more streamlined when it moves to real time information interchange that is the essential component of an efficient and effective COB–TrOOP system. The MMA has given Medicare the opportunity to create a real time COB–TrOOP system that reflects the purpose of HIPAA's Administrative Simplification requirements that were enacted in 1996:

"to improve the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."

The private sector has already taken advantage of the standards that have been adopted by HHS. However, they are still waiting for some to be adopted (e.g., unique payer identifiers) and for the NPI regulation to be modified to require that all prescribers obtain an NPI, not only those that submit electronic payment claims on their own behalves.

In general, real time payment transactions will force Medicare to review and revise its outdated paper administrative programs. Medicare administrative procedures are often too complex for both beneficiaries and providers. Moving to a real time information system will force the streamlining of the Medicare paper and batch claim process.

Today's processing of Medicare Part B claims incorporates policies and procedures that are vastly different from the norm of processing private third party prescription claims. Consequently, Medicare Part B's requirements result in increased pharmacy workflow and increased patient wait times, which is the antithesis of HIPAA's promised "Administrative Simplification". These administratively burdensome Medicare Part B policies include**:**

- Medicare will not cover a DMEPOS item if the community pharmacy has a verbal order at the time that the payment claim is submitted. If the pharmacy does not have a detailed written order for an item prior to submitting a payment claim, that claim will be denied as not medically necessary. Pharmacists have traditionally been allowed by state laws to take verbal orders from prescribers and reduce them to writing as legally valid prescriptions. These transcribed orders are recognized as valid prescription orders for payment claims made to all non–Medicare third party payers, including state Medicaid programs. The few exceptions to this recognition include prescriptions for Schedule II controlled substances and DAW 1 prescriptions for some state Medicaid programs, both of which are currently not factors in Medicare pharmacy claims. Not recognizing a prescriber's order taken and transcribed by a pharmacist as valid for Medicare claim submission is contrary to current industry practice that exists for the care and

convenience of patients. This Medicare policy results in additional labor cost for community pharmacies and the needless delay in service for Medicare beneficiaries.

- Medicare policy prohibits community pharmacies from entering medical necessity information (e.g., an ICD–9 diagnosis code, narrative description of the patient's condition, abilities, limitations, etc.) on the prescriber's order when the prescriber has omitted that information. This Medicare policy, like many others, is totally inconsistent with the policies of other third party payers. Rather than allowing community pharmacies to simply add the missing information to written prescriber's orders like other third party payers, Medicare requires pharmacies to obtain a new written order from the prescriber. This Medicare policy is not administrative simplification.

- Medicare policy has recently been interpreted by a Regional DMERC to require community pharmacies to obtain a new detailed written order, personally signed and dated by the prescriber, when the prescriber has written the words take "as directed" on the original order. This Medicare policy, like many Medicare policies, is totally inconsistent with the policies of other third party payers, which allow pharmacists to clarify the "as directed" instructions on the original order. This Medicare policy is not administrative simplification.

- In general, Medicare's certificate of medical necessity (CMN) must be streamlined to reflect the changes provided by the online real time prescription billing process used by the private sector and state Medicaid programs. The same drugs covered by Medicare Part B (e.g., immunosuppressive and oral anti–cancer agents) are prescribed, billed online real time, and dispensed daily to patients covered by numerous private prescription drug benefit plans, including state Medicaid programs. The prescription drug's NDC number, quantity, and days supply provide payers with all the knowledge they need to adjudicate claims real time.

- For initial fills under Part B of immunosuppressive drugs, Medicare requires community pharmacies to provide the ICD9 diagnosis code, the name of the organ transplanted, the date of discharge along with data about where and when the transplant occurred. This information is known by the prescriber. While pharmacy recognizes that the billing from these entities may not yet have occurred, it is unreasonable to expect pharmacies to track down this data in order to provide patients with medication necessary for their discharge and quality of care. Additionally, all of the existing HIPAA unique identifiers (Medicare Supplier Number as the Provider ID should suffice to identify who is providing the dispensing; UPIN for the prescriber should suffice to identify the prescriber thus negating the need for further prescriber information; NDC for the drug, etc.) should be used to increase the speed of payment claim transaction rather than forcing busy pharmacies to input identifiers in text data, which is much more time consuming.

- If prescribers are mandated to provide the ICD9 diagnosis and date of discharge on initial prescription orders, these values can be input and transmitted on the claim, but

there should only be the minimum additional data requirements in order to receive payment for dispensing the immunosuppressive drug.

- Medicare should process these claims as commercial health plans currently do by having the payer update the patient's file via a prior authorization for the drug for those patients who are eligible. The claim will process for eligible patients who have had the drug prior authorized. This suggestion is consistent with commercial programs and the system supports this process.

The SPOCS proposal would be more efficient and more effective than the automatic cross–over procedures that CMS is considering, according to the preamble, for drugs potentially covered by Part B that are dispensed by a pharmacy that is a Medicare supplier. According to the preamble, CMS is considering requiring that the:

- Pharmacy submit the claim to the appropriate Part B carrier; and
- If it denies the claim, the carrier submit the claim automatically to the PDP (or its claims processing agent) through which the beneficiary has Part D coverage. This assumes that the beneficiary receives Part D through a PDP. For beneficiaries enrolled in MA-PD plans, coordination of benefits will generally occur internally within the MA organization.

CMS should not be considering expanding the automatic voluntary complementary cross over billing system to provide the COB for Part D because it is not working well today. Medicare Part B has a complementary cross over billing system operating today with Medicaid for dual eligible-individuals and also between Medicare and Medicare supplemental insurers.

The complementary cross over paper claim billing system is not working well today for the following reasons:

- Community pharmacies do not always know which insurers, with the exception of the state Medicaid programs, are participating in the complementary cross over billing system;
- One of our chain members requested from the DMERCS a list of complementary cross over payers and to date, only one DEMERC could supply that list;
- Community pharmacies waste time trying to determine who the cross over payer is so that claims can be reconciled;
- The cross over/secondary payer does not always respond to these paper cross over claims in those cases when they deny payment;
- Community pharmacies waste time watching for unpaid or short paid claims and then go back to Medicare to determine who to contact to resolve the payment issues;
- Community pharmacies work load is high for the reasons mentioned above even for the relatively small number of the current cross over claims, but this work load can be expected to become unduly burdensome if this cross over billing program is expanded in 2006; and

- The increase in cross over claims in 2006 will slow the processing of these claims and updating the TrOOP, which to be accurate must involve a real time processing system like SPOCS.

