CMS-4068-P-701

Submitter : Mr. Paul McDonald **Date & Time:** 10/01/2004 09:10:59

Organization : The Medicine Shoppe Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

I am writing on behalf of the Pharmacists Society of the State of New York, Inc. as it relates to the Medicare Part D regulations. We have several concerns as it relates to the follow:

Negotiated Prices

Under the proposed rule, plans are required to offer beneficiaries ?access to negotiated prices for covered Part D drugs included in the plan?s formulary.? PSSNY strongly supports this requirement. Requiring plans to negotiate with manufacturers for lower prices should result in lower co-payments for beneficiaries and lower overall drug costs for the Medicare program. However, PSSNY is concerned because the regulation fails to establish minimum requirements for the amount of the discount or price concession that the plan must pass on to beneficiaries. We are concerned with the lack of specificity in this requirement. There is no guaranteed minimum discount. The amount of the discount shared with beneficiaries can vary greatly from plan to plan and from product to product. Plans could meet the requirement to offer access to negotiated prices by simply passing on one cent to enrollees.

To ensure that beneficiaries receive the bulk of the negotiated savings from the manufacturer, the final regulation should specify that a majority of the savings must be passed through to beneficiaries either directly or indirectly through pharmacies. We recommend that the Agency add a requirement to the regulation that a ?substantial portion? of the manufacturer rebates or discounts be passed through to beneficiaries. The regulation should also provide a definition for ?substantial portion? of at least 75 to 80%.

PSSNY is also concerned that the regulation is silent on how the negotiated discounts will move from the plan, to the pharmacy, and ultimately to the patient. The regulation requires plans to provide access to negotiated prices by negotiating price concessions. We expect that

plans will obtain these price concessions from manufacturers and pharmacies. However, the regulation fails to explain how the price concessions will be passed through to the pharmacy.

Under the prescription drug benefit, plans will negotiate price concessions, establish a price for each of its covered drugs, and inform participating network pharmacies of the price they should charge beneficiaries. The price set by the plan is based on the price concessions obtained from the manufacturer and/or pharmacy. However, it is important to note that the pharmacy?s cost to obtain and provide the product remains the same. The pharmacy must be reimbursed at least a portion of the difference between the pharmacy?s usual and customary price and the price negotiated by the plan. This can be accomplished by requiring plans to provide a portion of the negotiated discounts from manufacturers to participating pharmacies to compensate them for providing the drug at a lower price.

Under the proposed rule, plans are merely required to offer discounted prices on covered drugs; it does not require plans to use the negotiated discounts to reimburse pharmacies for offering drugs at lower prices. The final regulation must include language to ensure that the financial administration or adjudication process assures that pharmacies are adequately reimbursed for providing drugs at a lower price. The reimbursement must also be made to pharmacies in a timely manner.

PSSNY also requests that the Agency strengthen its reporting requirements for prescription drug plans. Under the proposed regulation, plans are required to disclose to CMS ?data on aggregate negotiated price concessions obtained from manufacturers and passed through to beneficiaries, via

pharmacies and other dispensers,? in the form of lower subsidies, or to beneficiaries as lower monthly premiums or lower drug prices. It

CMS-4068-P-702

Submitter : Mr. Nick Barsan **Date & Time:** 10/01/2004 09:10:53

Organization : Walgreens

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.
Nick Barsan

CMS-4068-P-703

Submitter : Mr. Larry Palmer **Date & Time:** 10/01/2004 09:10:22

Organization : Thrifty White Pharmacy Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As the regulations are currently written and being proposed, the community pharmacy is at risk of losing a big portion of their Medicare patient prescription business to mail order. The proposed regulations do not properly implement the TriCare pharmacy access standards that are in place today and would reduce the ability of patients to obtain their prescriptions from their local pharmacist.

The new regulations should prohibit PBMs from using economic incentives that all but force their patients to use mail order services to fill their prescriptions.

Lastly, the regulations are not specific enough in the medication therapy management program (MTM). Who would be eligible to provide these services and are the providers compensated for these services. The regulations are not specific as to the nature and scope of MTM services that the plans would have to provide.

CMS-4068-P-704

Submitter : Dr. Billie Minton **Date & Time:** 10/01/2004 09:10:47

Organization : Medication Management Center

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Dear Ladies/Gentlemen,

My name is Billie J. Minton, Pharm.D. I am a Doctor of Clinical Pharmacology and have been practicing pharmacy for over twelve years and have been in private practice for the past four years.

In February 2003, I co-wrote a Medication Counseling Bill named "Reimbursement for Pharmacists Services SB 1899 Dixon/HB 1958 Vaughn" which passed both the full Senate and House May 2003. This bill passed but with restrictions stating that anyone that takes 6 or more medications and desires medication counseling "SHOULD BE" reimbursed by their insurance company. We were hoping for "WILL BE" reimbursed to be approved. This has created many road blocks for patients. I have Medicare patients on a list waiting for medication counseling services. They are unable to afford it out of pocket due to the numerous medications they have to buy each month. I find that many of these patients are over medicated and have multiple drug interactions. These interactions are posing serious risks to their health while exacerbating their existing disease states. The United States has clearly become a nation of pill poppers! Medication counseling, disease management and wellness programs are solutions to this problem. Medications are being prescribed for side effects from other medications. More medications, more side effects, and then more medications! My company is called Medication Management Center and we are not a pharmacy with pills. My practice focuses on medication counseling, disease management and patient education. Each patient receives a written comprehensive evaluation plan which provides detailed information based on the patient's past and present medical history, symptomology, medication list, diseases, social history, exercise, diet, drug-drug and drug-disease interactions. This patient plan identifies drug related problems, cost effective solutions and teaches patients about their medications, disease states and diet. Our evaluations recommend modifications in the patient's
current regimen.

Several insurance companies are already taking advantage of this health care savings. Since Medicare does not currently recognize Pharm.D.'s Medication Managment Therapy services there are many road blocks for patients; especially patients that have both Medicare and other health insurance. Medicare is usually considered primary.
It is frustrating to know that billing Medicare for this service has to be billed under a physician's number since my specialty is pharmacology.

The PharmAssist program used by the state of Wyoming was derived from AARP and is saving millions of dollars through medication counseling and disease management by pharmacists.

Your consideration for reimbursement for pharmamists for Medication Management Therapy Services is greatly appreciated.

For more information regarding my services, please visit our website at www.medicationmanagement.net or www.takefewerpills.com

Sincerely,
Billie J. Minton, Pharm.D.
Medication Management Center
1000 E. Center ST
Suite 200
Kingsport, TN 37660
(423)378-6337 Office
(423)378-6333 Fax
www.medicationmanagement.net
www.takefewerpills.com

CMS-4068-P-705

Submitter : Mr. Tom Wells **Date & Time:** 10/01/2004 09:10:52

Organization : Mr. Tom Wells

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Being from a rural state with a large elderly population it is important that seniors will still be able to use their local pharmacy.
The new regulations must prohibit plans (PBM's) from incentivizing patients to switch to mailorder , which in my opinion, penalizes the patient and lines the pockets of the PBM's.
There must be specifics put in place as pertains to Medication Therapy Management (MTM).
Thank you,
Tom Wells

Submitter : Dr. Brad Tice **Date & Time:** 10/01/2004 09:10:04

Organization : Dr. Brad Tice

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 1, 2004

Centers for Medicare & Medicaid Services
Department of Health & 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.

? Subpart C: Benefits and Beneficiary Protections
? The benefit must require plans to meet the TRICARE pharmacy access standards on a local level, not on the plan?s overall service level. This is the only way to ensure all beneficiaries have convenient access to a local pharmacy. I am from a rural state. The needs of all beneficiaries must be met. This does not mean allowing mail order. Purported mail order savings are only smoke and mirrors put out by PBMs that own their own mail order facilities and have conflict of interest and are able to manipulate the system. The only way to protect benefits and beneficiaries is to support a system based on value being provided and not on network size or other non-quality measures. This leads to point 2.
? The preferred/non-preferred status needs to be based on value criteria, not on network size, a preferred mail-order facility owned by the PBM, etc. The benefit will be extremely costly and only encourage consumption if it is not based on VALUE!
? NO incentives for mail order! It is not less expensive. Just because the mail order people say it is so does not make it so! When consumers have equal choice, they make the smarter choice of the local care provider who can establish a trusting relationship with them. No coercion.
? Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes the need to MTM services. It needs to recognize that Pharmacists are the ideal providers of these services. Pharmacists are the trained professionals in medications and need to be able to use that expertise to benefit patients and the healthcare system. I am concerned that as written, these benefits will be swallowed up by the PBMs through call centers. I have been on a Benefits Committee and seen the employer side of these company relations. One example is where the PBM had its ?Clinical Solutions? that called for a ?50/50 cost sharing on their interventions.? The interventions were performed from a call center and claimed on reports. There was no quality assurance and the 50/50 cost savings meant that when they did an intervention and claimed it saved $1,000, they sent a bill to the employer for 50%, or $500. Additionally, this was only offered to their mail-order customers, so while the company saw the benefit, they did not extend it to the majority of patients to offer it at the community level.
? Thank you for the opportunity to comment. It is exciting to see the movement towards a value-based healthcare system. Your work is extremely important for setting the healthcare system on the right track. Pharmacists have been the most underutilized professional and can really solve a lot of the current problems with the structure to allow them to use their expertise. Please make sure that gets set up to happen for all beneficiaries and pharmacist providers.

Sincerely,
Brad Tice, PharmD
6143 Oakwood Dr.
Urbandale, IA 50322
(515)254-9329
brad.tice@drake.edu

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Protect beneficiaries by using the TRICARE pharmacy access requirements on a local level, not on the plan's overall service level.
Do not allow for preferred or non-preferred pharmacies with no requirements on number and/or value being provided. Open access is key. PDP's should not be allowed to route prescriptions to entities that they own, as in a mail facility of theirs.
Equal access, equal choice, equal plan designs for all providers.

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

Value is the key. Medication Therapy Management must be provided by pharmacists in all settings and not limited to a component of the PDP as in a mail order call center.

PAYMENTS TO PDP AND MA-PD PLANS

Please make payments based on value being provided and be subject to access to all pharmacists/pharmacies.

CMS-4068-P-706-Attach-1.doc

CMS-4068-P-706-Attach-1.doc

CMS-4068-P-706-Attach-1.doc

CMS-4068-P-706-Attach-1.doc

October 1, 2004

Centers for Medicare & Medicaid Services
Department of Health & 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.

- **Subpart C: Benefits and Beneficiary Protections**
- The benefit must require plans to meet the TRICARE pharmacy access standards on a local level, not on the plan's overall service level. This is the only way to ensure all beneficiaries have convenient access to a local pharmacy. I am from a rural state. The needs of all beneficiaries must be met. This does not mean allowing mail order. Purported mail order savings are only smoke and mirrors put out by PBMs that own their own mail order facilities and have conflict of interest and are able to manipulate the system. The only way to protect benefits and beneficiaries is to **support a system based on value being provided and not on network size or other non-quality measures.** This leads to point 2.
- The preferred/non-preferred status **needs to be based on value criteria, not on network size, a preferred mail-order facility owned by the PBM, etc.** The benefit will be extremely costly and only encourage consumption if it is not based on VALUE!
- NO incentives for mail order! It is not less expensive. Just because the mail order people say it is so does not make it so! When consumers have equal choice, they make the smarter choice of the local care provider who can establish a trusting relationship with them. No coercion.
- **Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Plans**
- I appreciate that CMS recognizes the need to MTM services. It needs to recognize that **Pharmacists are the ideal providers of these services.** Pharmacists are the trained professionals in medications and need to be able to use that expertise to benefit patients and the healthcare system. I am concerned that as written, these benefits will be swallowed up by the PBMs through call centers. I have been on a Benefits Committee and seen the employer side of these company relations. One example is where the PBM had its "Clinical Solutions" that called for a "50/50 cost sharing on their interventions." The interventions were performed from a call center and claimed on reports. There was no quality assurance and the 50/50 cost savings meant that when they did an intervention and claimed it saved $1,000, they sent a bill to the employer for 50%, or $500. Additionally, this was only offered to their mail-order customers, so while the company saw the benefit, they did not extend it to the majority of patients to offer it at the community level.

- Thank you for the opportunity to comment. It is exciting to see the movement towards a value-based healthcare system. Your work is extremely important for setting the healthcare system on the right track. Pharmacists have been the most underutilized professional and can really solve a lot of the current problems with the structure to allow them to use their expertise. Please make sure that gets set up to happen for all beneficiaries and pharmacist providers.

Sincerely,
Brad Tice, PharmD
6143 Oakwood Dr.
Urbandale, IA 50322
(515)254-9329
brad.tice@drake.edu

Submitter : Ms. Karen Reitan **Date & Time:** 10/01/2004 09:10:21

Organization : AIDS Foundation of Chicago

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

In regards to the relationship between Medicare drug beneficiaries and the AIDS Drug Assistance Program (ADAP), we urge CMS to reconsider guidance that prohibits the use of ADAP as supplemental coverage for inadequate plans. We recommend that ADAP be allowed to fill gaps left by drug plans that do not include the full range of HIV/AIDS treatments, thus ensuring that beneficiaries have access to appropriate medical care. We also recommend that CMS allow ADAP funds to be used for premiums, deductibles, cost-sharing, and expenditures required during the ?doughnut hole? period to ensure that the poorest and most vulnerable Medicare beneficiaries will be denied coverage because they cannot afford it. Finally, we strongly recommend that CMS allow states to count state-appropriated ADAP funds towards incurred costs in the same way that State Pharmaceutical Assistance Programs will be allowed to do.

?423.120?We strongly recommend that CMS designate recipients with HIV/AIDS as a special population requiring access to an open formulary. The advances in HIV/AIDS treatment seen over the last decade have made clear that people living with HIV/AIDS must have unrestricted access to all available medications. The challenges of treating HIV infection including side effects, poor or harmful drug interactions, co-morbidities, and drug resistance require that physicians are able to change a patient?s prescription as needed. Anti-retrovirals and other drugs used to treat HIV infection are not interchangeable and the complexity of the disease and benefits of treatment demand that beneficiaries have access to all available treatment options.

?423.120(B)(1)?Policies that determine drug formularies must be informed by experts in the field of HIV/AIDS. We support the recommendation by CMS that the Pharmaceutical and Therapeutic (P&T) Committees have greater independence, authority and increased representation by specialized medical providers. Although we agree that these committees should have the authority to make binding formulary decisions, we are concerned that the committees will not be staffed by medical providers who understand the complexity of HIV/AIDS treatment. Requiring at least one independent physician and one independent pharmacist on each committee does not ensure an expertise in HIV/AIDS, and we recommend that CMS require that each P&T Committee include representation from those who specialize in the treatment of HIV.

ELIGIBILITY, ELECTION, AND ENROLLMENT

?423.30(d)(1)?Individuals who are dually eligible for Medicare and Medicaid must not be limited to the ?average cost plan.? Dual eligibles are the most vulnerable individuals impacted by the MMA. The are the sickest and poorest Medicare recipients, and need the most options available to ensure that they can access all FDA-approved HIV/AIDS treatments. By limiting the federal premium subsidy to that of the average cost, these rules prevent dual eligibles from choosing the plan that best suits their needs. We recommend that dual eligible participants be exempted from premiums associated with enrolling in the plan that they, in consultation with the doctor, determine is most appropriate. If a premium must be charged, we recommend that states be allowed to pay them.

?423.44(d)(2)?Protections against disenrollment must be strengthened. The provision allowing drug plans to disenroll beneficiaries for ?disruptive, unruly, abusive, uncooperative or threatening? behavior is unclear and gives too much power to drug plans. There is nothing to prevent a plan from labeling a client?s behavior as disruptive when they are merely questioning the drug plans coverage or operating procedures. We recommend that protections be provided to address this issue and to address recipients whose disruptive or threatening behaviors may be attributed to drug interaction, mental illness, or diminished mental capacity caused by HIV/AIDS or another medical condition.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

The grievance procedures outlined in this section are not adequate and place beneficiaries with HIV/AIDS in danger of interrupted treatment. We recommend that MMA grievance procedures be similar to those allowed to Medicaid recipients and include both mandatory and enforceable

provisions allowing for continued treatment during an appeal and notification of the reasons for which medications were denied and an explanation of the right to appeal.

CMS-4068-P-707-Attach-1.doc

CMS-4068-P-707-Attach-1.doc

CMS-4068-P-707-Attach-1.doc

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

Dear Mr. McClellan:

On behalf of thousands individuals living with HIV/AIDS in Illinois who will be impacted by the Medicare Modernization Act (MMA), the undersigned organizations are sending public comment on docket number CMS-4068-P, Medicare Program; Medicare Prescription Drug Benefit. We appreciate the opportunity to provide this feedback. Our comments will address the following sections of the rules: Eligibility and Enrollment; Benefits and Beneficiary Protections; and Grievances, Coverage Determinations, and Appeals.

Subpart B—Eligibility and Enrollment:

§423.30(d)(1)—Individuals who are dually eligible for Medicare and Medicaid must not be limited to the "average cost plan." Dual eligibles are the most vulnerable individuals impacted by the MMA. The are the sickest and poorest Medicare recipients, and need the most options available to ensure that they can access all FDA-approved HIV/AIDS treatments. By limiting the federal premium subsidy to that of the average cost, these rules prevent dual eligibles from choosing the plan that best suits their needs. We recommend that dual eligible participants be exempted from premiums associated with enrolling in the plan that they, in consultation with the doctor, determine is most appropriate. If a premium must be charged, we recommend that states be allowed to pay them.

§423.44(d)(2)—Protections against disenrollment must be strengthened. The provision allowing drug plans to disenroll beneficiaries for "disruptive, unruly, abusive, uncooperative or threatening" behavior is unclear and gives too much power to drug plans. There is nothing to prevent a plan from labeling a client's behavior as disruptive when they are merely questioning the drug plans coverage or operating procedures. We recommend that protections be provided to address this issue and to address recipients whose disruptive or threatening behaviors may be attributed to drug interaction, mental illness, or diminished mental capacity caused by HIV/AIDS or another medical condition.