The SPOCS proposal would eliminate all current Medicare cross over billing system problems because it is a real time system that will assure that secondary payers will be billed in the proper order. The real time SPOCS will eliminate the time lag for payment, the needless administrative time spent "looking for payment"; and will assure an accurate determination of the TrOOP. Medicare beneficiaries will also benefit from SPOCS because it will help assure that they receive the benefits due from their secondary payers.

*Medicare Part D as Secondary Payer (MSP) to another payer***.** Medicare currently pays as a secondary payer when payment has been made or can reasonably be expected to be made by another party such as workers compensation, automobile insurance, a liability insurance policy, or another health insurance policy (for example, when a beneficiary's spouse has primary insurance through their employment).

Although RITE AID assumes that most instances of COB under Part D will occur when Medicare is the primary payer, the SPOCS proposal would still need to be implemented to bill the appropriate payer as the primary payer. The necessary information to do this would be included in the SPOCS' data base and would be used by the pharmacy as the single point of contact to submit Part D enrollees' real time pharmacy claims.

Tracking True Out-Of-Pocket (TrOOP) Costs

As discussed in 69-CFR-46705 RITE AID understands from the preamble that CMS is considering the following options for operationalizing the data exchange related to the Part D coordination of benefits system and TrOOP accounting:

- *Option* 1: The PDPs and MA–PD plans would be solely responsible for tracking TrOOP costs. Data collected by a PDP or MA-PD plan would be annotated to the Medicare Beneficiary Database and be available to pharmacies for the purposes of proper billing.

- *Option* 2: CMS would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary and secondary. CMS could use existing fee-for-service coordination of benefits processes to implement many of the processes needed to implement these provisions. Information concerning primary and secondary plans would be shared with and PDPs and MA-PD plans, as well as annotated in the Medicare common working file/Medicare Beneficiary Database to enhance pharmacy billing and beneficiary customer service.

RITE AID prefers CMS' Option 2, but Option 2 does not go as far as it must to really maximize the efficiency and effectiveness of COB and the calculation and tracking of TrOOP. The SPOCS proposal extends Option 2 to also include community pharmacies in its single point of contact system, not only the primary and secondary payers. SPOCS would thereby

increase the efficiency and effectiveness of CMS' Option 2 considerably. RITE AID proposes SPOCS, in response to CMS' request for comment on these options and input on the best means to ensure an efficient and effective coordination of benefits related to the Part D Medicare program.

The SPOCS proposal would eliminate the need for CMS to spend the time and money building the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 as described in the preamble. Rather than having 50,000 pharmacies querying this eligibility system, the SPOCS Proposal would build this information into the SPOCS' database and make the SPOCS responsible to route pharmacies' claims to the correct payers in the correct billing order. The CMS eligibility query system would be far less efficient. CMS is even concerned about the eligibility system they propose:

> *"We are concerned that with the significant expansion of health care options available to beneficiaries that providing information to pharmacies about Medicare and other coverage is essential to facilitate proper claims processing. We are requesting comments concerning the development of this system."*

CMS' suggested use of the X12 270/271 Eligibility Query and Response (69-CFR-46706) to determine eligibility before submitting the payment claim is <u>not</u> working now in Medicare Part B pilots with chain pharmacies and more importantly would be totally unnecessary if CMS implemented the SPOCS. Many problems currently exist with the proposed Part D 270/271 Eligibility Query and Response in the current Medicare Part B's Beta Tests with several pharmacy chains:

- The X12 270/271 is not used by community pharmacy because eligibility is already built into the real time HIPAA NCPDP 5.1 transaction standard. That standard will process about 3.5 billion prescriptions online real time for prescription medications and supplies;
- The 270/271 eligibility queries and response transactions have not been able to be made to work in the real time community pharmacy environment. Most testing has been batch testing, and the average response time does not approach the real time rate of less than 10 seconds;
- Not being able to perform real time transactions increases administrative waiting time for the response information that is necessary before the prescriptions can be filled;
- Increased administrative time requires Medicare beneficiaries to wait longer for their prescription drugs and supplies;
- Dispensing prescriptions medications and supplies is a very high volume business that makes real time information essential;
- Requiring Medicare beneficiaries to wait longer for their prescriptions than other patients whose payers use a real time eligibility response creates a lower level of service for Medicare beneficiaries;
- These transaction standards have not been incorporated into the vast majority of community pharmacy practice software;

- Developing the software to incorporate the X12 270/271 eligibility standards and to implement those new standards into the 50,000 community retail pharmacies would be very costly and time consuming;
- There is virtually no experience with the X12 270/271 eligibility standards within community pharmacy. The DMERCs are in the testing phases only, which is going very slowly; and,
- Even if the concept to use the X12 270–271 is proven, the DMERCs would still need to go into production with clearinghouses and community pharmacies, an expense of both time and money.

Even if the X12 270/271 Eligibility Query and Response transactions were proven in the future to be able to share eligibility information real time, their use would still not be as efficient or as effective as the SPOCS Proposal.

Eligibility information would be contained in the SPOCS' data base so that pharmacies would not have to spend the money to develop and implement the 270/271 Eligibility Query and Response transaction standards. And, even more important than these cost savings, is the savings of administrative time that would otherwise be spent performing the required eligibility queries and waiting to receive responses.

The SPOCS Proposal would reduce the Part D enrollees' privacy concerns because the Proposal would reduce the amount of patient identifiable health care information shared between different plans as contemplated by CMS in the preamble:

> *"… beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA compliant beneficiary "release" or authorization. For instance, if we were to clearly require that all Part D plans coordinate benefits and that all Part D enrollees provide consent for release of third-party data on their Part D enrollment forms, the Part D plans would have the authority to implement inter-plan reporting mechanisms in order to coordinate benefits…."*

The SPOCS Proposal can be implemented by January 1, 2006, so its implementation would remove CMS' concern that "temporary or phased-in approaches that may be necessary or advisable given the short timeframe between publication of the final rule and program implementation." RITE AID does not support a temporary or phased–in COB system because the proposed SPOCS can be implemented by January 1, 2006, and therefore avoid the extra time and money CMS would need to spend to develop a temporary or phased in COB system.

The SPOCS Proposal can also solve CMS' concern that cancelled/reversed prescriptions could disrupt the calculation of the initial deductible and TrOOP because they could throw off the correct sequencing of those calculations.

CMS expresses its concern about the sequencing of payment claims:

> *"Another complicating factor in the sequencing of claims is cancelled prescriptions. Generally, a claim is adjudicated when a prescription is filled. If the prescription is not picked up, and is eventually cancelled, the claim needs to be cancelled. If, in the meantime, other claims have been adjudicated, the sequencing is thrown off by the cancelled prescription, potentially disrupting the calculation of the initial deductible and TrOOP, and making coordinating benefits and tracking TrOOP costs more difficult." [F.R. page 46707]*

By using the SPOCS system, CMS would have a solution to the "claims cancellation/reversal" problem. Since SPOCS is real time any reversed payment claim would immediately be sent by the community pharmacy to the SPOCS' data base for the SPOCS to route to the appropriate Part D Plan. A reversed claim would follow the same routing path as an initial claim in the SPOCS' scenario and the appropriate parties would receive the adjustment payment request just as they would receive the final TrOOP calculation for a paid claim. Subsequently processed claims would be appropriately priced.

CMS states in the preamble that it prefers a real time system like the SPOCS, but does not believe it could be operational by January 1, 2006. RITE AID believes SPOCS can meet that operational deadline:

> *"Ideally, we would prefer that the system actually coordinate the adjudication of claims and provide real-time claims processing across multiple insurers, but we do not believe that such a complex and unique system could be operational by January 1, 2006." [F.R. page 46707]*

RITE AID does not agree with CMS that the majority of employers, group health plans and other third party payers would participate in a voluntary system because they would receive a clean claim:

> *"We anticipate that the majority of employers, group health plans and other third-party payment arrangements would participate in a voluntary system since they would receive a clean claim from the pharmacy that has already been adjudicated by the Part D plan. In return for the clean claim, we would request that third-party payers provide information back to the coordination of benefits system regarding how much they paid on the claim for purposes of calculating the TrOOP under Part D…."* [F.R. page 46707]

Today, the Medicare complementary cross over process is voluntary and not all employers or managed care organizations participate. However, the TrOOP can only be accurately calculated for each Medicare eligible if <u>all</u> employers, managed care organizations, and <u>all</u> other payers are <u>required</u> to participate in the system. If all payers are not required to participate, how would a workaround system be developed for those non–participating payers and who would develop and pay for such a system.

RITE AID' response to CMS' request for "comment and relevant information (if any exists from current market practices) on how these situations should be resolved under Part D at the point of sale…" is again that the COB–TrOOP system must be real time and like the proposed SPOCS, include community pharmacies as well as payers. RITE AID knows that the private sector is ready for real time information sharing because that is going on currently at a rate of about 3.5 billion times this year.

RITE AID also believes that Medicare can meet the January 1, 2006, deadline if it not only moves quickly to real time information sharing, but also stream lines its policies and requirements so they can be accommodated in a real time electronic environment.

Interaction of Part D with State Pharmaceutical Assistance Programs

RITE AID has strongly supported the establishment of state pharmaceutical assistance programs, and believes they have been a significant source of meaningful prescription drug coverage for older Americans in many states. With the advent of Part D, we believe that many of these programs will have to be substantially modified from their existing structure. We expect that states may approach restructuring their programs differently. Some may subsidize the purchase of a standard Part D plan or a supplemental Part D plan for beneficiaries, while others may wrap around a standard Part D prescription drug plan. We strongly support the provision of the law and proposed regulation that allows PDP plans to issue one single card to Medicare beneficiaries that are enrolled in both a PDP that is supplemented by a state pharmaceutical assistance program. This will create simplicity for the Medicare beneficiary and administrative simplicity for the pharmacy.

We would support CMS allowing existing state pharmaceutical assistance programs that meet the actuarial equivalence tests for Part D prescription drug coverage to qualify as a PDP. These states could receive subsidies from Medicare for that portion of the prescription drug coverage that they provide that is equivalent to that year's Part D standard benefit package. This approach will allow hundreds of thousands of Medicare beneficiaries that currently have good prescription drug coverage through their state programs to retain this coverage and benefit structure without disruption in quality of care. There are several states that offer more generous prescription drug coverage than would be offered under a standard Part D prescription drug benefit program. These beneficiaries should be able to retain their coverage just as other retirees with private sector prescription drug coverage will be able to retain their coverage if actuarially-equivalent.

Medicare beneficiaries in these state programs have become stabilized on certain medications that they have obtained through certain retail pharmacies of their choice. Many of these programs have no mail order programs, and in the programs that have voluntary mail order, the overwhelming majority of beneficiaries have opted to obtain their medications through their local pharmacy rather than through mail order. Moving them to a Part D plan could be significantly disruptive to these beneficiaries because they will have to potentially switch to the drugs on the Part D plan's formulary rather than being able to continue to take their current medications. They may also have to give up using their local pharmacy, or have to obtain their prescriptions through the mail. By qualifying SPAPs as PDPs, CMS would assure

that beneficiaries that are comfortable with their long-standing state pharmaceutical assistance program can continue to use that program.