Subpart C—Benefits and Beneficiary Protections:

In regards to the relationship between Medicare drug beneficiaries and the AIDS Drug Assistance Program (ADAP), we urge CMS to reconsider guidance that prohibits the use of ADAP as supplemental coverage for inadequate plans. We recommend that ADAP be allowed to fill gaps left by drug plans that do not include the full range of HIV/AIDS treatments, thus ensuring that beneficiaries have access to appropriate medical care. We also recommend that CMS allow ADAP funds to be used for premiums, deductibles, cost-sharing, and expenditures required during the "doughnut hole" period to ensure that the poorest and most vulnerable Medicare beneficiaries will be denied coverage because they cannot afford it. Finally, we strongly recommend that CMS allow states to count *state-appropriated* ADAP funds towards incurred costs in the same way that State Pharmaceutical Assistance Programs will be allowed to do.

§423.120—We strongly recommend that CMS designate recipients with HIV/AIDS as a special population requiring access to an open formulary. The advances in HIV/AIDS treatment seen over the last decade have made clear that people living with HIV/AIDS must have unrestricted access to all available medications. The challenges of treating HIV infection including side effects, poor or harmful drug interactions, co-morbidities, and drug resistance require that physicians are able to change a patient's prescription as needed. Anti-retrovirals and other drugs used to treat HIV infection are not interchangeable and the complexity of the disease and benefits of treatment demand that beneficiaries have access to all available treatment options.

§423.120(B)(1)—Policies that determine drug formularies must be informed by experts in the field of HIV/AIDS. We support the recommendation by CMS that the Pharmaceutical and Therapeutic (P&T) Committees have greater independence, authority and increased representation by specialized medical providers. Although we agree that these committees should have the authority to make binding formulary decisions, we are concerned that the committees will not be staffed by medical providers who understand the complexity of HIV/AIDS treatment. Requiring at least one independent physician and one independent pharmacist on each committee does not ensure an expertise in HIV/AIDS, and we recommend that CMS require that each P&T Committee include representation from those who specialize in the treatment of HIV.

Subpart M—Grievances, Coverage Determinations and Appeal:

The grievance procedures outlined in this section are not adequate and place beneficiaries with HIV/AIDS in danger of interrupted treatment. We recommend that MMA grievance procedures be similar to those allowed to Medicaid recipients and include both mandatory and enforceable provisions allowing for continued treatment during an appeal and notification of the reasons for which medications were denied and an explanation of the right to appeal.

Again, we appreciate the opportunity to provide comments on these rules, and urge CMS to consider our comments carefully. For more information, contact Karen A. Reitan at 312-922-2322.

This letter is signed by the following organizations:

AIDS Foundation of Chicago
AIDS Legal Council of Chicago
Alderman Mary Ann Smith, Chicago's 48th Ward
Central Illinois FRIENDS of PWA, Inc.
Chicago Legal Advocacy for Incarcerated Mothers (CLAIM)
Health and Disability Advocates
Howard Area Community Center
Howard Brown Health Center
Hyde Park Union Church
Medical Advocates for Social Justice
Winnebago County Health Department

Submitter : Dr. Louis Achusim **Date & Time:** 10/01/2004 09:10:07

Organization : UNM Health Sciences Center

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

September 30, 2004

Mark McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4068-P

Dear Administrator McClellan:

I write today to offer comments regarding the proposed Medicare Part D rules. As the Executive Director of Pharmaceutical Services and Associate Professor, College of Pharmacy, University of New Mexico Health Sciences Center (UNMHSC), I have a deep concern about the rules as currently proposed, as they are likely to negatively impact the services provided to Medicare beneficiaries.

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

BENEFITS AND BENEFICIARY PROTECTIONS

1. Plans should be required to offer standard contract language to all pharmacies willing to participate in the program as a prescription and MTM services provider. Plans need to make it easy for patients to have convenient access to their pharmacy of choice. They should not be able to limit the number of pharmacy providers as this would negatively impact patient access to needed medications and pharmacy services. New Mexico has several rural counties where access to health care is often limited and pharmacist is the only available healthcare provider. The isolation and transportation issues faced by the elderly may be exacerbated if access is defined at the county or regional level. Furthermore, in order to provide the highest quality care and service to Medicare beneficiaries who receive their care at UNMHSC, it is absolutely essential that our pharmacies are able to dispense medications to beneficiaries as an approved/preferred pharmacy provider.

2. Punitive co-payment formula should not be utilized to coerce beneficiaries into using "preferred" pharmacy providers solely on the basis of pricing or cost. This will provide incentives for beneficiaries to use low cost, low quality providers and ultimately may increase healthcare cost. While steering patients to a limited number of pharmacies that are willing to accept deep-discounted reimbursement rates may result in reduced ?drug-silo? costs for the plan, which under the current legislation may in fact be in the plan?s best interest as they may only be at risk for pharmaceuticals cost, this savings will undoubtedly be offset by much higher medical costs to Medicare as a result of poor quality pharmaceutical care, poor patient medication therapy management and medication regimen non-compliance.

3. CMS must act responsibly by assuring an adequate reimbursement formula that at a minimum covers the average cost of filling a prescription or providing a service.

4. CMS should encourage plan sponsors to provide beneficiaries incentives to use ?preferred? pharmacies over others based on well defined and evidence based pharmaceutical care and MTM services for patients. It would be advantageous for all pharmacy providers to strive to achieve and adhere to the defined quality standards and be designated ?preferred? MTM service provider when those standards are achieved.

5. If mail order service is offered, the quality of its services must be same as those of non mail order pharmacies, drugstores, hospitals, etc.

6. To prevent conflict of interest, plan sponsors should be prohibited from promoting or requiring the use of pharmacies in which they have an ownership interest.

ELIGIBILITY, ELECTION, AND ENROLLMENT

1. All pharmacists must be afforded the opportunity to provide MTM, pursuant to Medicare Part D. Pharmacists at UNMHSC are an integral part of the healthcare team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve patient outcomes, but also dramatically lower total healthcare costs by avoiding unnecessary hospitalizations, emergency room and clinics visits and excessive utilization on ancillary services ? pharmacy, radiology, laboratory and durable medical equipments. Some of the services provided by pharmacists at UNMHSC include 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, renal failure and dialysis patients management, heart failure patients management and psychiatric patients management.

2. All pharmacists practicing within a region, practice settings notwithstanding, should be afforded the opportunity to provide and be paid for MTM services. Plan sponsors should be directed by CMS to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service. Furthermore, all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

3. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required by CMS to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services.

4. Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services and be eligible to provide MTM services to these patients. Identification of targeted beneficiaries should not be left solely to the health plan. Health plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. MTM service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription.

5. MTM services should be able to be provided in conjunction with and/or above and beyond medication dispensing.

6. An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.

7. Plan sponsors should be required to establish a CMS-specified set of MTM services, similar to diagnosis related groups (DRG). The specified set of services should be the floor not the ceiling, as additional services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management, elderly patients medication management, and adverse drug event assessment and prevention should be included.

8. CMS should consider developing a program to accredit plans that agree to meet the above stated conditions that add value to and lower healthcare cost.

GENERAL PROVISIONS

In order for this program to be successful, I urge CMS to incorporate rule language that will

ensure compensation for all pharmacy providers that perform medication therapy management (MTM) services and allow for all willing pharmacies to serve as a prescription product provider for Medicare beneficiaries. Below are specific and detailed recommendations for the rules concerning MTM services and prescription access that will ultimately help provide high quality healthcare to the patients:

CMS-4068-P-709

Submitter : Dr. Charles Turck **Date & Time:** 10/01/2004 09:10:41

Organization : Walgreen Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I greatly appreciate the chance to comment with respect to the proposed drug benefit-inclusive expansion of existing Medicare law.
With regard to Subpart C, I respectfully request a revision to the pharmacy access standards stipulating that plans meet the TRICARE pharmacy access requirements on a local level, as opposed to the plan's regional or "average" overall level. Mandating that a plan meets more local standards empowers all beneficiaries with choice of access to a local pharmacy. Oversight to the contrary could potentially favor mail order pharmacies.
With respect to Subpart D, I respectfully request that CMS mandates that plans are required to include community pharmacists as purveyors of Medication Therapy Management services to beneficiaries. These professionals provide an excellent means of providing such services to beneficiaries.

Thanks again for taking my comments into consideration in a fashion that may best serve all Medicare beneficiaries.

CMS-4068-P-710

Submitter : Mrs. Kathy Migita **Date & Time:** 10/01/2004 10:10:54

Organization : LACERA

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

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

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

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CMS-4068-P-711

Submitter : Mr. jim mccall **Date & Time:** 10/01/2004 10:10:57

Organization : thrifty white pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I am from a state with a small popuation with many eldererly people.
It is important for them to be able to see their pharmacists. the new plan should not penalize seniors from seeing their local pharmacist by offering cheaper prescription through PBM's. There also needs to be
medication therapy management practices put in place to show more accurately the important role community pharmacists play as health care professionals. Your consideration is appreciated. Jim McCall

Submitter : Mr. Bradley Rood **Date & Time:** 10/01/2004 10:10:04

Organization : Mr. Bradley Rood

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 am responding to the proposed rule 'Medicare Program; Medicare Prescription Drug Benefit,' 69 FR 46632. I am concerned that the current rule does not provide sufficient protection for people living with HIV/AIDS who will receive their treatment through this benefit.

CMS must designate people living with HIV/AIDS as a 'special population' and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

The importance of keeping PLWA healthy has been greatly underscored by current administration. The few pennies that are being saved now will ultimately cost a massive amount more in the future to care for these indivduals. Please understand that prevention is key to the success of battling this epidemic, and we cannot prevent what we cannot medicate.

Thank you for considering my comments as you finalize the regulations.

Sincerely,

Bradley T. Rood
2681 E. Glen Magna Way
Bloomington, IN 47401

Submitter : Mr. Michael DeVinney **Date & Time:** 10/01/2004 10:10:28

Organization : Mr. Michael DeVinney

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached

CMS-4068-P-713-Attach-1.doc

October 1, 2004

CMS,

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

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

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. I am very concerned that, notwithstanding the best intentions or efforts by CMS, these 7 million people with disabilities the Part D program will destroy their present safety net provided by Medicaid, resulting in poor health and in going into nursing homes and mental institutions to get needed medications that have become unaffordable in the community, contrary to the Olmstead and the Freedom initiative supported by CMS.

I am personally appalled that the Part D Program, touted as a benefit, could, as it is written, negate years of hard work.

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.

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

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress. So once again I ask that CMS DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES.

Thank you for your consideration of my views.

Michael DeVinney

Submitter : Mrs. Elaine Swyer **Date & Time:** 10/01/2004 10:10:46

Organization : ElderNet of Lower Merion and Narberth

Category : Social Worker

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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. Even the lowest income consumers who qualify for the full subsidy may have difficulty paying their copayments, especially if they take a high number of medications. In addition, this could be especially problematic for consumers who are unable to get an exception to have a non-preferred drug covered at the preferred drug co-pay and who may be unable to afford the higher level of cost sharing 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

Pharmacy access standards in Section 423.120(a)(1) should be based on travel time and not on mileage. In urban areas, for example, 2 miles can take two hours on public transportation. Such travel times would be unreasonably burdensome for lower-income or frail individuals. We suggest that plans be required to follow access standards based on time such that pharmacies must be within 10 minutes travel time of 90% of the consumers in an urban area, within 20 minutes travel time of 90% of the consumers in a suburban area, and within 30 minutes travel time of 75% of the consumers in a rural area. Time based standards have worked well in Pennsylvania?s Medicaid mandatory managed care program, ?HealthChoices.? Additionally, we recommend that all PDPs and MA-PDs be required to contract with pharmacies that offer home delivery service. A same-day or next day need for medications makes mail-order an impracticable solution for urgent or emergent situations.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Consumers should receive quarterly notice detailing their out of pocket costs. Additionally, there should be a procedure in place for consumers who dispute the amount of out of pocket cost recorded to challenge and correct the amount. Given the importance of out of pocket costs for the beneficiaries, there should be very clear guidelines regarding how these costs are tracked.

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

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 final regulations must also standardize the process for how new medications will be classified under a plans therapeutic class and category structure. Leaving this up to each plan to decide will lead to disparities and disparities lead to access barriers. We encourage the use of the USP for classifying new medications.

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. Notifying enrollees about formulary changes primarily through a website is simply inadequate. Too many elderly and disabled individuals 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.

ELIGIBILITY, ELECTION, AND ENROLLMENT

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.

We are pleased to see 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. Coupled with the prohibition on de jure or de facto discrimination against any disability or group, this piece will be a critical protection for our consumers with disabilities. We believe enforcement of this provision will be essential and offer comments throughout the following sections that urge clarification to insure that this intent is clear.

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.

It is unacceptable that, under Section 423.50, a plan?s marketing materials are deemed approved if CMS fails to approve them within a certain time period. Even worse, these same marketing materials from one region are then deemed approved in all other regions in which the plan operates, except for state specific information. Many of the Medicare beneficiaries to whom the Part D plans will be marketing are frail elderly, consumers with cognitive or memory impairments, persons with limited education or who have LEP. In short, they are persons who may have difficulty

understanding a complicated program like Part D, and who may be easily taken advantage of. We have seen letters sent out by Medicare+Choice plans that had been approved in Region II, which contained what could arguably be considered generic information, except that the rules for the program described were different for Pennsylvania. CMS should either craft model forms that, if used unaltered, could be deemed approved within 10 days or it must review and actively approve all materials before they go out.

GENERAL PROVISIONS

Whether through examples or more descriptive language, the definition of actuarial equivalence in Section 423.4 must be refined. The proposed definition of actuarial equivalence simply says that something is actuarially equivalent if ?generally accepted actuarial principles? make it so. Because this concept is so critical to whether a consumer has creditable coverage (Subpart B) and whether an alternative prescription drug plan (Subpart D) is comparable to a standard prescription drug plan, the definition must be more descriptive and more tangible to the consumer.

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.

Issues 11-20

FALLBACK PLANS

The final regulations must give fallback plans incentives to reduce costs. The proposed regulations create a cost-reimbursement structure which reimburses fallback plans for actual and administrative costs, giving fallback plans no apparent incentive to reduce costs. The final regulations must address this, and provisions should be designed to ensure beneficiaries will not ultimately be charged more for their drugs because there is a poor incentive structure to control costs for fallback plans. This is particularly true because a structure that allows fallback plans to overcharge will act as an incentive for companies to pursue fallback plans rather than become full PDP and MA-PD plans.

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are 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). 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.

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 allow appeals for determinations about prescription drugs if the enrollee has no further liability to pay for them and about coverage of drugs obtained from a non-network pharmacy. The proposed regulations omit an appeals process for these two important scenarios and this must be added into the final regulations.

Consumers must either be allowed to select whether they want their complaint to be treated as a grievance or appeal, or to dispute the plan?s determination. The proposed regulations state that when a drug plan gets a complaint, it is responsible for first deciding whether to send the complaint through the grievance or the appeal process, and then telling the enrollee. There must be a process to allow a beneficiary to select which process they are choosing and/or to dispute the plan?s decision on this matter.

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 where they have independently purchased or obtained the medication. This is especially critical for lower-income individuals and those with pharmaceutically complex situations. 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. Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a redetermination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless. We refer CMS to the website of the Florida Agency for Health Care Administration, http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/multi_source.shtml.

INTERMEDIATE SANCTIONS

Plans should be sanctioned for the failure to provide medically necessary services, regardless of the actual or possible adverse effect on an enrollee. The proposed regulations at Section 432.752(a)(1) state that a basis for imposing sanction is failure to provide medically necessary services, with adverse effect on the enrollee or substantial likelihood of adverse effect on enrollee. Requiring that there be an ?adverse effect? on the enrollee before a sanction can be imposed is untenable. To condition this requirement in any way with an `effects? test only encourages plans to cut corners.

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

SupPart P ? Low Income Subsidies

Family size should be defined in 423.772 to automatically include children under the age of 21 as part of the applicant group. In addition, pregnant women should be counted twice. The proposed regulations define family size to include (1) applicant, (2) a spouse who lives in residence, and (3) related individuals in the same residence who depend on the applicant or his/her spouse for at least ? of their financial support. There should be an assumption of eligibility for children under the age of 21, so as not to create a useless administrative burden to prove a child?s financial support. There should also be a provision to count pregnant women as two, to more adequately reflect the family size.
If CMS plans to design a universal application for subsidies, the regulations at 423.774 should set out standards for the application and establish a process for public comment on the application. The comments to the proposed regulations state that CMS will be designing one model application form that will be able to assess for all subsidies. This form is not mentioned in the regulations, and there is no provision for the public to view and/or comment on that form.

The regulations should clearly set limits as to how telephonic proxy designations can be made and acted upon, to protect vulnerable enrollees. In addition proxy certifications should only apply to the accuracy of the proxy?s transcription, and not to the accuracy of the underlying information. The proposed regulations create a proxy signature process. This process raises two concerns. First, inconsistencies between the regulations and the comments to the regulations, leave us unclear as to when proxies will be allowed to take telephonic applications on behalf of clients. The regulations should be clear, in order to protect applicants from improper/inaccurate solicitations via telephone by private companies which attempt to gain their consent to apply for benefits, particularly in light of the fact that some choices (for example plan choice) for some consumers will be choices they are `locked? into for the year. Second, the regulations require proxies to certify the accuracy of the information they are communicating to CMS or the state administrator. This standard must be changed to certification of the accuracy of the proxy?s transcription of the information as provided by the applicant. Otherwise, there will be a great chilling effect on the number of legitimate proxies willing to assist enrollees.

The regulations at 423.780 must require plans and/or CMS to provide clear notice to consumers about set premium standards, such as ?benchmark? premium levels, so consumers can evaluate plans with full understanding of their premium options and liability. The regulations also must place clear responsibility upon plans ? subject to punishment for noncompliance ? to ensure that enrollees always receive the most favorable base-premium calculation, as per the proposed regulations. The proposed regulations allow full reimbursement for subsidy premiums for full subsidy eligibles, up to the greater of certain complex premium level calculations (for example, ?benchmark premiums?, which are based on a weighted average of basic premiums). This presents two problems for enrollees. First, they have no way of understanding what the set premium limit will be at any time. Notice about premium levels, such as the benchmark premium, should be provided to clients so that they can choose plans with a full understanding of how much of their premium will be subsidized. Second, even if clients do understand what the premium calculations are, it is not clear in the regulations how the requirement to apply the greater of the calculation options will be applied and enforced. The regulations need to place a clear responsibility on plans to ensure enrollees are informed and provided with the greater premium calculation option.