Under an approach by which a state would supplement or wrap around an existing Part D program, we would support the ability of states to pay for drugs not on the Part D plan's formulary, as well as designate as "preferred" pharmacies those pharmacies that may be designated as non preferred by the plan. That is, if a SPAP wants to use its own state funds to supplement the pharmacy network developed by the PDP plan by increasing reimbursement to all pharmacies to the SPAP rate, or designating all current SPAP network pharmacies as "preferred", then the SPAP should be allowed to do this. This is what many SPAPs did in implementing the Medicare-approved discount card in their state. To assure access to pharmacies that beneficiaries had been using for years, some of the SPAPs increased the pharmacy reimbursement rates provided under the plan to the existing SPAP pharmacy reimbursement rates. This should be allowed for SPAPs that either purchase a standard or supplemental policy, or wrap around an existing Part D plan.

RITE AID also encourages states to use some of the $125 million in funding that it can apply for over 2005-6 to develop outreach programs to pharmacists regarding the changes in their SPAP program's design. Pharmacists interact with Medicare beneficiaries daily, including those that are enrolled in SPAPs. Using some of these funds to work with the national and state pharmacy associations to develop educational programs for pharmacists would be a wise investment. Pharmacists can be very helpful to the state in helping beneficiaries understand the changes, given that many beneficiaries are likely to be concerned about how the changes affect their ability to obtain prescription drug coverage.

II. Subpart K-Proposed Application Procedures and Contracts with PDP Sponsors

This section requires a PDP to have procedures and policies to ensure a prompt response to detected offenses and to develop plans of corrective action. It requires PDP sponsors to conduct inquiries in a timely, reasonable fashion, if it learns from any source, of evidence of misconduct relating to payment or delivery of prescription drugs items or services under the contract.

If, after “reasonable inquiry”, the PDP sponsor determines that such misconduct may violate civil, criminal or administrative law, it must report the existence of such misconduct to the appropriate government agency within 60 days or to the HHS Inspector General if the misconduct relates to any of the numerous laws and statutes that are enforced by the HHS Inspector General.

RITE AID has several concerns with this section. For example, there is no determinant of “reasonable”. Hence, PDP sponsors, in order to be compliant with the rules, will respond to any misconduct reports eagerly, conduct a hurried inquiry, and forward findings to the appropriate government agencies. These agencies, presumably, will then conduct their own investigation.

There is no discussion of due process, nor of a process to allow the accused to rebut or appeal allegations before they get to government agencies. There is a concern that PDP sponsors, in

their rush to pursue inquiries in order to with the rule may arrive at conclusions that may be inaccurate, biased, and even not factual. While one understands the desire to detect misconduct, safeguards must be in place to assure that entities are not improperly accused of misconduct due to over zealous auditors, or whistle blowers.

Since this section proscribes a method of what steps to follow if an allegation is made, it should also contain proscriptive methods for guaranteeing due process, as well as an appeals process for any entity that is alleged to have engaged in misconduct.

Section §423.505(b)(9)(i) of the proposed regulation requires the PDP to provide to CMS, information that CMS determines is necessary for carrying out the payment provisions in subpart G. Any information relating to claims, patients, prescriptions, or prescribers will originate at the pharmacy. If CMS determines that information that is not part of the existing data elements captured by pharmacies and as spelled out in NCPDP standards, are needed, pharmacies will be subjected to unfair burdens in attempting to capture and report this information. The final rule should identify the necessary data to be submitted by pharmacies or make some statement that CMS will not require pharmacies to provide data that is not part of the NCPDP standards.

Section §423.505(e)(2) spells out the documents that the Comptroller may review. It states that "…books, records… or *information as the secretary may deem necessary to enforce contract.*" Information that the *Secretary deems necessary* that occurs subsequent to the capture and reporting of the information mentioned in the section will be extremely difficult or impossible for pharmacies to obtain. Here, again, the rule should limit itself to requiring only that information which is spelled out in the rule and is included in the NCPDP standards.

Section §423.505(l) (3) requires contractors or subcontractors (presumed to include pharmacies) to have its CEO, CFO, or a person who is delegated by and reports directly to such executive, certify that based on the individual's best knowledge, information and belief, that the claim data it submits are accurate, complete, and truthful, and that the claims data will be used for the purpose of obtaining Federal reimbursement.

Pharmacy claims are submitted electronically on line at point of sale. Pharmacies submit millions of claims daily. There is no reasonable way every claim could be certified, nor is there a way of batching claims with an accompanying certification. Perhaps the easiest way of obtaining a certification is by including such a phrase in the participating pharmacy contract.
In Section §423.504(b)(4)(G)(5) the agency requests comments on whether a provision requiring PDP sponsors to have standard contracts with reasonable and relevant terms and conditions of participation, whereas any willing provider could access the contract and standard provision and participate as a network pharmacy, should be included in the rules.

Subpart M – Grievances, Coverage Determinations and Appeals

The new Medicare Part D prescription drug program will introduce a system of grievances and appeals for Medicare beneficiaries that are generally unfamiliar to pharmacists. As we note above in comments made in the formulary section, pharmacists cannot be put in the middle of

the coverage appeals and grievance process. Pharmacists can only provide medications that are part of the Part D plan's formulary, or drugs that are not on the formulary (or in a different tier of cost sharing), if they are approved by the plan.

We are concerned that the refusal of the pharmacist to dispense the prescription presented to the pharmacist as written could be designated as a "coverage determination" that triggers a set of legal and procedural obligations regarding the ability of that beneficiary to obtain the prescription. Pharmacists do not want to deny dispensing prescriptions as written to Medicare beneficiaries or any beneficiary for that matter. However, as is the case with private commercial third party programs, the pharmacist can only dispense products that are on formulary, unless a formulary exception is granted. If the pharmacist refuses to fill the prescription, it is likely because the plan does not cover the drug on the formulary, and the pharmacist will usually contact the physician to switch to an acceptable formulary drug. In some cases, the pharmacist will not fill the prescription because a potential medication-related problem has been identified and the pharmacist wants to contact the physician before filling the prescription.

If the pharmacist cannot contact the physician to obtain approval to switch from a non formulary drug to a formulary drug, and the beneficiary agrees to the switch if the physician does, then some standard procedure should be put in place to allow the pharmacist to dispense an emergency supply of the prescription medication as written until the physician can be contacted. The plan should pay the pharmacist for this non formulary prescription and the beneficiary should be charged the formulary cost sharing amount for this drug.