CMS-4068-P-714

SPECIAL RULES FOR STATES

That States must require a personal representative applying for a low-income subsidy to certify under penalty of perjury as to the accuracy of the information provided within will single-handedly halt outreach and enrollment activities by social workers and community service organizations. The definition of personal representative does not refer only to persons with power of attorney or guardians with legal authority and obligation to sign in an applicant?s stead. As written, the proposed regulations at Section 423.904 (d)(2)(ii) would expose any agency, volunteer, SHIP program staff, friend or neighbor to legal liability.

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CMS-4068-P-714-Attach-2.doc

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Comments to the Proposed Medicare Prescription Drug Regulations
File code CMS-4068-P
Subpart A to Subpart S

Submitted electronically by Elaine Swyer, Projects Director of ElderNet of Lower Merion and Narberth on October 1, 2004

Subpart A—General Provisions

Whether through examples or more descriptive language, the definition of actuarial equivalence in Section 423.4 must be refined. The proposed definition of actuarial equivalence simply says that something is actuarially equivalent if "generally accepted actuarial principles" make it so. Because this concept is so critical to whether a consumer has creditable coverage (Subpart B) and whether an alternative prescription drug plan (Subpart D) is comparable to a standard prescription drug plan, the definition must be more descriptive and more tangible to the consumer.

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 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.

We are pleased to see 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. Coupled with the prohibition on de jure or de facto discrimination against any disability or group, this piece will be a critical protection for our consumers with disabilities. We believe enforcement of this provision will be essential and offer comments throughout the following sections that urge clarification to insure that this intent is clear.

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.

Auto-enrollment of dual eligibles into PDPs as proposed in Section 423.34(d) should occur on November 15, 2005, not May 15, 2006. While we understand that the initial enrollment period runs from November 15, 2005 to May 15, 2006, we are gravely concerned about full dual eligibles who will lose Medicaid prescription drug covered on January 1, 2006. Dual eligibles should be auto-enrolled immediately to insure that they maintain access to drug coverage. 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, we suggest 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.

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.**

We suggest adding "but no later than the 1st day of the second calendar month following the month of the request for the enrollment change" to the end of Section 423.38(c).

We 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. For example, a consumer knows she has creditable coverage but that it is ending in December when she leaves her job. The person does not disclose it because her PDP enrollment effective date is January 1 by which time the creditable coverage was to have ended. Instead, the employer decides not to terminate the creditable coverage until January 31st. In such a case, the consumer should be allowed to cure and obtain payments from their other coverage, or make out-of-pocket payments to the PDP to remain in her plan. This person should not be disenrolled and it is insult to injury to deny this person a SEP if she is disenrolled.

There is an error in Section 423.44(b)(1). The provision referring to the disenrollment of an individual who has engaged in disruptive behavior should be cited as Sec. 423.44(b)(1)(ii) rather than Sec. 423.44(b)(1)(i) because 423.44(b)(1)(i) refers to disenrolling an individual when any monthly premium is not paid on a timely basis.

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 disenroll 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. We are 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 final regulations for Section 423.44 must set forth a process for appealing disenrollment decisions and denials of reenrollment. Our clients' experience with human and technological errors evidence a critical need for a process to appeal disenrollment decisions and denials of reenrollment.

It is unacceptable that, under Section 423.50, a plan's marketing materials are deemed approved if CMS fails to approve them within a certain time period. Even worse, these same marketing materials from one region are then deemed approved in all other regions in which the plan operates, except for state specific information. Many of the Medicare beneficiaries to whom the Part D plans will be marketing are frail elderly, consumers with cognitive or memory impairments, persons with limited education or who have LEP. In short, they are persons who may have difficulty understanding a complicated program like Part D, and who may be easily taken advantage of. It is critical that the marketing materials being sent out contain clear information as well as information that will not mislead or misrepresent the Part D program or the plan's product. We have seen letters sent out by Medicare+Choice plans that had been approved in Region II, which contained what could arguably be considered generic information, except that the rules for the program described were different for Pennsylvania. CMS should either craft model forms that, if used unaltered, could be deemed approved within 10 days or it must review and actively approve all materials before they go out.

The proposed regulations in Section 423.50 fail to require enrollment forms, marketing materials, and notices to be provided in alternative languages and alternative formats. The proposed regulations in Section 423.50 also fail to indicate that plans must have, and make available to consumers, interpreters and alternative communication methods. The only mention of any alternatives we found is that "For markets with a significant

non-English speaking population, provide materials in the language of these individuals." This is not adequate. Again, a Subpart devoted entirely to notice requirements should be developed and should address these issues.

Sec 423.56 Procedures to determine and document creditable status of prescription drug coverage.

Notices of Creditable Coverage must be sent to consumers several times a year, and in multiple formats, by Creditable Coverage entities between June 2005 and December 2006. Section 423.56 requires insurers to send consumers notices of creditable prescription drug coverage. The section does not require that these be sent out repeatedly. Distinct Notices of Creditable Coverage should be sent out quarterly during this time period and statements about coverage being creditable or not should be included on other mailings.

CMS should craft standard notices for both creditable and non-creditable coverage that include information explaining the relevance of whether prescription drug coverage is creditable or not and how that impacts Part D enrollment. These notices should be similar to standard notices and language required by Medigap insurers as noted in the preamble for Subpart S.

CMS should publish annual notices of actuarial equivalence for entities to utilize in assessing whether their coverage is creditable.

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. Even the lowest income consumers who qualify for the full subsidy may have difficulty paying their copayments, especially if they take a high number of medications. In addition, this could be especially problematic for consumers who are unable to get an exception to have a non-preferred drug covered at the preferred drug co-pay and who may be unable to afford the higher level of cost sharing **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

Pharmacy access standards in Section 423.120(a)(1) should be based on travel time and not on mileage. In urban areas, for example, 2 miles can take two hours on public transportation. Such travel times would be unreasonably burdensome for lower-income or frail individuals. We suggest that plans be required to follow access standards based on time such that pharmacies must be within 10 minutes travel time of 90% of the consumers in an urban area, within 20 minutes travel time of 90% of the consumers in a suburban area, and within 30 minutes travel time of 75% of the consumers in a rural area. Time based standards have worked well in Pennsylvania's Medicaid mandatory managed care program, "HealthChoices." Additionally, we recommend that all PDPs and MA-PDs be required to contract with pharmacies that offer home delivery service. A same-day or next day need for medications makes mail-order an impracticable solution for urgent or emergent situations.

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 and not a precise number. 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 final regulations must also standardize the process for how new medications will be classified under a plans therapeutic class and category structure. Leaving this up to each plan to decide will lead to disparities and disparities lead to access barriers. We encourage the use of the USP for classifying new medications.

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. Notifying enrollees about formulary changes primarily through a website is simply inadequate. Too many elderly and disabled individuals 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 4 distinct 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.

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.**

The proposed regulations in Section 423.132 require that pharmacies inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that drug available at that pharmacy. For mail-order pharmacies, this notice would be provided at the time of delivery of the drug. We would recommend that this notice occur at the time of order (to the extent that this is possible) so that a consumer can modify their order before delivery occurs if they choose to do so.

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.

The requirement in Section 423.153 that plans include medication therapy management program (MTMP) raises many concerns. Requiring plans to engage in this managed care activity would seem to go well beyond the capabilities of a stand-alone drug plan PDPs would be unlikely to have the appropriate specialists and counselors in their "network" needed to fulfill this requirement. Additionally, this requirement interferes with consumers' freedom of choice of provider to manage their healthcare. Dual eligibles, for example, might end up with discrete care management from their Medicare doctor, their Medicaid managed care plan, and their PDPs. This introduces unnecessary confusion. Offering a MTMP should be optional for plans and taking advantage of such a service must be optional for consumers within the plans.

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.

We support the development and use of consumer satisfaction surveys to gather comparative data on the plans (Section 423.156). **Consumers must be included in the survey design process and we recommend that the surveys be sent, and the results analyzed by CMS, prior to CMS's annual (May) notification to plans whether or not their contracts will be renewed.**

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)). Subpart C touches on this with regard to formulary development and review by CMS, but the review standards and criteria should be clearly defined.

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 G—Payments to PDP Sponsors and MA Organizations

No comments to CMS.

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

No comments to CMS.

Subpart J—Coordination Under Part D With Other Prescription Drug Coverage

Sec 423.464 Coordination of Benefits with Other Providers of Prescription Drug Coverage.

We strongly encourage CMS to develop a centralized data coordination system to track benefits and TrOOP for all consumers. While it seems logical that plans should track the information about who pays and what counts as an incurred expense in terms of calculating TrOOP, having a central repository of this information is critical to protecting consumers from overpayments because of inaccurate TrOOP tracking or problems in terms of sharing data between plans, especially when a consumer changes Part D plans mid-year. In addition, CMS seems to be leaning toward a voluntary system of reporting all payment information from any plan involved in the payment of a Part D drug, whereas reporting and tracking absolutely must be required of all PDPs and MA-PDs. This is vital to ensuring the accurate tracking of TrOOP (again to protect consumers from paying too much out of their pocket). In addition, this would assure consistency across the plans in determining what costs do or do not count toward TrOOP.

Consumers should receive quarterly notice detailing their out of pocket costs. Additionally, there should be a procedure in place for consumers who dispute the amount of out of pocket cost recorded to challenge and correct the amount. Given the importance of out of pocket costs for the beneficiaries, there should be very clear guidelines regarding how these costs are tracked.

Subpart K- Application Procedures and Contracts with PDP sponsors

Sec. 423.502 Application requirements.

PDP sponsor applicants should not be allowed to have their PDP sponsor application wholly exempt from FOIA disclosures. We recommend that PDP sponsors be permitted to petition to have distinct portions of their application exempt, but there is no reason to exempt the complete application. Additionally, CMS must set forth clear standards for when and why exemptions would be approved.

We are concerned about Section 423.507, which would require a PDP that is not renewing its contract to inform consumers of other PDP and MA-PD options and benefits in the same region. It is unclear how this obligation will materialize in terms of how a departing PDP will know the information about other plans in the PDP region, especially if other plans are changing or pulling out at the same time.

The proposed regulations in Section 423.507(b) require CMS to decide each year after only four months whether to renew a PDP's contract and this is too little time. It is

unclear how CMS could gather adequate information on a plan's performance in time to render a decision not to renew by May 1. The date should be pushed to at least July 1.

Subpart L— Effect of Change of Ownership or Leasing of Facilities

The final regulations for Section 423.552 must require notices to a PDPs enrollees if there is a change of ownership and these notices must include details about what impact, if any, the change will have on their access to care.

The proposed regulation at Section 423.552 on novations fails to explain what happens to beneficiaries if there is no novation by the new owner of the Medicare contract of the prior owner. If there is no novation, then the Medicare contract becomes invalid and the new owner would have to apply separately to be PDP. The regulation should provide a Special Enrollment Period for beneficiaries and a right to continuity of care.

Subpart M - Grievance, Coverage, Reconsiderations, and Appeals

We are deeply concerned that the proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution and to satisfy the requirements of the statute.

As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are 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. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, adopted 42 C.F.R. 422.626, which

establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D.

- 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 redeterminations 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.
- There are no requirements that any of the notices/decisions be provided in other languages or formats if the enrollee has LEP or is visually impaired.

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 require plans to provide information about appeals, grievances, etc. to enrollees in alternative formats. The proposed regulations at 423.562 only require drug plans to provide "written information" to all enrollees about appeals, grievances, etc. This requirement should be expanded to include alternate formats, for example, for the visually impaired.

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 <u>request</u> an expedited coverage determination (and redetermination) but not to <u>have</u> 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.

The final regulations must allow appeals for determinations about prescription drugs if the enrollee has no further liability to pay for them and about coverage of drugs obtained from a non-network pharmacy. The proposed regulations omit an appeals process for these two important scenarios and this must be added into the final regulations.

Consumers must either be allowed to select whether they want their complaint to be treated as a grievance or appeal, or to dispute the plan's determination. The proposed regulations state that when a drug plan gets a complaint, it is responsible for first deciding whether to send the complaint through the grievance or the appeal process, and then telling the enrollee. There must be a process to allow a beneficiary to select which process they are choosing and/or to dispute the plan's decision on this matter.

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.

All complaints about "quality of services" received by the plan should be forwarded to the Quality Improvement Organization (QIO). Under the proposed regulations, complaint about quality of services can be made to the drug plan or to the QIO or both. Ideally, while either should be able to receive complaints about quality of services, all such complaints received by the plan should be forwarded to the QIO. As written, the regulations would allow for two different review processes with no clarity as to how these two systems would work together, whose decision prevails, etc.

Consumers must be able to obtain an expedited coverage determination even where 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 redetermination, or about the drug plan's refusal to give an expedited coverage determination or redetermination, 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 final regulations must include better record-keeping requirements for grievance documentation. The proposed regulations have very minimal record-keeping requirements for plans for grievances. There must be additional requirements imposed including that plans track the entity (or the division within the plan) which is the subject of the complaint, how the enrollee was notified and by whom, what information was included in rendering the decision, etc.

Section 423.566(b) needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact a drug the plan claims is not covered under Part D, is covered.

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.

Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a redetermination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless. We refer CMS to the website of the Florida Agency for Health Care Administration, http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/multi_source.shtml, for an example of information Florida pharmacies must provide when they deny a prescription under the Florida Medicaid program.

Plans must not be allowed to delay making timely coverage determinations where the delay might or could affect health. The language in 423.566 of the proposed regulations states that PDP sponsors "must have a procedure for making timely coverage determinations", but offer too narrow a standard for reviewing delays ('that it would affect one's health'). The standard should instead be where it might or could affect health.

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.

Section 423.568(b) should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

The final regulations must account for the reality that pharmacies will more regularly be the ones informing the enrollees that the plans will not cover a prescribed drug. The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and the right to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Section 423.568(c) of the proposed regulations places the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes 14 days to decide whether or not to cover a drug. In reality, the pharmacy in most situations tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration. Any potential burden of requiring pharmacies to give out notices is minimized by the requirement that there be electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The final regulations must be more specific about content of the notices both for 423.568 and for 423.572. The proposed regulations talk about using "approved notice language in a readable and understandable form." They need to be more specific, and must include information about how to use the exceptions process. A recently settled Florida class action lawsuit filed on behalf of Medicaid recipients determined that the state had not provided written notification to people whose prescription coverage was denied of their right to appeal the decision. The settlement's provisions require the state to provide:

- Written notification that explains why the coverage request was denied
- Information on how to resolve the issues that triggered the rejection
- Instructions that explain how consumers can request an appeal

Steps consumers can take to receive medication coverage pending the outcome of an appeal. *Hernandez et al. v. Medows*, U.S. District Court for the Southern District of Florida (May 2003).

We suggest the following:

- Notice about exceptions and appeal rights should be presented immediately upon denial (including upon determination that a drug is not covered on formulary, and including by the pharmacist) and should explain why coverage was denied, options for obtaining necessary medications, and appeal procedures
- Notice should include the clinical or scientific basis for denial
- Notice should be in the language or format required by the enrollee

Plans must be required to make all notices available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking.

The notice notice should not include a description of the rest of the appeals process beyond the next step. Having info about the entire process given will make the notices too cumbersome, confusing and more intimidating to the consumer.

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 with mental illness and other vulnerable individuals 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. These days medications are vital to sustaining behavioral and physical 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.

We support the proposed regulation at 423.570 allowing an enrollee to request an expedited review for any coverage determination, unless it is about payment of a drug already received. However, we recommend several revisions to the regulations as written. This regulation should be expanded to allow an authorized representative as well as the enrollee and the prescribing physician to request an expedited process.

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, 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 only allow extension of the 72 hour timeframe in 423.572 by a showing that the extension is in the best interest of the enrollee. As written, an extension is allowed on a showing that extension is in the interests of enrollee. The regulations should be modified to read **best interest of the** enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately orally and in writing, not by the expiration of the extension.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to spend money they need for other necessities for their medications because of the uncertainty and length of the appeals process.

The final regulations must articulate a timeframe for sending a decision where an oral notification is not first provided. Section 423.572(c) gives a timeframe for notifying the consumer of an expedited decision when an oral notice is first provided-that is, the decision must be mailed within 3 days of the oral notification. However, if no oral notification is given, there appears to be no timeframe for the decision to be sent. Again, as time is of the essence in these matters, we recommend that if the plan does not provide oral notification of the decision, the decision must be mailed out the same day it is made.

The regulations should require plans to notify the prescribing physician as well the enrollee, in writing, of an expedited determination.

The notice of decision for expedited coverage determinations should contain all of the following: the name of the prescribing physician;the name of the prescribed drug; the date the request was received; <u>all</u> the specific reasons for denial; if the denial was based on insufficient information, identification of the medical or other information needed to render a decision.

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. Again, as before, we maintain a plan should not benefit from its failure to decide and notify an enrollee in a timely manner.

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 sothat itmeets the statutory requirement that the Secretary establish guidelines for an exception process. The statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests. **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 must not include as permissible criteria for an exceptions process, any items that are beyond the scope of the statute. Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The regulations propose a "limited number of elements that must be included in any sponsor's exception criteria," but the proposed list includes criteria that contradict the statutory provision for an exception if the physician determines that the preferred drug would not be as effective or would have adverse effects or both, for example -

- Consideration of the cost of the requested drug compared to the cost of the preferred drug has no bearing on whether a drug would not be as effective or would have adverse effects and should not be a consideration.

- Consideration of whether the formulary includes a drug that is the therapeutic equivalent also is not relevant to the statutory standard. The FDA requires that 80 percent to 125 percent of the medication be the same to be considered "therapeutically equivalent." Treatment for certain conditions, including mental illness, is highly individualized given the non-interchangeability of many medications even within the same class, the high degree of variability in how these diseases present themselves in terms of symptoms, and the many other factors that must be taken into account, including overdose lethality in light of heightened risk of suicide. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the deciding factor.
- Consideration of the number of drugs in the plan's formulary that are in the same class as the requested drug, for the reasons stated above, is not relevant to the determination of the treating physician that the requested drug is needed.

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 proposed regulatory standard exceeds the Secretary's authority in contradiction of the statute. A fail first standard could only apply if the statute required the doctor to certify that the drug is not as effective or has caused adverse effects.