Should the physician later determine that the formulary drug would be acceptable, then the pharmacist should create a new prescription and dispense the formulary drug to the beneficiary. If the physician wants the non-formulary drug, then the physician or the beneficiary must file a separate written document to initiate the coverage determination process. The pharmacist cannot be in the position to provide written documentation regarding a coverage determination in a busy pharmacy filling potentially hundreds of prescriptions each day. Such a process would be compounded by the potential for many Medicare beneficiaries to be using that same pharmacy, all attempting to appeal coverage determinations at the same time. It is important to note that a pharmacist refusal to fill a prescription may be based on clinical grounds, but may also be based on the fact that the plan will not pay for the prescription (or the quantity requested) because of formulary structure or plan design. These components are often out of the control of the pharmacy provider.

Based on our understanding of the process, the PDP will have up to 14 days to make a determination on a coverage request, even if an expedited request has been filed. This coverage request could occur, for example, if a plan is changing formulary drugs, or if the physician wants to switch the beneficiary to a drug that is on a different formulary tier or not on the formulary at all. In the former case, given that plans have to maintain formulary status of drugs for 30 days after a notice of change, it would seem likely that a beneficiary could resolve the coverage appeal by the 30 day lapse. It is not clear what would happen in the other case, where the physician wants to switch to another non formulary drug (or different tier drug). Would the beneficiary continue on the formulary medication until the switch is approved? What if the

beneficiary would continue to experience adverse effects from the formulary medication that they are taking, and should be switched to the non-formulary medication. We believe that all these decisions must be communicated to pharmacies through the real time claims adjudication system, and/or that a standard acceptable procedure should be in place to require plans to pay for an emergency supply of a non-formulary or higher-tier medication until the appeals process can be resolved. We are genuinely concerned that the number of appeals that are possible as this new program phases in – especially among the dual eligibles – can create significant patient care issues for beneficiaries and administrative and patient care issues for pharmacists.

III. Subpart O. Intermediate Sanctions

Sections 423.750 through 423.760 relate to the imposition of intermediate sanctions against PDP sponsors that violate Medicare Part D standards. RITE AID supports these sanctions. Without intermediate sanctions, the only penalty available in many situations would be termination of the PDP Sponsor's Medicare contract, which would result in major inconvenience and disruption for beneficiaries enrolled in the PDP Sponsor's plan.

CMS requests comments on "whether closing enrollment should be used in any situation or should we generally rely on civil monetary penalties as a sanction for PDPs." RITE AID believes that freezing a PDP Sponsor's enrollment activities should be one of the intermediate sanctions available to CMS. We understand the concern that freezing enrollment reduces beneficiary choices, and therefore we agree that enrollment freezes should be used sparingly, especially in regions where there are only two PDP sponsors. However, freezing enrollment should remain a potential sanction in order to deter violations of the rules by PDP sponsors. Freezing enrollment is a particularly appropriate sanction when a PDP Sponsor violates Medicare enrollment rules. For example, proposed section 423.752 lists "cherry picking" of enrollees and other enrollment violations as bases for imposition of intermediate sanctions. In those situations, freezing enrollment is an appropriate sanction. Otherwise, without an enrollment freeze beneficiaries the PDP Sponsor could continue to enroll beneficiaries pursuant to policies that violate Medicare enrollment standards.

IV. Subpart P – Premiums and Cost Sharing Subsidies for Low Income Individuals

The new Medicare Part D program will shift almost all dually-eligible Medicare beneficiaries (i.e. those also eligible for Medicaid) to the new Part D plans to obtain their prescription drug coverage. Unlike the case with Medicare beneficiaries that are not subsidy eligible, plans are prohibited from creating different deductible or cost sharing requirements other than those established by law for Medicare beneficiaries below 150 percent of poverty (i.e. $1 generic/$3 brand in 2006 for those up to 135 percent of poverty; $2 generics/$5 brands in 2006 for those up to 150 percent of poverty). That is, plans are prohibited from creating actuarially equivalent benefit plans for these individuals.

For that reason, because there cannot be differential cost sharing or “actuarially equivalent” plans for these individuals, any pharmacy (in network or out of network) that wants to provide prescription services for these individuals should be able to do so, as long as they meet the other terms and conditions of the contract. Allowing dual eligible Medicare beneficiaries to

obtain their prescription drugs from any pharmacy in the network will help assure appropriate pharmacy care for these individuals, many of whom do not have the means to travel long distances to "in network" retail pharmacies to obtain their prescription medications and pharmacy services.

Plans should be discouraged from using mail order pharmacies for these low-income populations, and should be prohibited (as they are for non dual eligibles) from varying the cost sharing amounts for these individuals to encourage the use of mail order pharmacy over retail pharmacy. There also should be no additional payment required from these individuals to obtain the same benefits (same quantity of medication) from retail pharmacy as through mail. This could possible make it prohibitive for these beneficiaries to obtain their medications from retail pharmacies.

Waiver of Copays for Low Income Beneficiaries: Neither the proposed rule or the preamble discusses implementation of an important part of the MMA regarding the conditions under which pharmacists can waive cost sharing for Medicare beneficiaries in Part D plans. The law allows the waiver or reduction by pharmacies of any cost sharing under the program under 1860D-42(e). This waiver is included in the section of the Medicare law that prohibits providers from offering inducements to beneficiaries to encourage them to obtain a service or product from the provider.

Under this provision, a pharmacy can waive the copayments if three conditions are met: the waiver is not offered as any part of advertisement or solicitation; the pharmacy does not routinely waive coinsurance or deductible amounts; and the pharmacy waives the coinsurance or deductible after determining that the individual is in financial need or fails to collect the coinsurance or deductible amounts after making reasonable collection efforts. For low income subsidy eligible individuals, the pharmacy only has to meet one condition: the waiver cannot be offered as any part of advertisement or solicitation. We believe that this issue should be addressed in the final regulation, if nothing more than to restate the law, so that pharmacies will have reaffirmed for them that they can waive cost sharing amounts under certain conditions. We are concerned that without this restatement of the law in the final regulation that it could make it more difficult for pharmacies to waive copays if they so choose.

V. Subpart Q - Guaranteeing Access to a Choice of Coverage (Fallback Plans)

Sections 423.851 through 423.875 establish requirements relating to fallback plans in PDP regions where two choices of plans are not available to Medicare beneficiaries. RITE AID supports the establishment of a fall back option for Medicare beneficiaries in regions (or areas of regions) where two choices for prescription drug coverage do not exist. We support the regulation's requirements that CMS be prohibited from contracting with a national fallback plan. This will allow more regional or local entities that have expertise in pharmacy benefits administration to be able to win contracts as a fallback plan.

RITE AID believes that the final rule should make clear that fallback entities have to comply with all the other access and quality standards that risk-bearing PDPs as well as MA-PD plans have to comply with. These include pharmacy access standards, mail order equity

requirements, electronic prescribing, out of network pharmacies, standard benefit card, medication therapy management, and others. These requirements should be explicitly stated in the final regulation.

To encourage traditional PBMs to serve as "risk bearing" entities, CMS should only allow pharmacy benefit administrators (PBA) to serve as fallback plans. These entities serve as traditional administrators of prescription drug programs, rather than the PBM entities that have evolved from the PBA model. This PBA model for the fallback plans would also prevent the conflict of interest that exists when a PBM owns and operates its own mail order facility. This situation encourages the PBM to shift beneficiaries away from their retail pharmacy to mail order pharmacy where the PBM collects significant rebates from manufacturers. The contract terms that we suggest above in the section relating to standard contracts should also be incorporated into a standard contract that would be offered by a fallback plan to a pharmacy.

CMS requests comments on how CMS should assess the performance of fallback plans, such as identifying the measures to determine whether fallback plans are containing costs, assuring quality, administering the benefit program efficiently, and providing customer service. We provide comments on potential performance measures for each of these areas.

Containing Costs: Fallback plans, like risk-bearing PDPs, should develop programs and drug formularies that help encourage the use of generics. These programs would include differential generic dispensing fees, as well as cost sharing to encourage generic use. Fallback plans, like risk-bearing plans, should also demonstrate that the majority of the discounts that they obtain on prescription prices are derived from drug manufacturers, not retail pharmacies, and passed through to the Medicare beneficiary in the form or lower prices or premiums. Failure to pass along all discounts from pharmacies and manufacturers would be a direct violation of the Federal Anti-Kickback Statute in a non-risk-bearing entity. The fallback plan must be reimbursed only the administrative fees and performance incentives, not reap profit from the reduced price of the pharmacy products/services.

While CMS has expressed interest in using a value like Average Sales Price (ASP) or Average Wholesale Price (AWP) to measure cost performance of these fallback plans, these references would measure the average price for each drug, for each plan, for designated time periods. It does not measure a plan's efforts or effectiveness in controlling costs but merely reports the price negotiated for a drug. Moreover, there are various AWPs for brand name drugs. (i.e. repackaged drugs that are commonly used in mail order have higher AWPs, but greater discounts, making it appear that the plan is offering the payer a better deal at mail order than retail.)

A more valuable measure that takes into account not only the price and discounts a plan negotiates, but also measures a plan's cost control efforts to minimize costs is the per member per month (PMPM) cost. PMPM aggregates all of a plan's measures to reduce the cost of providing prescription services to enrollees. This includes price discounts, the use of generics, step therapy, monitoring utilization, conducting drug utilization review, and the discontinuance of prescriptions identified as unnecessary or that duplicate therapy. Like risk-bearing plans,

these fallback plans should also provide bonus payments to pharmacies for performing cost management functions, such as formulary management and step therapy protocols.

Quality Performance Measures: Measures of a plan's quality efforts to avoid drug interactions and over utilization should be based, not on the number of warnings it discovers and sends to pharmacists but, on how often these warnings actually result in a therapy or utilization change. Almost all pharmacies have these types of electronic quality assurance and improvement programs incorporated into their prescription processing systems, so most pharmacies will be able to perform these functions. Plans (or their administrators) use electronic system edits to alert pharmacists to a whole host of situations that could affect a patient's therapy. Pharmacists, none-the-less, follow up these alerts with prescribers and patients and review the alert information and the patients' therapy.

Most of these alerts are determined to be inaccurate or non applicable and thus do not result in any therapy or utilization modifications, but does take up considerable time of pharmacists and prescribers. Plans should not be rewarded for generating large numbers of frivolous alerts that are not germane to a patient's treatment, just to inflate the plan's reported frequency of intervention alerts. The fallback plan should be able to provide information to pharmacists about prescriptions that a beneficiary may have filled at other pharmacies so that pharmacists can make an informed clinical judgment about the appropriateness of the new prescription, and work with the physician to make any modifications if necessary.

Benefit Administration: Any fallback plan should have to have a state of the art, contemporary infrastructure to support the processing and adjudication of prescription drug claims billed by pharmacies. These include being able to adjudicate claims using the online real-time NCPDP prescription processing standard, provide periodic reports and updates to pharmacies on prescription claims billed and paid, and pay pharmacists promptly, preferably by electronic funds transfer.

These plans also should maintain a call center for beneficiaries and pharmacies, as do risk-bearing plans. The call center should be measured by how quickly it answers beneficiaries and pharmacists calls, and how frequently it provides the correct answers. RITE AID believes that, should plans be able to access payments from CMS by "debiting" an account established for them, then payments to pharmacies should be turned around as quickly as the fallback plans collect payments from CMS. Plans should not be allowed to earn money on the payments due pharmacy providers.

RITE AID believes that these fall back plans, while not risk-bearing entities, must meet certain minimum standards for being successful at operating prescription drug insurance program. For example, CMS should establish some standards for operational longevity in the marketplace (i.e. operated for 3 years in the marketplace), ability to process prescription drug claims (i.e. has experience processing 3 million prescription claims or more), and adequate financial solvency and capital requirements. These plans should be well established in the market to avoid the possibility that they will not be able to meet the operational and financial demands of being a fallback plan. This would create significant access issues for beneficiaries since there would likely be no other Part D plans available in that particular area. Finally, CMS should

hold a public solicitation conference regarding more specific components of and expectations of fallback plans so that interested parties can provide input on the structure of this component of the program.