The final regulations must state that a plan "may only require the written certification to include the following". The proposed regulations say that the plan sponsor "may require the written certification to include only the following information…" Given that the statute requires a determination by the doctor that the preferred drug would not be as effective, would cause adverse consequences, or both, plans are going to require some kind of written statement. However, the regulation should limit the statement only to the statutory standard.

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. The only provision for extending coverage now in the regulations is on a one-time basis and occurs only when a drug is being removed from a formulary and the plan fails to provide a timely notice of decision to the enrollee. In that case, the plan must approve the medication for up to a month or until the decision is issued. That allows the plan to give less than a full month's coverage, to the significant inconvenience of enrollees, many of whom may live in rural area, or be elderly or persons with disabilities for whom extra trips to the pharmacy are a burden and an expense

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 However, we are concerned that the "exception" to this protection, which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

The lowest coinsurance amount should apply when an enrollee wins an exception through this process because the drug at issue has been determined medically necessary with no on-formulary drug as a suitable alternative. We agree with the regulation that

prohibits a plan from establishing a formulary tier or copay or cost-sharing structure just for drugs approved thru exception process. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

IRE should be able to review the validity of a plan's exceptions criteria and formulary. Under the proposed regulations, if an enrollee seeks an IRE review (assuming a redetermination upholds denying the exception request), the review is only about whether the plan properly applied its own exceptions criteria and not about the validity of the plan's exceptions criteria or formulary. IRE should be able to review the validity. Without some independent review, there is no way to monitor and assure that the formulary and exception criteria are reasonable or are not hurting individual enrollees. Even if the review can occur at the ALJ stage the enrollee can only go to that stage if the amount in controversy exceeds $100. If a lower amount, no review would ever happen.

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 redetermination, standard or expedited, and to request any necessary extensions. Currently, sections 423.580, 423.582 and 423.584 allow only the enrollee to seek redetermination of any coverage determination or an extension in asking for a redetermination, and permit only the enrollee or the prescribing physician to seek an expedited redetermination. Many enrollees need assistance to obtain their benefits and are not able to request redetermination on their own. There is no rational for limiting the prescriber's ability to assist the enrollee in this fashion. As a matter of practice in Pennsylvania, it is very difficult to get the prescribing physician to become involved in appeals, even in the most compelling cases, because of the time and cost involved. However, when the prescriber is willing to become involved, he should not be prevented from doing so by the Secretary.

The phrase "good cause" should be clearly defined in the regulations and should be very broad. Section 423.582 provides that an enrollee generally has 60 days from a determination to request a redetermination, unless the plan extends the timeframe for "good cause." The plans should be required to look at good cause in the light most favorable to the enrollee, given the remedial purpose of the statute, and the population which Part D serves.

All redetermination requests, and particularly those involving exceptions, should be treated as expedited. The proposed regulations indicate that if a prescribing physician says applying the standard timeframe for redetermination may seriously jeopardize the enrollee's life or health or ability to regain maximum function, the plan must expedite the redetermination.

This standard is too stringent. **Either all redermination requests should be expedited or the standard for expediting redeterminations should be changed require expedited redeetermination when the physician determines that the standard schedule may jeopardize the enrollee's ability to maintain maximum function. This is the appropriate standard that has worked well for years in Pennsylvania's mandatory Medicaid managed care system.**

The plans should be required to provide a notice in writing in acknowledgement of the request for the redetermination. This notice should inform the enrollee or the party making the request for redetermination on behalf of the enrollee of the right to submit evidence orally, if the request for redetermination is made orally. In Section 423.586, the proposed regulations state that the plan must provide a reasonable opportunity in the redetermination for the enrollee to present evidence and allegations of fact or law, in person as well as in writing, even in the expedited process. However, no further guidance is provided on this issue. It is crucial that the final regulations include clear criteria for informing the enrollee and her/her physician of their right to submit evidence in person or in writing.

There is also a lack of detail about the notice responsibilities during the redetermination process that must be addressed. The final regulations should be very clear about what notices must contain during the redetermination 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 redetermination and any denial of a request for expediting redetermination. 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 redetermination 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 redetermination, with a representative. The plans should be required to accommodated enrollees in the scheduling and conducting of the redetermination. 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 redetermination.

There are several problems with the required timeframes in section 423.590 of the proposed regulations that need to be addressed. As currently written, the proposed regulations state that if a plan fails to provide a redetermination decision within the required timeframe, it will be considered an upholding of an adverse determination, appealable to the IRE. This is problematic for several reasons. If plans are allowed to issue de facto denials by failing to make a decision, the plans will have no incentive to make redetermination decisions at all but rather have an incentive to sit on a request until the time period for making a redetermination is up. Furthermore, a deemed denial fails to provide any meaningful decision for the enrollee to appeal.

The plan is not required to provide a reason for its denial and the enrollee has nothing to refute if s/he wants to appeal the decision further. **This regulation should be changed so that when a plan fails to make a decision in the required time period, it will be deemed approved.**

Currently, the proposed regulations allow plans to extend the time in which they will make a redetermination decision even in expedited redeterminations. **Plans must only be permitted to extend the timeframe for a redetermination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interests of the enrollee, for example, when the plan needs to obtain additional information to support the enrollee's request.** This is particularly important in expedited redeterminations, which by definition involve jeopardy to the enrollee's health. **In expedited redeterminations, the plans should not be allowed an extension at all.** Furthermore, while the plan must notify an enrollee if it is extending the timeframe for making a decision, the regulations fail to specify when such notification must be sent. **The plan must be required to send the notice within the original 14-day period.**

There is also an inconsistency in the time period for deciding redeterminations of coverage issues versus redeterminations of payment requests, whereby redeterminations on drug coverage issues must be made within 30 days of the request but redeterminations of payment requests must be made within 60 days. **There is no explanation for this difference, and it should be 30 days in both cases.**

If a plan requests medical information in an expedited redetermination, 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 redetermination 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 redetermination 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.**

Sec. 423.600(a) contains an incorrect reference to 423.582(a). (a) states an enrollee must file a written request for reconsideration at "one of the places listed in sec. 423.582(a)". However, that section contains no list of places

The list of who can file reconsideration requests must be expanded. The proposed regulation allows only enrollees to file requests for reconsideration by an IRE. Many enrollees will need help with pursuing an appeal or may not be able to act on their own behalf. They cannot be denied their due process rights. **The regulations should be expanded to allow physicians and authorized representatives file requests for IRE reconsideration.**

The enrollee should be allowed to request reconsideration orally, especially in the case of an expedited review.

There should be an automatic referral to the IRE when a coverage redetermation is adverse to an enrollee. The proposed regulations do not cause an automatic reconsideration to occur when a redetermination is adverse to an enrollee (as happens with MA organizations under Part C), and requires enrollees to specifically request redetermination. In the background information for this section the drafters note that the reason for this requirement is that many cases would only involve small amounts in controversy. However, that reason supports the need for an automatic review as cases involving a small amount in controversy cannot go on to the ALJ stage. As a result, an IRE review is the only level of independent review available to these enrollees. The Part C requirement should be copied in Part D, and recondsidertions should trigger automatically when there is an adverse redetermination.

CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. At page 46721 the preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…the IRE would not have any discretion with respect to the validity of the plan's exception criteria or formulary". If the IRE does not review all of the evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied an independent review. In addition, the requirements of due process will not have been met. Because CMS is required by the statute to set standards for the exceptions process, the IRE must have the authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

The regulations should specify how the views of the prescribing physician will be solicited. The proposed regulations state that the IRE must solicit the views of the prescribing physician, but does not give guidance on how this will happen. More clear direction on this issue should be included in the regulations to provide how the solicitation can occur- by phone? By email? in writing? In person? If the solicitation is in writing, the enrollee should be copied on the letter so they can follow up with their physician and assure that they respond to the solicitation.

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.

The final regulations should set out specific parameters for how the reconsideration will occur. The enrollee should be permitted to submit additional evidence as well as the prescribing physician. The plan should be required to submit to the IRE all the information or evidence it had before it at the redetermination and provide the enrollee with a list of all the information/documents sent. The IRE's decision should also include a description of all

additional evidence or information that was solicited from the prescribing physician as well as the enrollee.

The list of who gets a copy of the IRE's decision in 423.602 should be expanded. The proposed regulations require the IRE to mail notice of its reconsideration decision only to the enrollee. The regulations should also provide for sending notice to the prescribing physician in every case, and to the authorized representative if one exists.

The regulations must clarify how the enrollee is told of their right to appeal a reconsideration as well as how, and by whom, an enrollee is told of the amount in controversy in their appeal. The proposed regulations indicate that a notice of an adverse decision must inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement. How the notice conveys this appeal right is important. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing. In addition, it is not clear how or by whom the enrollee will be informed what the actual amount in controversy is. The regulations must provide that the IRE is to determine the amount in controversy and clearly include it in their decision.

The standard in Section 423.610 must be clarified for when enrollees can join together and combine their appeals to meet the amount in controversy threshold. The proposed regulations state that an enrollee can combine appeals to meet the threshold amount as long as they were all reconsidered by IRE, the request lists all the appeals and is filed within 60 days of when all the reconsideration decisions were received, and the ALJ decides the appeals are all for the same enrollee. The final regulations should clarify that an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an ongoing, chronic condition, or for the number of refills authorized if the underlying condition is not chronic, when the plan denies coverage, in order to satisfy the jurisdictional amount. The regulations should also clarify whether the 60-day filing requirement means that none of the reconsideration decisions can be more than 60 days old.

The standard must be clarified for when an enrollees can join together and combine their appeals to meet the amount in controversy threshold. The proposed regulations state that two or more enrollees can combine their appeals to meet the threshold if they all went through reconsideration, if the ALJ request is within 60 days after all reconsideration decisions were received, and if the appeals are all about the same drug. The regulations should clarify whether the 60-day filing requirement means that none of the reconsideration decisions can be more than 60 days old.

In 423.612(a) there are two references that seem to be incorrect. They refer to "one of the places specified in 423.582(a)" and "the organizations specified in 423.582(a). There is no list of places or organizations in that section.

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. Without set timeframes, these entities could take long periods of time just to transmit information and thus add to the delay in processing and resolving ALJ appeals.

The IRE must send to the ALJ all of the information it has in its file. The regulations need to require the IRE to send all of the information in the file including doctor's statements, enrollee statements and information submitted by the enrollee, and any other information even if it was not relied on in making the IRE's decision. Consumers must be assured that evidence is not omitted when the file is transferred to the ALJ or another appeal entity.

The regulations must specify how the amount in controversy is clarified in an appeal. The proposed regulations indicate that if, on its face, a request for an ALJ hearing shows that the threshold is not met, the request will be dismissed. The regulations should clarify how such a showing would be made. We recommend that the amount in controversy be clarified in the IRE's determination and clearly included in the IRE decision.

The timeline in 423.634 for effectuating all coverage redeterminations should be the same. According to the proposed regulations, if a redetermination completely reverses an initial coverage determination regarding benefits, it must be effectuated within 30 days. However, if a redetermination completely reverses an initial coverage determination of a payment request, it must be effectuated in 60 days. There is no need for the difference in timeframes or any additional delay. All redeterminations should be effectuated within 30 days

All IRE decisions should be effectuated within 72 hours. The proposed regulations state that if the IRE reverses a plan's coverage determination for benefits, the plan must authorize the benefit requested within 72 hours of receiving notice of decision, or provide the benefit within 14 days of the decision. No reason is provided for allowing the alternative 14 day timeframe. It should be eliminated and the plans required to authorize benefits in 72 hours in all cases.

All other coverage decisions should be effectuated within 30 days. The proposed regulations state that plans must effectuate an ALJ, Appeals Council, or higher decision within 60 days of being notified of the decision. This timeframe is unnecessarily long and should be shortened to 30 days.

All other coverage decisions should be effectuated within 30 days. The proposed regulations at 423.638 with respect to expedited redeterminations or reconsidered determinations state that plans must effectuate ALJ, Appeals Council and higher decisions within 60 days of being notified of decision. This timeframe is unnecessarily long and should be shortened to 30 days.

Subpart N - Medicare Contract Determinations and Appeals

No Comments to CMS on this SubPart.

Subpart O - Intermediate Sanctions

Plans should be sanctioned for the failure to provide medically necessary services, regardless of the actual or possible adverse effect on an enrollee. The proposed regulations at Section 432.752(a)(1) state that a basis for imposing sanction is failure to provide medically necessary services, with adverse effect on the enrollee or substantial likelihood of adverse effect on enrollee. Requiring that there be an "adverse effect" on the enrollee before a sanction can be imposed is untenable. To condition this requirement in any way with an 'effects' test only encourages plans to cut corners.

The final regulations in Section 432.752 must be clearer about how the suspension of enrollment would impact the statutorily mandated requirement that a consumer has a choice of at least 2 plans. While CMS needs to have tools to enforce contractual obligations, consideration must be given to balancing how enforcement tools would impact consumers rights.

Sec. 423.756 Procedures for imposing sanctions.

The final regulations must provide for a reconsideration process that allows a plan to partially affirm or rescind decisions. The proposed regulations would only allow for an outright affirmation or rescission. This process should be expanded to include an option to affirm decisions in part. In addition, the regulations must be expanded to include time frames for the issuance of the reconsideration decision

The final regulations must include notification of enrollees, the public, and network pharmacies of the imposition or termination of sanctions. Notice will be a vital factor for the public (enrollees) and pharmacies to make educated decisions about plan choice, for pharmacies seeking to serve/counsel their customers and it will also give plans an additional incentive to conform to the regulations.

SupPart P – Low Income Subsidies

Family size should be defined in 423.772 to automatically include children under the age of 21 as part of the applicant group. In addition, pregnant women should be counted twice. The proposed regulations define family size to include (1) applicant, (2) a spouse who lives in residence, and (3) related individuals in the same residence who depend on the applicant or his/her spouse for at least ½ of their financial support. There should be an assumption of eligibility for children under the age of 21, so as not to create a useless administrative burden to prove a child's financial support. There should also be a provision to count pregnant women as two, to more adequately reflect the family size.

In addition to their definition of resources, the regulations should include specific examples of items that will and will not be counted as resources based on the "20 day" rule. The proposed regulations define resources as 'anything that can be converted into cash within 20 days' (excluding §1613 items, and real estate that is not a primary residence or related land). While this is an excellent proposed standard, the regulation is likely to cause significant confusion without clear guiding criteria or illustrative examples. For instance, is the cash value of an insurance policy a resource, and does the answer depend on how responsive the insurer is?

Increases in the resource limit after 2006 in 423.773 should never be rounded down. The proposed regulations provide for an annual adjustment of the resource limits for eligibility for subsidies. The increase is based on the 2006 resource limit adjusted for Consumer Price Index percentage change, as of September of the previous year, *rounded to the nearest $10*. This should be changed to adjust the resource limit *up to the nearest $10*, as it is illogical to round a resource limit *below* what has been determined to be a minimum level of need.

Subsection (c) should be edited to replace the term "full benefit dual eligibles" with "full subsidy eligbles", where appropriate. The proposed regulations appear to have an error in part (c). In (c)(1) the regulations indicate that *Full benefit dual eligibles* will be treated as full subsidy eligibles. In (c)(3) the regulations say the same will apply for *Medicare buy-in populations*, but then go on to state that state agencies must notify *full benefit dual eligibles* that they are eligible for full subsidy on Part D premiums and deductibles, and that they must enroll in a PDP/MA-PD plan or they will be randomly auto-enrolled. The term "full benefit dual eligibles" in (c)(3) should be changed to "full subisidy eligibles".

States should be required to notify "other subsidy eligibles" of their eligibility for subsidies. The proposed regulations require states to notify full subsidy eligibles of their eligibility for subsidies, but have no similar requirement that state agencies notify other low-income subsidy eligibles of their eligibility for subsidy, and language to this effect should be added.

The proposed regulations must require that eligibility for low-income subsidies be presumed for a fully year after eligibility is determined. The comments to the proposed regulations state that individuals who become eligible by "spending-down" excess medical expenses will not be "eligible as medically needy until he or she satisfies their spenddown obligation." Neither the comments nor proposed regulations address the rules for the "spend-down" individuals with respect to low-income subsidies. Due to the monthly yet continuous nature of their eligibility, the regulations should require that once an individual is determined eligible for a low-income subsidy, their eligibility is presumed for a full year, so as to avoid the buden to the enrollee and the administrative cost of re-applying for subsidies every month.

If CMS plans to design a universal application for subsidies, the regulations at 423.774 should set out standards for the application and establish a process for public comment on the application. The comments to the proposed regulations state that CMS will be designing one model application form that will be able to assess for all subsidies. This form is not mentioned in the regulations, and there is no provision for the public to view and/or comment on that form.

The regulations should clearly set limits as to how telephonic proxy designations can be made and acted upon, to protect vulnerable enrollees. In addition proxy certifications should only apply to the accuracy of the proxy's transcription, and not to the accuracy of the underlying information. The proposed regulations create a proxy signature process. This process raises two concerns. First, inconsistencies between the regulations and the comments to the regulations, leave us unclear as to when proxies will be allowed to take telephonic

applications on behalf of clients. The regulations should be clear, in order to protect applicants from improper/inaccurate solicitations via telephone by private companies which attempt to gain their consent to apply for benefits, particularly in light of the fact that some choices (for example plan choice) for some consumers will be choices they are 'locked' into for the year. Second, the regulations require proxies to *certify the accuracy of the information* they are communicating to CMS or the state administrator. This standard must be changed to *certification of the accuracy of the proxy's transcription* of the information as provided by the applicant. Otherwise, there will be a great chilling effect on the number of legitimate proxies willing to assist enrollees.

Verification should be done on a random basis, or by clear and defined criteria which do not disparately impact against any class of individuals based on demographic factors such as race, income, disability, age, etc. The comments to the proposed regulations indicate that verification processes will be designed using 'profiling criteria' to do 'specific targeting' of individuals who are likely to be committing misrepresentation in their applications. This 'profiling' and 'targeting' should not be allowed, and the verification analysis should be random, or at the very least, the criteria upon which it is based should be made public for commentary about potential abuses.