Subpart S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

This part of regulation describes the procedures by which subsidy eligible individuals will become aware of how they apply for these subsidies, and the responsibilities of the various state and Federal agencies to enroll these individuals.

The proposed regulation indicates that states must make available low income subsidy application forms no later than July 2, 2005. We believe that retail pharmacies can help identify those individuals that are eligible for low income subsidies and provide them with any applications that they might need. Millions of Medicaid recipients will be affected by this transition from Medicaid and Medicare and we believe that pharmacies can help provide information to Medicaid recipients about what they need to do to retain their drug coverage after January 1, 2006. We encourage CMS and plans to work with pharmacy providers regarding outreach to subsidy-eligible Medicare beneficiaries.

RITE AID is particularly concerned about the impact of this Part D drug benefit on dual eligible Medicare beneficiaries who have traditionally received their drug coverage through the state Medicaid program. The Medicaid program in each state has traditionally offered a relatively uniform drug benefit, has not required mail order for maintenance medications, has allowed freedom of choice of pharmacy, and has not subjected beneficiaries to strict formularies. Requiring beneficiaries to make these complex choices among Part D drug plans in their region may result in many not making a choice of drug plans during the early stages of the open enrollment period.

Many of these dual eligible enrollees will likely have to be automatically enrolled in the early part of 2006, but we are concerned that many dual eligibles will find themselves without prescription drug coverage on January 1, 2006. This can create serious health implications for Medicare dual eligible beneficiaries, and CMS should allow these dual eligible beneficiaries to have a transition period of no less than six months into 2006 to allow for a transition to this new drug benefit. We would urge that automatic enrollment of these individuals begin no later than December 1, 2005 so that we can be certain that these individuals will have drug coverage on January 1, 2006. We also urge CMS to include pharmacies in any educational efforts that may be started next spring to reach these dual eligible individuals so they can both obtain the subsidies for which they might be eligible, as well as get enrolled in a Part D prescription drug program.

States should continue to receive FMAP during this transition period to assure that pharmacy service to this critical population is not disrupted. RITE AID is also seriously concerned about the potential disruptions in care that may result in 2006 by transitioning these low income individuals to drug that they may have been receiving from their Medicaid program to drugs that are on their new PDP or MA-PD plan's formulary. This could involve hundreds of

thousands of calls to physicians to obtain authority to switch drugs, further justifying some type of special transition period for dual eligible Medicare beneficiaries who are transitioning from the Medicaid program.

As an alternative, CMS should consider requiring Part D plans to pay for a continuation of a dual eligible's existing drug therapy through the first six months of 2006 or until the individual can select a plan that is appropriate for them in terms of the drugs covered on the formulary. This extended time will also allow for the pharmacist to work with the physician to execute any formulary switches that are necessary, and exhaust any appeals process that might be initiated. This will also allow for a gradual switching of medications in the most logical clinical order if the dual eligible has to be switched from several existing drug therapies to several new drug therapies.

We are concerned that the benzodiazepine category of drugs may be excluded by Part D plans. The MMA law and regulation consider these drugs to be "excludable". Many Medicare beneficiaries likely take these medications, because they are safe, cost effective medications to treat such conditions as insomnia and anxiety. It is not clear what physicians might substitute for these drugs. The only way that beneficiaries can obtain these medications are if they pay for them or if they purchase (or are offered through an employer or state-based program) a supplemental Part D plan or wrap around that covers these drugs. We interpret the regulation at 69 CFR 423.906(C) as allowing state Medicaid programs to pay for these excludable medications, such as benzodiazepines, and collect Federal matching funds to help defray the cost.

III. Collection of Information Requirements

The information collection requirements regarding notice of formulary change seems to only envision that physicians, pharmacists and beneficiaries are notified by mass mailing. We believe that plans should be required to notify our corporate headquarters of these changes too, and that they develop a system to send these changes electronically to minimize the amount of paper that is sent to pharmacies.

We appreciate the opportunity to submit these comments and look forward to continued dialogue with CMS to assure that the Part D prescription drug program is implemented consistent with Congressional intent. Thank you.

Sincerely,

Mark de Bruin
Senior Vive President, Pharmacy Services
Rite Aid Corporation

Submitter : Dr. Meredith Aull **Date & Time:** 10/04/2004 03:10:40

Organization : Dr. Meredith Aull

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

As pharmacists working in transplantation and as members of the Immunology and Transplantation Clinical Specialist Network of the American Society of Health-System Pharmacists (ASHP), we would like to take this opportunity to comment on the proposed regulations for Medication Therapy Management Programs (MTMP).

Please see attached document.

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

Section 1860D4(c)(2)(A)(ii) of the Act states that MTMP services will be provided to 'targeted individuals', which is defined as patients with multiple chronic diseases, multiple Part D covered drugs, and likely to incur a certain level of annual costs. We encourage you to include solid organ transplant recipients as targeted beneficiaries under MTMP. Transplant recipients that receive Medicare benefits include kidney transplant recipients as well as solid organ transplant recipients over the age of 65 or with disabilities. Before and after transplantation, these patients often have multiple chronic conditions such as cardiovascular disease, diabetes, hypertension, and hyperlipidemia. Complex medication regimens are required to manage these multiple medical conditions and the transplant-specific conditions. These medication regimens often contain many high-cost medications and the medications require intensive monitoring.

Clinical pharmacists specializing in transplantation have a vital role in the management of this patient population in both the inpatient and outpatient setting. We work closely with the transplant surgical and medical teams not only to formulate appropriate immunosuppressive medication regimens, but also to manage medications for the co-morbid illnesses.

Many services that transplant pharmacists provide to transplant recipients fall under the categories defined in Section 1860D(4)(c)(2)(B). The transplant pharmacist is a healthcare professional focused on assessing the patient health status in relation to medications, adverse effects of those medications, and the unique patient-specific factors that may alter response to therapy or predispose patients to adverse events.