The regulations at 423.780 must require plans and/or CMS to provide clear notice to consumers about set premium standards, such as "benchmark" premium levels, so consumers can evaluate plans with full understanding of their premium options and liability. The regulations also must place clear responsibility upon plans – subject to punishment for noncompliance – to ensure that enrollees always receive the most favorable base-premium calculation, as per the proposed regulations. The proposed regulations allow full reimbursement for subsidy premiums for full subsidy eligibles, up to the greater of certain complex premium level calculations (for example, "benchmark premiums", which are based on a weighted average of basic premiums). This presents two problems for enrollees. First, they have no way of understanding what the set premium limit will be at any time. Notice about premium levels, such as the benchmark premium, should be provided to clients so that they can choose plans with a full understanding of how much of their premium will be subsidized. Second, even if clients do understand what the premium calculations are, it is not clear in the regulations how the requirement to apply the *greater* of the calculation options will be applied and enforced. The regulations need to place a clear responsibility on plans to ensure enrollees are informed and provided with the greater premium calculation option.

The regulations regarding full subsidy eligibles at 423.782 must place clear responsibility upon plans – subject to punishment for noncompliance – to ensure that non-institutionalized dual eligibles always receive the less costly cost-sharing option, as per the proposed regulations. The proposed regulations indicate that non-institutionalized dual eligibles who have exceeded the initial coverage limit will have cost-sharing that is the lesser of two specified amounts. However, the regulations provided no guidance as to how enrollees will be informed of their right to the lesser option, or how that right will be enforced. The regulations need to place a clear responsibility on plans to ensure enrollees are informed and provided with the less costly option.

Adjustments in required cost-sharing amounts after 2006 should never be rounded upward. The proposed regulations also indicate that some cost-sharing contributions by consumers will be adjusted annually based on the consumer price index, *rounded to the nearest* $.05 or $.10. This provision should be changed to round the adjustment *down to the nearest* $.05 or $.10, as it is illogical to round *upward* and charge consumers more than their estimated spending limit.

Adjustments in the deductible amounts after 2006 should never be rounded upward. The proposed regulation will adjust the deductible annually based on average per capita aggregate expenditures for Part D drugs, *rounded to nearest* $1. This provision should be changed to round the adjustment *down to the nearest $1*.

The regulations should authorize the use of state Medicare buy-in rules where a state's plan does not deviate substantially from the default regulatory standard. In the comments to the proposed regulations, it states that CMS was authorized to allow state Medicare buy-in rules to become the subsidy standard where the state's plan does not deviate much from the default plan of the regulations. The comments state that CMS has decided not to make use of this authority for reasons of (1) uniformity, and (2) administrative burden. It is unreasonable to argue that state rules should not be used for reasons of 'uniformity' when the statute specifically authorizes use of state rules. If uniformity were the highest priority, congress would not have prohibited the use of state rules, as it did in countless areas where they wanted to proscribe reference to state rules. Furthermore, because state agencies will be doing a significant portion of the subsidy administration, it is unreasonable to posit that administrative burden will be lessened by adding an additional standard to the states' calculations. CMS should use the authority of the statute, and authorize states to use their own Medicare buy-in rules to set standards for subsidies.

The regulations must set forth a clear required administrative process for plans to reduce cost-sharing and premiums for subsidy eligibles. The proposed regulations state that plans must reduce subsidy eligibles' premiums and cost-sharing, and inform CMS of this, in "a manner determined by CMS". This provision must be clarified, and the 'manner' must be defined, so as to ensure that the reductions and notice occur. A suggested methodology should be provided so that beneficiary groups can comment and understand how CMS will be informed.

The regulations must place clear responsibility upon plans – subject to punishment for noncompliance – for failure to reimburse subsidy eligibles when appropriate. The regulations must explain how CMS will monitor reimbursement, and set a 10-day minimum time period for reimbursement to occur after the date of subsidy effectiveness. The proposed regulations state that plans must reimburse individuals for cost-sharing paid by individuals before an individual is notified of subsidy eligibility and after the date the subsidy is effective. The likelihood of violation of this regulation requires that CMS adopt stronger policies to monitor this function and ensure compliance.

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

Section 423.871 Contract terms and conditions.

The final regulations for fallback plans should be clear about what structures, such as premiums or cost sharing, can be different, and about what protections must be in place to ensure that consumers are clearly informed of the differences and are protected from unfair practices. The proposed regulations create an entirely different structure for fallback plans, and beneficiaries in areas with these plans will struggle to understand these fallback plans. Failure to create strict guidelines for fallback plans and help inform beneficiaries will be exacerbated by the rural areas where most of these plans are likely to operate.

The final regulations must give fallback plans incentives to reduce costs. The proposed regulations create a cost-reimbursement structure which reimburses fallback plans for actual and administrative costs, giving fallback plans no apparent incentive to reduce costs. The final regulations must address this, and provisions should be designed to ensure beneficiaries will not ultimately be charged more for their drugs because there is a poor incentive structure to control costs for fallback plans. This is particularly true because a structure that allows fallback plans to overcharge will act as an incentive for companies to pursue fallback plans rather than become full PDP and MA-PD plans.

Subpart S-Special Rules for States-Eligibility Determinations for Subsidies and General Payment

Sec 423.904 Eligibility determinations for low-income subsidies.

We are very concerned about the eligibility and enrollment for the lower-income subsidies.

The Social Security Administration must be required to screen for eligibility in Medicare Savings Programs and other Medicaid programs that cover cost-sharing. Although the statute requires states that process applications to screen for eligibility in these programs, many consumers will apply directly through the SSA. In the alternative, the roles should be reversed and SSA should act as intake workers and the states should process the applications.

In order to screen for MSP and other Medicaid eligibility, SSA would have to have access to and understanding of all the Medicaid programs and rules that apply in each state. It does not seem possible that SSA could master the rules of Medicaid eligibility and thus, we believe SSA must be required to employ all computerized eligibility screening tools available by the states and contract with state staff to assist in screening for MSP eligibility.

That States must require a personal representative applying for a low-income subsidy to certify under penalty of perjury as to the accuracy of the information provided within will single-handedly halt outreach and enrollment activities by social workers and community service organizations. The definition of personal representative does not refer only to persons with power of attorney or guardians with legal authority and obligation to sign in

an applicant's stead. As written, the proposed regulations at Section 423.904 (d)(2)(ii) would expose any agency, volunteer, SHIP program staff, friend or neighbor to legal liability.

The process for how deemed eligibles are actually enrolled into the subsidies needs to be clarified. While the statute and proposed regulations both articulate that certain individuals on Medicaid are deemed eligible for the lower-income subsidies, the proposed regulations do not articulate how the enrollment into the lower-income subsidies will be effectuated. This must be made clear. For example, just because a person is presumptively eligible for Medicaid does not release them of a need to apply and affirmatively articulate a desire to obtain the benefits for which they are deemed eligible. The final regulations must make clear that states are required to send a monthly batch of deemed eligibles to SSA for SSA to effectuate the enrollment with an effective date of the first day of the following calendar month.

CMS-4068-P-715

Submitter : Joe Moore **Date & Time:** 10/01/2004 10:10:21

Organization : Moore Drug Co

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Consideration of the importance and value of patient care provided by Independent Pharmacies should not be over looked in this "walmart" world we now live in. Cheaper is not always better.Since most Independent Pharmacies are considered as small buisnesses special attention should be paid to reimbursment as not to be a hardship.Small buisnesses are responsable for creating most of the new jobs in this country. The elderly depend on thier pharmacist and it would be ashame if thier trusted health care provider was no longer available because his value was discounted.
Thanks You
Joe Moore

Submitter : Mr. Brian Roesler **Date & Time:** 10/01/2004 10:10:45

Organization : Mr. Brian Roesler

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Ladies and Gentlemen:

Thank you for this opportunity to offer my comments on the proposed regulations for the implementation of the new Medicare Drug Benefit. I hope that my remarks will contribute in a positive manner to the development of a high quality program for Medicare participants.

I believe that a high quality program will use the skills of our nation's community pharmacists to patients' greatest benefit. Community pharmacists are on the front line of patient care, up close and personal, every day. They are the most accessible health care professionals. A few of their duties include: monitoring drug usage by patients; watching for drug interactions; advising patients about medicines; teaching patients how to use home health care equipment; and answering medication-related questions from physicians and patients. In short, they are working to encourage positive outcomes of prescription drug therapy for their patients.

I believe that these services need to be encouraged and rewarded. Therefore please consider:

a)Allowing Medicare recipients to choose their own pharmacies. Let's keep the positive patient-pharmacist relationships that have developed. Let patients decide which providers serve their needes best. Let any willing pharmacy (who meets CMS requirements) participate in the program, and reimburse pharmacies adequately so that their are numerous local pharmacies willing to participate. Also prohibit plan sponsors from coercing patients into using a pharmacy which is owned by the sponsor.

b)Establishing Pharmaceutical Care Standards. I believe these are called Medication Therapy Management (MTM) programs in the legislation. Certain minimum MTMs should by required in every participating pharmacy. Again, let's take advantage of our pharmacists' skills. Encourage providers to provide a higher level of care to those patients who need it by adequately compensating the pharmacies for MTMs. Better care will result in better outcomes and more efficient use of the dollars spent on prescription drugs.

Again, thank you for this opportunity, and thank you for your consideration of my remarks.

Sincerely,
Brian G. Roesler

CMS-4068-P-717

Submitter : Mr. Steven Turck **Date & Time:** 10/01/2004 10:10:18

Organization : Mr. Steven Turck

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I greatly appreciate the chance to comment with respect to the proposed drug benefit-inclusive expansion of existing Medicare law. With regard to Subpart C, I respectfully request a revision to the pharmacy access standards stipulating that plans meet the TRICARE pharmacy access requirements on a local level, as opposed to the plan's regional or "average" overall level. Mandating that a plan meets more local standards empowers all beneficiaries with choice of access to a local pharmacy. Oversight to the contrary could potentially favor mail order pharmacies.

With respect to Subpart D, I respectfully request that CMS mandates that plans are required to include community pharmacists as purveyors of Medication Therapy Management services to beneficiaries. These professionals provide an excellent means of providing such services to beneficiaries. Thanks you again for taking my comments into consideration in a fashion that may best serve all Medicare beneficiaries.

Submitter : Ms. Grace McAndrews **Date & Time:** 10/01/2004 10:10:11

Organization : NAMI California

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

October 1, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

Attention: CMS-4086-P

The 14,000 members of NAMI California are pleased to submit the following comments on Notice of Proposed Rulemaking (NPRM) implementing the Medicare Prescription Drug Improvement and Modernization Act (MMA, P.L. 108-173).

It is of utmost importance to our families who have seriously mentally ill relatives that there be open access to ALL medications without barriers such as prior authorization, fail first, therapeutic substitution and step therapy. Restricting access to medications that work for mentally ill individuals will, in the long term, cost the system more in terms of unnecessary hospitalizations and medical care. Individuals respond differently to the various psychotropic medications based on the severity of their illness, ethnicity, gender and race. Simply put, one size does not fit all. We must protect this vulnerable population.

NAMI California recommends that the final regulations implementing the MMA include the following:

1. Requirement to ensure ?continuity of care? for dual eligible individuals with mental illnesses by requiring prescription drug plans and Medicare Advantage plans to continue coverage for medications that are already effective in maintaining stability for individual beneficiaries.

2. Inclusion of a requirement for prescription drug plans and Medicare Advantage plans to put in place alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies such as prior authorization, fail first, therapeutic substitution and step therapy.

3. Greater clarity to ensure that P&T Committee operations are more transparent and reflect an independent assessment of all coverage restrictions.

4. Protections for therapeutic substitution such as a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician.

5. Expansion of beneficiary protections in cases where a prescription drug plan enacts a change in the plan formulary in the midst of a plan year.

6. Simplification of the grievance and appeals procedures detailed in the Notice of Proposed Rulemaking by easing access, ensuring rapid results for beneficiaries and their doctors, and providing greater clarity for the expedited process for individuals with immediate needs.

7. Partnering with community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.

8. Establishment of greater protections for beneficiaries with mental illnesses threatened with and subjected to involuntary disenrollment by prescription drug plans and Medicare Advantage plans for ?disruptive behavior.?

NAMI California appreciates the opportunity to comment on these important regulations.

Sincerely,
Grace McAndrews
Executive Director
NAMI California

CMS-4068-P-718-Attach-1.doc

October 1, 2004

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

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7. Partnering with community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.

8. Establishment of greater protections for beneficiaries with mental illnesses threatened with and subjected to involuntary disenrollment by prescription drug plans and Medicare Advantage plans for "disruptive behavior."

NAMI California appreciates the opportunity to comment on these important regulations.

Sincerely,

Grace McAndrews

Grace McAndrews
Executive Director
NAMI California

CMS-4068-P-719

Submitter : Mr. Stan Rosenstein **Date & Time:** 10/01/2004 10:10:21

Organization : California Department of Health Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The State of California Department of Health Services submits the attached letter containing comments on the draft MMA regulations.

CMS-4068-P-719-Attach-1.doc

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

October 1, 2004

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

Dear Sir or Madam:

SUBMITTAL OF FORMAL COMMENTS AND QUESTIONS REGARDING PROPOSED FEDERAL RULES IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG BENEFIT – NPRM ISSUED IN THE FEDERAL REGISTER (VOLUME 69, NUMBER 148) ON AUGUST 3, 2004

This responds to the Centers for Medicare and Medicaid Services (CMS) request for comments on the Notice of Proposed Rule Making (69/148) dated August 3, 2004, regarding implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

The California Department of Health Services (DHS) is concerned that the formulation CMS uses for calculation of the State Contribution (a.k.a. the "clawback") penalizes Medicaid agencies in spite of CMS' statutory authority to accommodate more precise and timely information provided by Medicaid agencies. This concern has been communicated to CMS in a variety of forums (conference calls, public forums, e-messages). The intent of Congress in the passage of this bill was that the State Contribution amount be calculated in a manner that accurately reflects the state's cost of providing prescription services to dual eligibles. The proposed regulation does not do this and instead creates a formula that significantly over charges states as compared to a formula that accurately calculates the State Contribution amount. DHS believes that California will overpay the state's contribution by more than $91 million starting in 2006 and continuing at least at that level until 2015. The State cannot afford this excessive charge.

A State Contribution amount must reflect a comparison of data that properly links claims paid for dual eligibles with the manufacturer rebates obtained for these claims. Congress intended that 2003 be the base year for determining the State Contribution amount. CMS has accurately determined that amount for claims that are paid in that

year. However, the proposed formula inaccurately calculates the rebates collected for 2003 claims or prescriptions by using the dollar amount of rebates collected in 2003. Based on federal law and due to the process of billing and collecting drug rebates, rebates for prescriptions provided in 2003 are mostly collected in 2004. The proposed method of calculating the State Contribution amount does not account for this lag, instead the proposed formula incorrectly associates rebates collected in 2003 with claims paid in 2003. In reality, most of the rebates collected in 2003 are associated with claims paid in 2002. The calculation should associate 2003 prescriptions with the rebates collected for those 2003 prescriptions.

This apples to oranges comparison proposed in the regulation improperly hurts states who have experienced caseload growth, increased costs of prescription drugs, increased drug utilization and who have increased their rebate collections due to supplemental rebate programs. Since the intent of Congress was for the State Contribution amount to be the net cost of providing these prescriptions to dual eligibles, the formula must be calculated using claims for 2003 and the rebates collected for prescriptions provided in 2003. The data on what rebates states have collected for 2003 claims is available and it should be used to ensure a proper calculation of the State Contribution amount.

CMS has the statutory ability to use additional data beyond the CMS 64 to properly calculate the State Contribution amount. CMS stipulated in the NPRM that it has the statutory authority to use “other data” to calculate the state’s contribution; that is, “The gross per capita Medicaid expenditures for prescription drugs for 2003 is equal to the average (mean) per person expenditures (including dispensing fees) for a State during 2003 for covered Part D drugs provided to Medicare beneficiaries receiving full benefits under Medicaid who are not receiving medical assistance for drugs through a Medicaid managed care plan, based on data from the Medicaid Statistical Information System (MSIS) **and other available data**, as adjusted by an adjustment factor.” [emphasis added]

In order to accurately determine the state contribution amount, CMS must calculate it using both claims and rebates for services provided in 2003. Attached is a State of California Department of Health Services proposal with amendments (underscored) to the draft federal rule that resolves this error in the regulations. We have appended background materials demonstrating the need for the alternative to CMS’ state contribution formulation.

STATE OBLIGATION FOR SCREENING AND ENROLLMENT

Medicaid agencies should have the option of forwarding low-income subsidy applications and Part D enrollments to the Social Security Administration to assure consistency in the administration of the subsidy program and enrollment procedures. Medicare beneficiaries currently access care through the Social Security Administration and have no contact with state or county Medicaid offices. To require Medicare beneficiaries to go to Medicaid offices places an unnecessary, confusing and burdensome requirement on these people. This will serve as an unnecessary barrier to enrollment.

Further, to require states to develop new processing methods and systems to determine eligibility for low-income subsidies will be very expensive, confusing and add to the complexity of already overly complex programs and systems. Every state calculates income and resources differently and the method that CMS decides to use will by its nature be different than what states are currently using. Requiring states to operate this program will require over 51 computer programs and processes to be changed. This is a massive undertaking especially given the implementation date. It would be more economical to have the Social Security Administration make a singular change to their processing that can be implemented nationwide.

If you have any questions, please do not hesitate to contact me at (916) 440-7800.

Sincerely,

ORIGINAL SIGNED BY STAN ROSENSTEIN

Stan Rosenstein
Deputy Director
Medical Care Services

Enclosures

CALIFORNIA DEPARTMENT OF HEALTH SERVICES
STATE CONTRIBUTION ALTERNATIVE LANGUAGE

Sec. 423.902 Definitions.

The following definitions apply to this subpart:

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year. All States and territories shall have the individual option of annually presenting other data to the Secretary for 2004 and succeeding years by demonstrating:

State receipt of financial settlements received from drug manufacturers or providers that have the net effect of reducing a State's outpatient drug expenditure.

Continued cost containment consequences of State or territorial policies adopted during 2003 or before that have a lagged implementation impact occurring beyond 2003. Adoption of such policies shall be documented in public records as to the date of adoption. Documentation of the cost containment impact shall demonstrate the financial impact on the State's contribution. Changes to the contribution shall be effected through the normal financial transfers occurring between States/Territories and the federal government with appropriate adjustments made to the base year for future contribution calculations.

Base year Medicaid per capita expenditures is equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor which may include, at the State's option, an adjustment

(a) limiting the expenditures and rebates to those associated with Part D dual eligibles and

(b) for 2003 rebates not collected until 2004 due to lagged reporting and dispute resolution; and

(2) The estimated actuarial value of prescription drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full benefit dual eligibles with managed care and non-

managed care are weighted by the respective average monthly full dual eligible enrollment populations…

…Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated by 1/12th of the product of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals, and multiplied by the--

(1) State medical assistance percentage;

(2) Applicable growth factor;

(3) Number of the State's full-benefit dual eligibles for the given month; and

(4) Phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio for the State for the four quarters of calendar year 2003 of aggregate rebate payments <u>adjusted by the rebate adjustment factor and</u> received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

CALIFORNIA DEPARTMENT OF HEALTH SERVICES

COMMENTS ON FEDERAL NOTICE OF PROPOSED RULE MAKING REGARDING IMPLEMENTATION OF THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

APPENDIX LISTING

APPENDIX A

California Department of Health Services
Proposed Alternative to the
Federal Government's Calculation of the State Contribution
September 2004

Following are adjustments to the proposed "State contribution" definition presented in draft federal regulations that guide implementation of the Medicare Modernization Act (MMA).

REBATE LAG AND POPULATION (DUAL ELIGIBLE) ADJUSTMENT

Proposal: From the Medicaid outpatient drug expenditures spent on dual eligibles in calendar year (CY) 2003, subtract the drug manufacturers' rebates that Medicaid agencies do not collect until after CY 2003 due to inherent time lags in the collection process, extended dispute resolutions, or other extenuating circumstances, as documented. Additionally, adjust the population base used in the federal government's proposed formula to allow for calculations according to the number of dual eligibles – which is the only Medicaid group involved in the Act – and not the total Medicaid population, which includes mothers and children who are not a part of this Medicare expansion.

Rationale: The federal government's current interpretation of the MMA is the statutory reference to "2003" means financial transactions only occurring within CY 2003; that is, provider reimbursements paid and rebates collected and deposited within that year. This interpretation does not allow any retroactive adjustment for netting rebates related to 2003 expenditures against the "Medicaid per capita expenditures", even though the rebates are not collected until 2004 or later for reasons identified previously.

Therefore, CMS' current interpretation of the Act does not allow for lagged rebate collections that occur in the normal course of business during rebate collection efforts, and differences between the dual eligible population and the total eligible population that includes children and mothers who do not use as many drugs nor as many expensive drugs as the dual eligible population. The current federal formula is based on state data reported for the total Medicaid population because that is all its current reporting format can accommodate. States having the data processing capability to distinguish between dual eligibles and the total Medicaid population should be allowed to do so, in concert with the latitude provided in the Act, provided the data calculations are transparent and available for federal audit.

FINANCIAL RECOVERY ADJUSTMENT

Proposal: From information provided by the federal Department of Justice, subtract financial recoveries from judicial settlements when those recoveries have the net effect of reducing a Medicaid agency's outpatient drug expenditure.

Rationale: Recent collaborative efforts by the federal and state governments have produced hundreds of millions of dollars in settlements[1] between drug manufacturers and law enforcement agencies. These settlements, which are shared with state governments, have the net effect of reducing a Medicaid agency's outpatient drug expenditures and should be reflected in the clawback formula.

CONTINUITY OF COST-CONTAINMENT ADJUSTMENT

Proposal: Medicaid agencies should have the authority to provide "other data" to the federal government as allowed by the MMA that documents the continuity of cost-containment consequences attributable to federally supported initiatives Medicaid agencies have launched prior to 2003 to contain costs.

Rationale: Medicaid agencies have adopted a wide variety of collaborative cost-containment efforts with the federal government that have origins in 2003 and before. These efforts are rarely short-term in nature and usually have long-lasting consequences that extend far beyond 2003. These efforts have a continuity of consequences that transcend a single-year impact and should be recognized for their enduring cost-containment effects. For example, California adopted new policy authorizing implementation of drug pricing according to average selling price effective in state fiscal year 2003. Because of the innovative and pioneering nature of this initiative, it will not realize its full potential until 2005 and beyond. California should receive ongoing credit for the continuity of consequences associated with this federally-supported effort by continual adjustments to the 2003 baseline that reflect the decreased expenditures associated with costs would have occurred had the initiative not been launched.

IMPLEMENTATION OF BASELINE YEAR ADJUSTMENT ALTERNATIVES

The routine accounting adjustments that take place between federal and state governments in administering the Medicaid program should be followed; that is, when a Medicaid agency makes a post-2003 adjustment to the Act's clawback baseline, it will document the transaction as a fiscal amount that is to be subtracted from its normal state obligation to the federal government. This would be the contra-transaction to the type of transaction where the federal government, in accordance with the Act, can reduce its financial transfer to state Medicaid agencies in the event of a late or missed payment of the state contribution. The Medicaid agency will stipulate that its claim is auditable by the federal government with all applicable federal auditing rules and regulations.

[1] For example, $345.5 million by Schering-Plough in 2004, $257 million by Bayer in 2003, and $86.7 million by GlaxoSmithKline in 2003 (Abelson, R, *New York Times*, July 31, 2004)

APPENDIX B

California Department Of Health Services
Methodology for Estimating the Financial Impact of the Federal Government's Current Interpretation of the MMA Regarding Calculation of the State Contribution
September 2004

The Center for Medicare and Medicaid Services is proposing to use financial transactions occurring within calendar year 2003 (covered outpatient drug expenditures and rebates collected) as reported on the CMS 64 Report. Expenditures represent services in that year as pharmacies bill on-line real time. These claims will show whatever growth occurred that year. However, rebates associated with those expenditures have a significant delay in collection due to quarterly billing cycles. Thus states are being unfairly penalized for natural lag times in invoicing and collecting rebates.

Additionally, due to the limitations of the CMS 64 Report structure, expenditures and rebates associated with dual eligibles – the only Medicaid population who is the focus of Medicare Part D – cannot be accounted for without some data refinement that sorts out a Medicaid agency's experience with dual eligibles. Due to the CMS 64 Report's lack of capability to account for dual eligibles, CMS' current position is that calculation of the total expenditures in the baseline has to be based on the total Medicaid population because that is all the CMS 64 Report can currently handle.

When adjusting for the lagged rebate collections occurring in 2004 but linked to expenditures in 2003, and adjusting for expenditures and rebates associated with dual eligible utilization instead of the total Medi-Cal population, the California Department of Health Services calculates it would have overpaid the federal government by at least $91 million in state funds compared to what it would have paid under the federal government's current interpretation of the Act.

However, there is authority in the Act for the federal government to accommodate submission of "other data" to supplement the deficiencies in the current federal reporting requirements.

The Act provides that in determining drug expenditures for duals, "data from the Medicaid Statistical Information System (MSIS) and other available data" are to be used.

Data for the adjustment factor, i.e. rebate factor, is "based on information reported by the State in the Medicaid financial management reports (form CMS-64) for the 4 quarters of calendar year 2003 and such other data as the Secretary may require". This provides CMS with flexibility to use other data to be sure that the volume of drug rebates is representative of the claims they are being counted against.

APPENDIX C

California State Contribution Calculation

for

2006

Comparing

CMS' Current Proposal

with the

Alternative State-Level

Rebate Lag/Dual Eligible Adjustment

California State Contribution Calculation for 2006 Comparing CMS' Current Proposal with the Alternative State-Level Rebate Lag/Dual Eligible Adjustment

Description	Line #	Description	Formula	CMS-64 CY 2003	With Dual Eligible and Lagged Rebate Adjustment	Difference
Gross per capita CY 2003 expenditures for Rx drugs of FFS dual, Part D covered drugs (Medical Supply dollars from FY 2002/03)	(1)	Drugs		$ 2,495,234,870	$ 2,495,234,870	
	(2)	Medical Supplies		$ 662,014	$ 662,014	
	(3)		(1) + (2)	$ 2,495,896,884	$ 2,495,896,884	
	(4)	Total duals	(5) + (15)	1,069,280	1,069,280	
	(5)	FFS duals		943,740	943,740	
	(6)	Per Capita	(3) / (5)	$ 2,644.69	$ 2,644.69	
Aggregate State payments under rebate agreements for CY 2003 (Shaded is rebates for dual eligibles)	(7)	Fed Rebates		$ 889,538,833		
	(8)	State Supp		$ 418,991,759		
	(9)	Total	(7) + (8)	1,308,530,592	884,859,806	423,670,786
Gross state Medicaid expenditures for Rx drugs in 2003 (Shaded is for dual eligibles in 2003)	(10)			$ 4,369,594,713	$ 2,495,318,976	
Rebate adjustment factor	(11)		(9) / (10)	29.95%	35.46%	-5.51%
Adjusted per capita FFS expenditures for Rx drugs	(12)		(6) * [1 - (11)]	$ 1,852.70	$ 1,706.86	$ 145.84
Estimated actuarial value of Rx drug benefits under capitated managed care plans for FY 02-03	(13)	Annual Dual Count		1,506,475	1,506,475	
	(14)	Annual Rx Value		$ 180,912,007	$ 180,912,007	
	(15)	Monthly Dual Count	(13) / 12 months	125,540	125,540	
	(16)		(14) / (15)	$ 1,441.07	$ 1,441.07	
Average number of FFS duals in FY 02-03	(17)		(5)	943,740	943,740	
Average number of MC duals in FY 02-03	(18)		(15)	125,540	125,540	
Base year state Medicaid per capita expenditures for covered Part D drugs for dual eligibles (Weighted Average)	(19)		[[(17) * (12)] + [(18) * (16)]] / [(17) + (18)]	$ 1,804.37	$ 1,675.65	$ 128.72
State FMAP %	(20)		(19) * .50	50% $ 902.19	50% $ 837.83	$ 64.36
Nat'l Rx Drug Expenditures Average Annual Percent from 2003 to 2006	(21)		(20) * [1 + .4225]	42.25% $ 1,283.36	42.25% $ 1,191.81	$ 91.55
Phase-down % for 2006	(22)		(21) * .90	90% $ 1,155.02	90% $ 1,072.63	$ 82.40
Estimated Monthly Clawback Cost per Dual	(23)		(23) / 12 months	$ 96.25	$ 89.39	$ 6.87
Est Duals in 2006, does not include woodwork duals found in 2006	(24)		(22) * 1,106,263	1,106,263 $ 1,277,761,227	1,106,263 $ 1,186,609,247	$ 91,151,980

APPENDIX D

Methodology for Adjusting the State Contribution for the Dual Eligible Population

The following two databases were pulled for calendar year 2003 for the dual eligible population state contribution calculation:

DRUG DATABASE FOR DUAL ELIGIBLE POPULATION CY 2003: A ten percent sample database with fee-for-service (FFS) drug usage data based on National Drug Codes (NDCs-*see italics note below*) for Medi-Cal beneficiaries with Medicare coverage was pulled for drug claims and beneficiaries for the incurred period of January, 2003 through December, 2003 using claims paid from January, 2003 through June, 2004. A ten percent sample allows an adequate level of precision (all numbers are multiplied by ten in the final results). This ten percent random sample was created by selecting records that have a social security number with a "7" in the eighth byte. The data includes claims and eligibility data only for Medi-Cal beneficiaries with Medicare Part A and/or Part B. There were 13,517 NDCs in this database and for each NDC the quantity paid for and the amount paid for the dual eligible population was provided.

REBATE DATABASE FOR CY 2003: A database with fee-for-service (FFS) drug rebate data based on NDC numbers for rebates that were paid and actually received by us from January 2003 through December 2003 was pulled. For each NDC the following was provided: the number of units actually paid for by the labeler, the federal rebate per unit per NDC actually paid by the labeler and the state supplemental rebate per unit per NDC actually paid by the labeler.

The following calculations were made using the DRUG DATABASE FOR DUAL ELIGIBLE POPULATION CY2003 and the REBATE DATABASE FOR CY2003:

TOTAL AMOUNT PAID FOR DRUGS FOR DUAL ELIGIBLE POPULATION FOR CY2003: This amount was calculated by totaling the amount that was paid for each NDC for the dual eligible population for calendar year 2003.

TOTAL AMOUNT PAID AND RECEIVED FOR DRUG REBATES FOR DUAL ELIGIBLE POPULATION FOR CY2003: This amount was calculated by multiplying the quantity that was paid for each NDC for the dual eligible population times the total rebate per unit that was actually paid and received by us for the calendar year 2003 including rebates that were linked to 2003 expenditures but not collected until the period between January, 2004 through June, 2004. These amounts were then totaled for all NDCs.

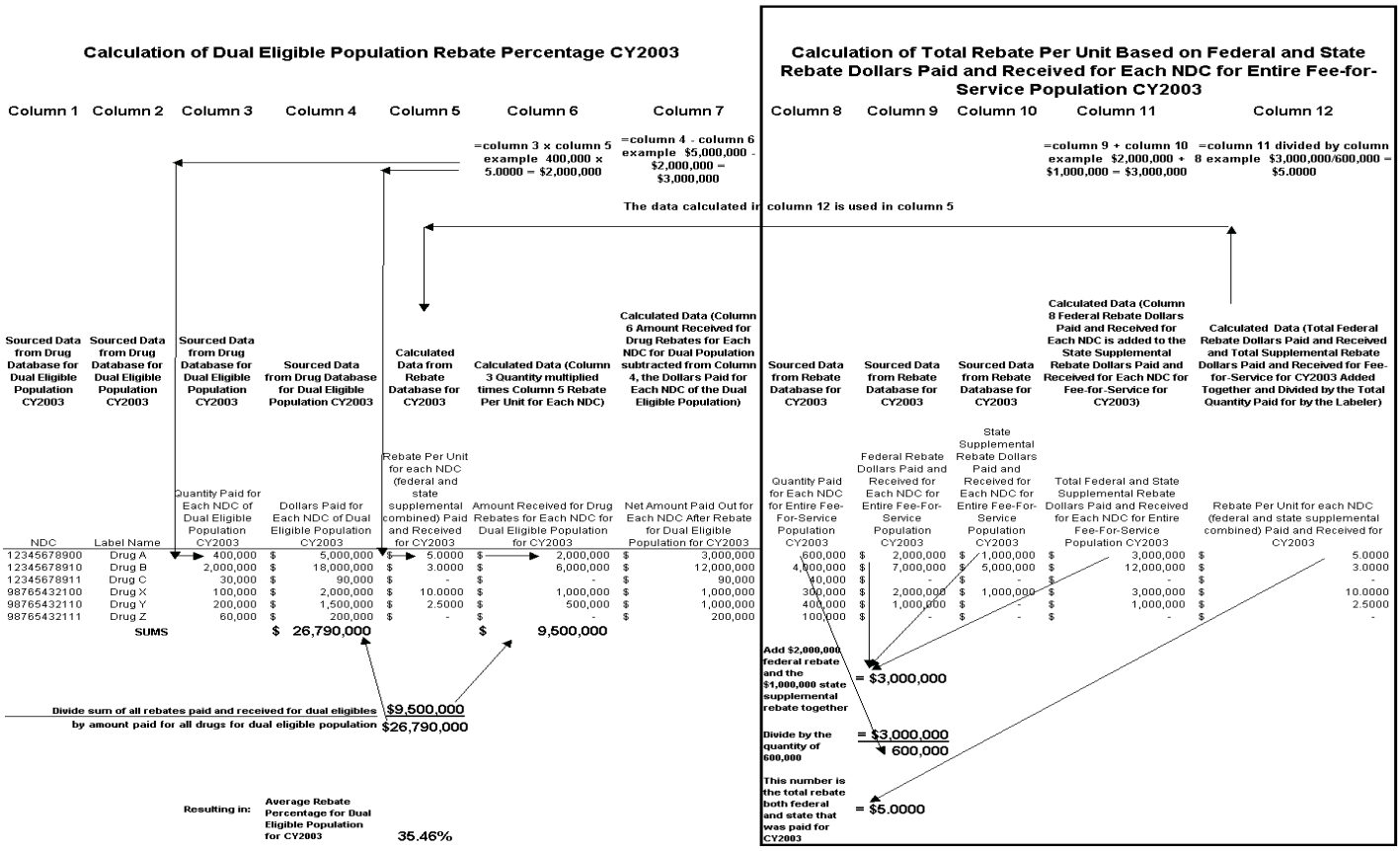
NET AMOUNT PAID FOR DUAL ELIGIBLE POPULATION FOR CY2003: This net amount was calculated for each NDC by subtracting the drug rebate amount actually paid for the dual eligible population for each NDC for CY2003 from the total amount

paid for the dual eligible population for each NDC for CY2003. These net amounts for each NDC were then totaled.

DRUG REBATES FOR DUAL ELIGIBLE POPULATION FOR CY2003 AS A PERCENTAGE OF TOTAL AMOUNT PAID FOR DRUGS FOR DUAL ELIGIBLE POPULATION FOR CY2003: This percentage was calculated by dividing the total amount actually paid for drug rebates for the dual eligible population for CY2003 by the total amount paid for drugs for the dual eligible population for CY2003.

NOTE: (NDC numbers are unique numbers identifying every drug according to its manufacturer, the drug/the drug strength/the drug dosage form and the package size).

SOURCED DATA BASES AND CALCULATIONS TO DETERMINE THE REBATE ADJUSTMENT FACTOR USING DUAL ELIGIBLES AND LAGGED REBATE COLLECTION



CMS-4068-P-720

Submitter : **Date & Time:** 10/01/2004 10:10:37

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Submitter : Dr. Tara Green **Date & Time:** 10/01/2004 10:10:02

Organization : Kroger Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 1, 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 wanted to thank you for all of your hard work in revising and updating Medicare regarding the prescription drug benefit. I would like to take this opportunity to offer some comments for CMS to consider as you develop the final regulations.

Regarding Subpart C: Benefits and Beneficiary Protections:

I would like to suggest that you revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local, and not the plan?s overall, service level. If plans meet the standard on the local level, that is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and would allow my patients to continue to use the pharmacies near their home or work.

Additionally, I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans may identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Further, plans should not be allowed to count their non-preferred pharmacies when evaluated as to whether they meet the access standards. Congress seems to have intended that patients have fair access to their local pharmacy. As the regulation is currently written, it could lead to a restriction of access for many of my patients and Americans in general. I would ask that CMS require plans to offer a standard contract to all pharmacies.