Many transplant pharmacists undergo post-graduate residency and/or fellowship programs that provide training in devising the safest, most efficacious, and most cost-effective regimen. These medication regimens require intense therapeutic drug monitoring and dose modification, evaluation of various side effects of the medications, and management of drug-drug interactions. Pharmacists spend a great deal of time educating patients and their families about these complex medication regimens. This is essential in order to minimize adverse drug events and drug-drug interactions, and to ensure patient compliance with their medication. This is also necessary to avoid emergency room visits, hospital readmissions and unnecessary physician office visits. Patient compliance is often sub-optimal in transplant recipients, due to complexity of the drug regimen, misunderstanding about the devastating impact of non-compliance, and the high cost of the medications. In order to avoid non-compliance, we work closely with social workers, financial coordinators, and other healthcare professionals to ensure that the patient has access to the necessary medications. Collaborative practice agreements are an obvious next step for pharmacists who participate in the care of these transplant recipients.

ELIGIBILITY, ELECTION, AND ENROLLMENT

CMS-4068-P-893-Attach-1.pdf

CMS-4068-P-893-Attach-1.pdf

CMS-4068-P-893-Attach-1.pdf

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

Re: CMS – 4068 – P

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Recently, the United Network of Organ Sharing (UNOS), the governing body for solid organ transplant programs, recommended that transplant pharmacists be included as integral members of the transplant team. Based on the information presented above and the recommendations by UNOS, we request that solid organ transplant recipients be included as beneficiaries, since we believe it is obvious that these patients have much to gain from Medication Therapy Management Programs. Thank you for your consideration of this matter.

Sincerely,

Meredith J. Aull, Pharm.D.
Network Facilitator, 2004 – 2005

Agnes Lo, BSP, Pharm.D.
Network Facilitator 2003 – 2004

Immunology & Transplantation Clinical Specialist Network of ASHP

CMS-4068-P-894

Submitter : TEST TEST **Date & Time:** 10/04/2004 02:10:56

Organization : TEST TEST

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment. -TEST

CMS-4068-P-894-Attach-1.doc

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

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CMS-4068-P-895

Submitter : Mr. Walter Herbster **Date & Time:** 10/04/2004 02:10:22

Organization : Mr. Walter Herbster

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Under Subpart C, please revise the pharmacy access standards to ensure that plans meet the TRICARE pharmacy access requirements on a local (zip code) level, not on the plan's regional or "average" overall level. Requiring a plan to meet the standard on a local level is the only way to make sure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intent to provide a level playing field for community pharmacies is followed and that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

Under Subpart D, please ensure that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries.

Thank you for making the needed revisions to best serve all Medicare beneficiaries.

Submitter : Mr. Barry Scher **Date & Time:** 10/04/2004 02:10:56

Organization : Ahold USA

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

No General Comment

CMS-4068-P-897

Submitter : Mrs. Susan Sutter **Date & Time:** 10/04/2004 02:10:15

Organization : Marshland Pharmacies, Inc.

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for the opportunity to comment on this proposed regulation. I am an owner of an independent community pharmacy in rural Wisconsin. To be able to continue to serve my patients, the plans must be required to meet access standards on a local level not just meet access standards on an overall average for the plan service area.

Patients in the rural area will have even less access to healthcare if attention is not paid to allowing rural pharmacies into the plan's network. Plans that have networks with 'preferred' and 'non-preferred' status should not be able to lower a beneficiary's co-pay to drive patients to a particular pharmacy. The law was intended to allow patients to use the pharmacist of their choice.

And finally, plans must allow a community pharmacy to provide larger supply of medicines, such as a 90-day supply, and not just require the patients to use mail-order. It is impossible to answer questions and be a healthcare provider to patients when they are not able to get their medications from one pharmacy or pharmacist. Allowing or encouraging this type of disconnect for seniors, simply increass the chance for misunderstanding of medications and medication errors.

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

Without question, pharmacists are the best suited to be the providers of medication therapy management (MTM). With the frequent contact, access, and relationship many patients have to their community pharmacist, a plan should not be able to require beneficiaries to go to a specific provider that would disrupt any existing patient-pharmacist relationships. CMS must monitor the fees any plan proposes to pay for MTM to be certain they are adequately reimbursing a pharmacist for their time to provide the MTM service. Finally and ideally, the MTM service should be provided face-to-face with the patient.

Thank you for your consideration of these comments.

Submitter : Dr. Alan Corley **Date & Time:** 10/04/2004 03:10:31

Organization : Corley's Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense?s TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than ?on average? in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower

co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.

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

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

I appreciate that CMS recognizes that different beneficiaries will require different MedicationTherapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. Pharmacists are

the most accessible health care provider to Medicare beneficiaries, and the best trained to provide MTM. Pharmacists also interact with beneficiaries on a more regular basis than do other providers.

CMS-4068-P-899

Submitter : Susan Hoskins **Date & Time:** 10/04/2004 02:10:40

Organization : Princeton Senior Resource Center

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I have serious concerns about this bill as described to me by the disability community. As a social worker who has served low income mentally ill for 20 years and now focusing on seniors for 3 years, I know that switching those who are dual-elligible people from their medicaid rx benefits (no copay) to medicare (hefty copays) will mean than most go without the meds they need to stay healthy mentally and physically.

CMS-4068-P-900

Submitter : **Date & Time:** 10/04/2004 03:10:36

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Under subsection C, the pharmacy access standards need to be revised to ensure that the plans meet the TRICARE Pharmacy access requirements on a 'zip code' (local) level as opposed to regional or average overall level. By doing this, it will ensure that all beneficiaries have access to the local pharmacy of their choice. CMS should insure that Congress' intends to provide a level and fair playing field for community pharmacies and that these plans will not favor mail order pharmacies by locking them into 'preferred' Networks.
Under subsection D, Please ensure that the plans are required to include community pharmacists and community pharmacies in the delivery of MTM (medication Therapy Management) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services, face-to-face, to beneficiaries. We as community pharmacists will come into contact with and have more 'face' time with these patients which will ultimately improve their healthcare.