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

I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I am also excited to see that CMS has recognized that pharmacists will likely be the primary providers of MTM services. However, I am concerned that leaving the decision to the plans to choose their provider may lead to the choice of less qualified providers, or worse, providers that they pay to perform these services?a conflict of interest to say the least.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently work in a chain community pharmacy (Kroger) and offer a comprehensive medication review program as well as patient education and medication management services for diabetes, hypertension, hypercholesterolemia, and smoking cessation to highlight a few. Plans should be encouraged to use my services and the services of all pharmacists helping patients each and every day. I believe that I speak for my profession when I say that our primary goal is to help patients gain the best benefit from their medications, with the highest level of safety, and at the lowest possible cost to both the patient and the system.

In conclusion, I would like to thank you for allowing me the opportunity to express my views and applaud you for all of your hard work.

Thanks so much,

Tara R. Green, R.Ph., Pharm.D.
Pharmacist
Kroger Patient Care Center

1955 West Henderson Road
Columbus, Ohio 43220
614-340-0144
columbuspcc@kroger.com

Submitter : Dr. Marsha Martin **Date & Time:** 10/01/2004 10:10:13

Organization : AIDS Action

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

AIDS Action is pleased to have the opportunity to comment on CMS? proposed rule for the new Medicare Prescription Drug Benefit. These comments come to you on behalf of our membership all over the country, comprised of AIDS service organizations, local health departments, and other stakeholders in the forefront of HIV prevention, research, treatment, and care.

Again, AIDS Action appreciates the opportunity to comment on the proposed rules for the Medicare Part D plan. If you have any further questions on this matter, feel free to contact me at (202)530-8030 ext. 3044.

Sincerely,

Marsha A. Martin, DSW
Executive Director

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

AIDS Action would like to comment on several of the provisions in this section.

? AIDS Action agrees with CMS? interpretation of the ?requirement at section 1860D-4(b)(3)(A) of the Act that a formulary be `developed and reviewed? by a P&T [pharmaceutical and therapeutic] committee as requiring that a P&T committee?s decisions regarding the plan?s formulary be binding on the plan.?

? We appreciate CMS? assertion that P&T committees must have ?at least one practicing pharmacist and one practicing physician?[who is expert] in the care of elderly and disabled individuals.? However, this proposed requirement is much too vague as it is written. The categories of ?elderly? and ?disabled? are not clear and must be made more specific.

AIDS Action recommends that ?elderly? and ?disabled? be clearly defined with specific medical specialties. Without relying on clear definitions, this membership requirement will be impossible for P&T committees to satisfy.

? Although we were glad to read that the regulations ?encourage that plans select P&T committee members representing various clinical specialties in order to ensure that all disease states are adequately considered in the development of plan formularies,? we would like this language strengthened by replacing ?encourage? with ?require.? Of course, we realize that the regulations would also need to be much more specific if this requirement were made.

AIDS Action recommends that a pharmacist and a physician with expertise in HIV be required to be members of the committee. If this recommendation cannot be met, we recommend that some arrangement be set up where the P&T committee could take advantage of HIV expertise in another way, from an outside consultant for example.

The health of the Medicare population at large is much too important to risk the validity of drug coverage decisions by relying on P&T committee members whose thinking may be clouded by financial and other conflicts. The credibility of the P&T committees would be further strengthened by having more than one independent pharmacist and more than one independent physician on the committees.

AIDS Action recommends that a majority of committee members be independent and free of conflict.

? HIV is treated with complicated drug regimens of antiretroviral (ARV) therapies. People living with HIV often develop resistances to certain ARVs; therefore, the full range of these drugs need to be available to them so they can easily switch medications once they have developed a resistance to a particular drug. Furthermore, HIV positive individuals are often subject to a number of opportunistic infections (OI) which must be treated with drug therapies. People living with HIV can also have other conditions which are produced by ARV treatment or can add to the complexity of ARV treatment management, such as cervical cancer, hepatitis C, depression, heart disease, and liver disease. Such conditions also need to be considered when establishing an open formulary.

AIDS Action strongly recommends that people diagnosed with AIDS be classified as a special population with access to an open formulary. For ARVs and OIs, AIDS Action recommends that the open formulary be based on the Public Health Service guidelines for the treatment of HIV and OIs.

Moreover, we ask CMS to realize that access to an open formulary is only truly valuable if cost considerations are also taken into account. Most of the people living with HIV who will be depending on Medicare for their drug treatments?roughly 80,000?will be dual eligible, roughly 60,000 people. The dual eligible population comprises people living at or below 135% or the federal poverty level, and even small co-pay increases make a huge difference in their ability to access treatments.

AIDS Action recommends that drugs for the treatment of people living with AIDS be placed on the lowest cost-sharing tier of the plan.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

AIDS Action is extremely concerned about the proposed rules regarding the interaction between the Part D benefit and state ADAPs. We find no logic in the assertion that when ADAPs ?subsidize [Part D] costs?[these payments] would not count as incurred costs.? This restriction will result in an inefficient use of ADAP dollars; moreover, it creates an inequitable system wherein ADAPs are forced to bear an increased financial burden. If state pharmacy assistance programs (SPAP) are permitted to apply their ?wrap-around? expenditures (funded with state dollars) on behalf of clients toward incurred costs, then ADAP programs should have the same option.

AIDS Action recommends that contributions made by ADAPs on behalf of clients to the cost requirements of the Part D benefit be counted as incurred costs, thereby working toward reaching the annual out-of-pocket threshold and catastrophic drug benefit.

ELIGIBILITY, ELECTION, AND ENROLLMENT

AIDS Action requests that the dual eligible population living with HIV and an AIDS diagnosis not be restricted to subsidized MA-PD or PDP plans with a ?monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries.? As this subsidy is based on the ?low-income benchmark premium,? it does not allow access to the full range of plans that may be required by the beneficiary. The health of people diagnosed with AIDS is often dependent on the administration of expensive and complicated drug regimens which must be strictly adhered to so that drug resistances can be avoided. In order for this option to be possible

AIDS Action recommends that beneficiaries be allowed to choose the plan that meets their needs, rather than have a ?choice? guided by a legislative principle dictated by cost concerns.

(AIDS Action realizes that this subsidy amount is written into the Medicare Modernization Act, but would nonetheless like to go on record as being opposed to this provision.)

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Treatment interruptions are directly linked with the development of drug resistances, and the development of such resistances limits the treatment options of people living with HIV. Such a limitation is unacceptable, especially if it can be prevented. This situation can be prevented by dispensing an emergency supply of the ARV medication being considered during any appeals process.

AIDS Action recommends that any appeal concerning a coverage determination for ARV medication should automatically be considered an emergency appeal. Further, beneficiaries living with HIV should be given an emergency supply of the anti-HIV drug being considered during the appeal process, in an amount to cover the time it takes for the PDP or MA-PD to come to a decision.

CMS-4068-P-722-Attach-1.pdf

CMS-4068-P-722-Attach-1.pdf

CMS-4068-P-722-Attach-1.pdf

CMS-4068-P-722-Attach-1.pdf

CMS-4068-P-722-Attach-1.pdf

until it's over
AIDS ACTION

September 30, 2004

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

To Whom It May Concern:

AIDS Action is pleased to have the opportunity to comment on CMS' proposed rule for the new Medicare Prescription Drug Benefit. These comments come to you on behalf of our membership all over the country, comprised of AIDS service organizations, local health departments, and other stakeholders in the forefront of HIV prevention, research, treatment, and care.

Part D Enrollment Process (§ 423.34)

AIDS Action requests that the dual eligible population living with HIV and an AIDS diagnosis not be restricted to subsidized MA-PD or PDP plans with a "monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries." As this subsidy is based on the "low-income benchmark premium," it does not allow access to the full range of plans that may be required by the beneficiary. The health of people diagnosed with AIDS is often dependent on the administration of expensive and complicated drug regimens which must be strictly adhered to so that drug resistances can be avoided. In order for this option to be possible

AIDS Action recommends that beneficiaries be allowed to choose the plan that meets their needs, rather than have a "choice" guided by a legislative principle dictated by cost concerns.

(AIDS Action realizes that this subsidy amount is written into the Medicare Modernization Act, but would nonetheless like to go on record as being opposed to this provision.)

Procedures To Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56)

AIDS Action is extremely concerned about the proposed rules regarding the interaction between the Part D benefit and state ADAPs. We find no logic in the assertion that when ADAPs "subsidize [Part D] costs…[these payments] would not count as incurred costs." This restriction will result in an inefficient use of ADAP dollars; moreover, it creates an inequitable system wherein ADAPs are forced to bear an increased financial burden. If state pharmacy assistance programs (SPAP) are permitted to apply their "wrap-around" expenditures (funded with state dollars) on behalf of clients toward incurred costs, then ADAP programs should have the same option.

AIDS Action recommends that contributions made by ADAPs on behalf of clients to the cost requirements of the Part D benefit be counted as incurred costs, thereby working toward reaching the annual out-of-pocket threshold and catastrophic drug benefit.

Access to Covered Part D Drugs (§ 423.120)

Formulary Requirements

AIDS Action would like to comment on several of the provisions in this section.

- AIDS Action agrees with CMS' interpretation of the "requirement at section 1860D-4(b)(3)(A) of the Act that a formulary be 'developed and reviewed' by a P&T [pharmaceutical and therapeutic] committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan."

- We appreciate CMS' assertion that P&T committees must have "at least one practicing pharmacist and one practicing physician…[who is expert] in the care of elderly and disabled individuals." However, this proposed requirement is much too vague as it is written. The categories of "elderly" and "disabled" are not clear and must be made more specific.

  AIDS Action recommends that "elderly" and "disabled" be clearly defined with specific medical specialties. Without relying on clear definitions, this membership requirement will be impossible for P&T committees to satisfy.

- Although we were glad to read that the regulations "encourage that plans select P&T committee members representing various clinical specialties in order to ensure that all disease states are adequately considered in the development of plan formularies," we would like this language strengthened by replacing "encourage" with "require." Of course, we realize that the regulations would also need to be much more specific if this requirement were made.

  AIDS Action recommends that a pharmacist and a physician with expertise in HIV be required to be members of the committee. If this recommendation cannot be met, we recommend that some arrangement be set up where the P&T committee could take advantage of HIV expertise in another way, from an outside consultant for example.

  The health of the Medicare population at large is much too important to risk the validity of drug coverage decisions by relying on P&T committee members whose thinking may be clouded by financial and other conflicts. The credibility of the P&T committees would be further strengthened by having more than one independent pharmacist and more than one independent physician on the committees.

  AIDS Action recommends that a majority of committee members be independent and free of conflict.

- HIV is treated with complicated drug regimens of antiretroviral (ARV) therapies. People living with HIV often develop resistances to certain ARVs; therefore, the full range of these drugs need to be available to them so they can easily switch medications once they have developed a resistance to a particular drug. Furthermore, HIV positive individuals are often subject to a number of opportunistic infections (OI) which must be treated with drug therapies. People living with HIV can also have other conditions which are produced by ARV treatment or can add to the complexity of ARV treatment management, such as cervical cancer, hepatitis C, depression, heart disease, and liver disease. Such conditions also need to be considered when establishing an open formulary.

  AIDS Action strongly recommends that people diagnosed with AIDS be classified as a special population with access to an open formulary. For ARVs and OIs, AIDS Action recommends that the open formulary be based on the Public Health Service guidelines for the treatment of HIV and OIs.

Moreover, we ask CMS to realize that access to an open formulary is only truly valuable if cost considerations are also taken into account. Most of the people living with HIV who will be depending on Medicare for their drug treatments—roughly 80,000—will be dual eligible, roughly 60,000 people. The dual eligible population comprises people living at or below 135% or the federal poverty level, and even small co-pay increases make a huge difference in their ability to access treatments.

AIDS Action recommends that drugs for the treatment of people living with AIDS be placed on the lowest cost-sharing tier of the plan.

Subpart M—Grievances, Coverage, Reconsiderations, and Appeals

Treatment interruptions are directly linked with the development of drug resistances, and the development of such resistances limits the treatment options of people living with HIV. Such a limitation is unacceptable, especially if it can be prevented. This situation can be prevented by dispensing an emergency supply of the ARV medication being considered during any appeals process.

AIDS Action recommends that any appeal concerning a coverage determination for ARV medication should automatically be considered an emergency appeal. Further, beneficiaries living with HIV should be given an emergency supply of the anti-HIV drug being considered during the appeal process, in an amount to cover the time it takes for the PDP or MA-PD to come to a decision.

Again, AIDS Action appreciates the opportunity to comment on the proposed rules for the Medicare Part D plan. If you have any further questions on this matter, feel free to contact me at (202)530-8030 ext. 3044.

Sincerely,

Marsha A. Martin

Marsha A. Martin, DSW
Executive Director

CMS-4068-P-723

Submitter : Mr. Bradley Rood **Date & Time:** 10/01/2004 10:10:18

Organization : District 10 Consumer Advisory Board

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

I am responding to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit.

CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

Without these medications, people living with hiv/aids will ultimately cost taxpayers more in care. We cannot continue to approach this epidemic in this manner. Please realize the importance and magnitude of prevention of this epidemic to the future of this country. Without the proper medications, prevention of the spread of this disease is not feasible.

Thank you for considering my comments as you finalize the regulations.

Sincerely,

Bradley Rood; Chair
District 10 Consumer Advisory Board
2681 E. Glen Magna Way
Bloomington, IN 47401

CMS-4068-P-724

Submitter : Ms. Mary Kay Hensley **Date & Time:** 10/01/2004 10:10:30

Organization : Ms. Mary Kay Hensley

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

This comment is related to Vitamin exclusion on page 46646 under 'a. Covered Part D Drug' in column 2 and 3. I request that this exclusion of vitamins be changed to allow for the coverage of water-soluable vitamins lost during dialysis. Replacement vitamins prevent severe deficiencies, have been found to lower homocysteine (a cardiovascular risk factor and a cause of vascular access thrombosis) and are important for erythropoiesis. Patients in Gary, IN cannot afford to pay for these prescription products but still wish to live as healthy a life as possible by reducing their risk for cardiac events. Often combination products with vitamins, prescription strength folic acid and iron are prescribed to reduce pill burden for the patient. Providing vitamins seems like it should be more economical than treatments, hospitalizations, and surgery related to cardiac events and other manifestations of vitamin deficiencies.

CMS-4068-P-725

Submitter : Mrs. Kathy Magita **Date & Time:** 10/01/2004 11:10:23

Organization : LACERA

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4068-P-725-Attach-1.doc

September 29, 2004

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

Gentlemen:

Listed below are our comments to you relative to the proposed Medicare prescription drug subsidy regulations.

Overall

- The Los Angeles County Employees Retirement Association (LACERA) is an association that administers and has fiduciary responsibility for the medical plans provided to the retirees of the County of Los Angeles. The plans are funded by the County of Los Angeles and members (based upon the member's years of service at the time of retirement). We, as with other similar governmental agencies, need your confirmation that we are considered a plan sponsor eligible to receive subsidy payments.

Subsidy Application

- Our retirees enter and leave the LACERA retiree medical plans throughout the year. Therefore, we would not be able to provide you with a fully accurate identification of the retirees participating in each plan 90 days before the start of the year.

- We have a 7/1 policy period. The submission is based upon a calendar year period. If plan changes were made for 7/1 during a policy period, how would the submission requirement of plan changes be satisfied?

- We cover domestic partners under our plans. If a domestic partner has Medicare coverage due to qualified employment of his/her own, can he/she be included in the calculation for the subsidy? How do you want these individuals identified?

Creditable Coverage Notice

- You should provide sample wording for this notice, but allow for significant LACERA flexibility in how the notice is delivered. Retirees are accustomed to seeing communications from LACERA in the form of an annual letter as well as a quarterly newsletter. Our retirees look to these documents for all information on their health plans.

- As a public entity, we have retirees and spouses in our plans who are not eligible for Medicare – some because they are not yet age 65, others because they did not participate in Social Security during their employment. Providing creditable coverage notice only to a subset of participants (those eligible for Part D) is not only burdensome to us, but may not accurately reach all eligible individuals. Furthermore, given the timing of the subsidy application process, you will not have identified for us those Part D eligible individuals in time for the November 15, 2005 notice deadline. Instead, we suggest that you allow creditable coverage notice go out to all retirees with clear language, possibly dictated by you.

- We suggest that you support and recognize “employer-provided” retiree health coverage by including language in your Part D application directing retirees who have “employer-provided” health coverage to check with their “employer” to determine creditable coverage status before enrolling in Part D.

- We currently offer both Medicare HMOs and a Medicare supplement plan. Members and their dependents are allowed to switch plans subject to a waiting period. This will create the need for creditable coverage notices for the Medicare supplement plan members moving to a Medicare HMO plan. You need to allow for periodic enrollment and disenrollment in Medicare Part D without penalty for members who move among “employer-sponsored” plan options.

Creditable Coverage Test

- In order to avoid unnecessary actuarial fees and data collections costs, we recommend that you develop safe harbor plan design minimums that meet the Part D requirement and would automatically qualify for creditable coverage. There are only a limited number of plan design approaches in practice today (e.g., copayments, coinsurance with or without deductible) and "employers" can easily compare current benefits against safe harbors.

Plan-Wide Testing

- We have significant membership in Medicare HMOs. If these benefit packages are considered by you to constitute PDP or MA-PDP (that is, Part D coverage), then it is likely that we will fail the plan-wide test and not be eligible to seek the subsidy on our participants in non Medicare HMO plans. We encourage you to address this issue.

Data Submission and Recordkeeping

- The insurance carrier, not the plan sponsor, should maintain claims and financial data.

- Given the additional recordkeeping burden that will be imposed on plan sponsors, we recommend that you consider exempting organizations that elect the subsidy from further Medicare secondary audit procedures.

- We have insured health plans, with discounts, rebates, charge backs, etc. factored into the overall insured premium payments we make. We suggest for insured plans that you accept an insurance carrier attestation that claims used in the subsidy calculation are net of such discounts, rather than require information that we do not have.

- Your record retention requirement is six years after the incurral period. Most carriers keep only 36 months of claims and eligibility data online with the remaining amounts archived. This issue needs to be addressed.

Allowable Retiree Cost

- Our health care program for our retirees includes features that help retirees avoid over or underutilization of prescriptions, avert harmful drug interactions, encourage generic drugs usage, etc. We would like you to consider the cost of these programs as part of the cost of the drug itself.

Actuarial Equivalence

- We have a large number of different retiree contribution amounts, based on plan elected, years of service, Medicare status, and family status. This approach is common. Plan sponsors will need relief on how to calculate “employer cost”.

- In addition, retirees’ contributions cover their share of medical and prescription drug benefits. Plan sponsors will need guidance on how to allocate the retiree’s contribution between medical and prescription drug coverage.

Subsidy Payment Process

- To minimize administrative burden, we prefer the annual subsidy payment option, which eliminates the need for a year-end reconciliation.

We appreciate your consideration to our concerns.

Sincerely,

Kathy Migita, Director
Health Care Benefits Program

CMS-4068-P-726

Submitter : Dr. Edward McMenamin **Date & Time:** 10/01/2004 11:10:25

Organization : AIDS Federation of Chicago

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

My major concerns are that people who are afflicted by AIDS are NOT restricted to only a few drugs to fight the infection, when anyone involved in AIDS pt care realizes that there are so many different side effects and interactions with different drugs to be used and relative to the patient's needs may benefit from a different group of drugs than another patient. Please all access to all meds used to fight this major epidemic. In that vein, please see that patients with AIDS should be designated as a "special needs population" and thereby give them offer them an "open formulary" . In addition, please consider that patients who are eligible for Medicare and Medicaid benefits do not get short changed in this conversion/change and lead to less of a benefit for these underprivileged citizens. Please do not allow any of these citizens to lose any benefits for even a short time in the transition period, because loss of benefits leading to loss of medications could only increase the chances for the virus to become more aggressive in these struggling bodies. Lastly please care for the privacy of these patient's lives, their medical histories and not allow them to be pried into unless there is truly a medical need for the information to be given out regarding their past medical history. Thank you for your attention, and God bless. Ed McMenamin, MD, Downers Grove, ILLINOIS

CMS-4068-P-727

Submitter : **Date & Time:** **10/01/2004 11:10:45**

Organization :

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Testing submission.

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-728

Submitter : Mr. Michael Willden **Date & Time:** 10/02/2004 12:10:26

Organization : Nevada Department of Human Resources

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Attached are comments from Nevada Department of Human Resources.

CMS-4068-P-728-Attach-1.doc

CMS-4068-P-728-Attach-8.doc

CMS-4068-P-728-Attach-4.doc

CMS-4068-P-728-Attach-2.doc

CMS-4068-P-728-Attach-6.doc

CMS-4068-P-728-Attach-7.doc

CMS-4068-P-728-Attach-5.doc

CMS-4068-P-728-Attach-3.doc

CMS-4068-P-728-Attach-9.doc

General Comment – Administrative Costs/Infrastructure

State agencies are subject to restrictive processes in terms of both timing and process to develop the infrastructure and automated systems support to support implementation of new programs. Nevada is currently preparing budgets for State Fiscal Years 2006 and 2007, which will not be approved by the State Legislature until May 2005 at the earliest.

> *Recommend that final rules be issued in a timely manner to ensure States have the necessary information to correctly implement the program. For example, in 423.904, the State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS. Will this require a new system interface to be programmed?*

Definitions – Applicable Growth Factor

Rule 423.902, Page 46861 –

The definition of "applicable growth factor" specifies that the basis will be "the most recent National Health Expenditure (NHE) projections for the years involved." During various CMS teleconferences held this year, CMS representatives have stated that other data could be used as the basis for determining the applicable growth factor. Medicaid expenditure projections have specifically been named as a possible resource since Medicaid has historically kept costs down more efficiently than in the private health care arena. This is an essential element since the applicable growth factor will directly affect the amount of the phased-down contribution (clawback) that States will be required to pay. Additionally, using the NHE projections assumes a uniform cost of drugs nationwide. Drug pricing varies even in small geographic regions and across state lines.

> *Recommend that CMS substitute Medicaid as the source of data on which growth projections will be based. Additionally, recommend that the formula be modified to include state specific data to ensure an equitable approach to estimating drug expenditures.*

Definitions – Base Year Medicaid Per Capita Expenditures

Preamble, Page 46752, and Rule 423.902, Page 46861 –

The definition of "base year Medicaid per capita expenditures" specifies that the base year will be calendar year 2003. This is in accordance with the MMA legislation. However, many States did not see the results of some recently implemented cost-saving measures in calendar year 2003. Therefore, States may be required to make a phased-down contribution (clawback payment) that does not accurately reflect actual prescription drug costs.

> *Recommend that CMS support States by submitting to Congress an amendment to the MMA legislation that allows the base year Medicaid per capita expenditures to be recalculated based on calendar year 2005. This is the last year during which full-dual eligibles will receive full prescription coverage under Medicaid. Recalculations would also apply to all other factors that currently use 2003 as a base year (e.g., actuarial value of capitated prescription drug benefits, gross base year Medicaid per capita expenditures, and rebate adjustment factor).*

Eligibility Determinations for Low-Income Subsidies

Preamble, Page 46751, and Rule 423.904(d)(1), Page 46862 –

This provision requires States to make available low-income subsidy application forms, information about eligibility requirements, and assistance with completion of the forms no later than July 1, 2005. However, plan enrollment may not begin for another five months since the bid and contracting process will not be complete until late 2005. There are advantages to pre-qualifying subsidy-eligible individuals, not the least of which is distributing the workload over a longer period of time. Yet, there are significant disadvantages as well. Specifically, this approach creates a two-step process that may prove difficult for beneficiaries to navigate. Many may mistake the act of applying for a subsidy for the act of enrolling in a prescription drug plan. The open enrollment period may slip by before these beneficiaries discover they missed a step. This should not pose an insurmountable problem for individuals who are deemed eligible for subsidies based on their current participation in certain government programs. Additionally, full-dual eligibles will automatically be enrolled in a plan if they do not voluntarily do so by the end of the open enrollment period. However, many other beneficiaries without these protections may be faced with lack of prescription coverage and/or late enrollment penalties if they inadvertently delay enrollment.

> *Beginning no later than October 1, 2005, recommend that CMS conduct a dynamic enrollment campaign targeted toward beneficiaries who have been determined eligible for subsidies during the pre-qualification process. Recommend that CMS focus on an approach that emphasizes one-on-one contact.*
>
> *Additionally, develop a one-step application/enrollment process that requires all prescription drug plans to include information about the availability of subsidies in their marketing materials and requires plans to include specific eligibility questions on enrollment forms. Require plans to send copies of enrollment forms that include applications for subsidies to the local agency responsible for determining eligibility (States or the Social Security Administration). Any necessary follow-up would be conducted at that point by the responsible agency. (Note that this approach was taken during the drug discount card program. Originally, CMS developed an application form for transitional assistance and instructed card programs to develop separate enrollment forms based on a CMS model. Later, CMS changed direction and required card programs to use a single application/enrollment form to simplify the process for participants.)*

Guaranteeing Access to a Choice of Coverage (Fallback Plans)

Contract terms and Conditions

Rule 423.871, Page 46857 –

This section sets forth requirements associated with fallback prescription drug plans. Among other things, the section lists performance measures by which a plan's performance will be gauged. The list includes a brief reference to customer service, but it does not appear to include requirements for a grievance and appeals process, nor does it address issues such as convenient access to network pharmacies and toll-free customer service hotlines.

Recommend that CMS add language to this section specifying that fallback prescription drugs plans must comply with the provisions of:

- *Subpart C – Benefits and Beneficiary Protections – including but not limited to Rules 423.120 (Access to Covered Part D Drugs) and 423.128 (Dissemination of Plan Information); and*
- *Subpart M – Grievances, Coverage Determinations, and Appeals – Rules 423.560 through 423.638 inclusive.*

Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Definitions – Institutionalized Individual

Rule 423.772, Page 46854 –

CMS currently defines an "institutionalized individual" as a "full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month." Section 423.782(a)(ii) on page 46855 of the proposed rule exempts institutionalized individuals from cost-sharing for covered Part D drugs. Meanwhile, non-institutionalized full benefit dual eligibles will have a copayment ranging from $1 to $5 depending on their income level. Years ago, federal directives and decisions required States to develop programs that allow individuals to reside in the least restrictive setting [e.g., Olmstead v. L. C., 119 S.Ct. 2176 (1999)]. As a result of programs such as Nevada's Community Home-Based Care Initiative Program (CHIP), individuals who would otherwise be residing in skilled nursing facilities are able to remain at home with appropriate supportive services. The current definition of an institutionalized individual appears to discriminate against these non-institutionalized individuals by requiring them to make co-payments. This will result in an obvious financial impact to these individuals as well as to any State that decides to provide wrap-around coverage for co-pays.

> *Recommend that CMS expand the definition of an institutionalized individual to include individuals who meet the level of care for a nursing facility or intermediate care facility for the mentally retarded (ICF/MR) even if their care needs are being addressed in less restrictive settings (e.g., home-based care or waivered group care.*

Definitions – Resources

Rule 423.772, Page 46854 –

The proposed rules define resources as liquid resources that can be readily converted to cash within 20 days. This 20-day timeframe is purely subjective. For example, property stock certificates may be converted within 20 days. However, if the applicant is not competent and guardianship/power of attorney must be established, the sale may take longer than 20 days. A specific timeframe may not be known to staff determining eligibility. This is problematic both for creation of consistent policy rules and staff training. In addition, there is no similar rule pertaining to resources in any other program the State agency administers.

> *Recommend that States be allowed latitude in defining what counts as an asset, even allowing them to disregard all assets, and remove the 20-day time frame. There is precedent for this flexibility in the Medicare Savings programs including the Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), and Qualified Individual-1 programs, which are administered by State Medicaid agencies and include an asset test. States are given latitude in what resources are counted and what level of verification is required. Some States currently use the SSI asset criteria in determining eligibility in its Medicare Savings programs.*

Requirements for Eligibility
Rule 423.773, Page 46854 –
The proposed rules apply one resource requirement to one group, and one resource requirement to another group. This is complicated and confusing. This proposal also has significant systems impact.

However, additional flexibility is allowed in statute. Section 1860D-14(3) defines a subsidy eligible individual and provides that there is an option to apply one of two potential resources tests. 1860-14(3)(A)(iii) provides the individual must meet the resources requirement described in subparagraph (D) or (E). CMS has proposed to apply each of the tests to the two different eligibility groups [below 135% of poverty and between 135% and 150% of poverty]. This creates a real issue, as systems will have to be programmed to consider different asset tests for different income levels and adds to the complexity and expense of complying with these requirements. Although the Secretary has authority to exercise the option of using 1905(p) as a resource test and is opting not to, it does not appear from the statute that the Secretary has authority to mandate two separate resource tests when the statute grants the option.

Subparagraph (E) describes an alternative resource standard and (E)(iv) provides for methodology flexibility. The preamble indicates the Secretary proposes not to exercise this option without allowing States the opportunity to request or justify the use of alternative resource budgeting methods.

> *The Nevada State Pharmaceutical Assistance Program (SPAP) does not have an asset test. Applicants attest to their income and are not required to submit documentation. For a seamless transition of SPAP enrollees to Medicare Part D, it would be preferable to eliminate the asset test altogether. It would result in an additional administrative burden for enrollees and the SPAP.*
>
> *However, if this is not possible, recommend that the Secretary permit States that have more liberal asset or resource disregards in their Medicaid or Medicare Savings Programs to use the same methodology in establishing eligibility for Part D low-income subsidies. Beneficiaries of Medicare Savings programs are automatically deemed eligible for full premium subsidies. States need to use the same resource criteria for Medicare Part D as for their Medicare Savings programs to avoid having two different limits for qualifying for Medicare Part D within the same state (one limit for those automatically deemed eligible based on participation in a Medicare Savings program and a different limit for those who meet the resource limit of the MMA but do not participate in a Medicare Savings program).*

Eligibility Determinations, Redeterminations, and Applications
Rule 423.774, Page 46855 –
Under the statute and proposed regulations, either State Medicaid programs *or* the Social Security Administration will determine whether Medicare Part D eligible individuals are eligible for premium and cost-sharing subsidies. The proposed regulations provide that eligibility determinations are made by the State Medicaid plan, if the individual applies with the Medicaid

agency, or by the Social Security Administration (SSA), if the individual applies through a SSA office. The preamble to the proposed regulations states that although there are two avenues for eligibility determinations for low-income subsidies, the goal is to achieve two procedures that would produce the same outcome. Where an individual makes an inquiry to a PDP or MA-PDP regarding application or eligibility for low-income subsidies, individuals "should be referred to state agencies *or* SSA." The discussion states that, under the statute, redeterminations and appeals are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. The discussion notes that the Commissioner of the SSA will decide how to conduct redeterminations and appeals for those determinations made by Social Security.

> *Recommend that the final rules make the redetermination and appeals process consistent among SSA and Medicaid agencies to eliminate confusion among applicants/recipients and to avoid the perception of disparate processes.*

Premiums and Cost-Sharing Subsidies for Low-Income Individuals
Rules 423.780 and 423.782, Page 46855 –
We have been hearing that the Social Security Administration wants States to simply take applications and forward them to the Social Security Administration. This is not in compliance with either the statute or the proposed regulations. We are therefore confused and concerned.

P.L. 108-173, the Medicare Prescription Drug, Improvement and Modernization Act of 2003, provides for amendments to Title XIX of the Social Security Act in Section 103. That section specifically provides that Section 1902(a) of the Social Security Act [42 USC § 1396a(a)] is amended by adding a new subsection 66 which reads as follows:

> (66) provide for making eligibility determinations under section 1935(a).

A new section 1935 to the Social Security Act [42 USC § 1396u-5] is then provided for. The pertinent sections of that new statute provide:

> SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE PRESCRIPTION DRUG LOW-INCOME SUBSIDIES AND MEDICARE TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a) subject to subsection (e), a State **shall** do the following:
>
> (1) INFORMATION FOR TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE VERIFICATION.—The State shall provide the Secretary with information to carry out section 1860D–31(f)(3)(B)(i).
>
> (2) ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.— **The State shall—**

> (A) **make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1860D–14** [42 USC § 1395w-114];
>
> (B) inform the Secretary of such determinations in cases in which such eligibility is established; and
>
> (C) otherwise provide the Secretary with such information as may be required to carry out part D, other than subpart 4, of title XVIII (including section 1860D–14).
>
> (3) SCREENING FOR ELIGIBILITY, AND ENROLLMENT OF, BENEFICIARIES FOR MEDICARE COST-SHARING.—As part of making an eligibility determination required under paragraph (2) for an individual, **the State shall** make a determination of the individual's eligibility for medical assistance for any Medicare cost-sharing described in section 1905(p)(3) and, if the individual is eligible for any such Medicare cost-sharing, offer enrollment to the individual under the State plan (or under a waiver of such plan).
>
> (b) REGULAR FEDERAL SUBSIDY OF ADMINISTRATIVE COSTS.—The amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under the appropriate paragraph of section 1903(a).

Therefore, as a condition of a State's Medicaid State Plan, States are required to determine eligibility for Part D benefits. It appears that neither the Social Security Administration nor CMS has the authority to change this statutory requirement. In addition, the regulations as proposed comport with the statute and require the States to perform eligibility determinations for applicants that come through the State's door, including providing redeterminations and hearing rights.

If, indeed, CMS intends the States to be merely intake sites, taking applications and forwarding them to the SSA, the regulations need to clearly state this so that if any litigation occurs over this issue, CMS will defend it.

Premium Subsidy

Preamble, Page 46728 and 46729 –

The portion of the preamble discusses how premium subsidies will be determined in each region. As stated on Page 46728, "the premium subsidy amount is equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region," whichever is greater. As stated on Page 46729, if an individual who is eligible for a premium subsidy enrolls in a plan for which the premium is higher than the established premium subsidy, the individual will be responsible for paying the difference. This approach could force low-income individuals into plans that do not adequately meet their prescription drug needs. For instance, a plan that charges a premium amount that would be fully subsidized might conceivably have a more restrictive formulary than

a plan that charges a higher premium. The approach could unintentionally create "classes" of beneficiaries, specifically segregation between low-income and higher-income beneficiaries.

> *Recommend that premium amounts charged by prescription drug plans be regulated to ensure that a low-income individual may enroll in ANY basic prescription drug plan and be assured of a fully subsidized premium.*

Premium Subsidy

Preamble, Page 46730, and Rule 423.780(c), Page 46855 –

This provision deals with late enrollment penalties for full subsidy eligible individuals. Specifically, these individuals will be entitled to "an additional premium subsidy equal to 80 percent of the late penalty for the first 60 months during which the penalty is imposed and 100 percent of the penalty thereafter." The same benefit is not available to other low-income subsidy eligible individuals, even though these individuals also subsist on very low incomes (no more than 150 percent of the Federal Poverty Level) and cannot afford late penalties. Confusion about the implementation of Part D is likely to delay enrollment for many people, low-income or not. Imposing late penalties on those least able to afford it will only diminish Part D's overall value for these individuals.

> *Recommend that CMS increase the late penalty enrollment subsidy to 100 percent beginning at the time the late fee is first imposed, and recommend that the benefit be extended to both full subsidy eligible individuals and other low-income subsidy eligible individuals.*

Administration of Subsidy Program

Preamble, Page 46732 –

CMS requests comments on whether beneficiaries should be responsible for reimbursing any cost sharing or premiums paid on their behalf by another program or charity. Programs and charities that provide financial assistance of this kind generally do so because the individual meets certain low-income criteria. To ask that these individuals then reimburse the charities for assistance after Medicare Part D becomes their primary payer defeats the purpose of the assistance. If a charity is to be reimbursed, the funds should come from the primary payer.

> *Recommend that Medicare (or prescription drug plans) be required to reimburse programs and charities that pay cost sharing or premiums on behalf of Part D beneficiaries.*

General Comment – Subpart M

This subpart does not address who is responsible for the cost of a drug during any of the appeal processes described. The potential always exists for a prescription drug plan (or other entity) to make a decision that favors the enrollee. When any doubt exists about the outcome, prescription drug plans should be required to cover the disputed drug while the proper reviews are conducted. This provision would benefit the enrollee in two ways – it would make the drug available to the enrollee and it would provide an incentive for prescription drug plans to make coverage decisions in a timely manner. For prescription drugs plans that are affiliated with managed care plans (or other plans that provide medical coverage), it would reduce the risk of further, potentially costly medical intervention if an enrollee is not able to purchase and use a prescribed drug.

> *Recommend that CMS add a provision to Subpart M that requires prescription drug plans to cover the cost of a disputed drug while any form of appeal is in process.*

Definitions – Authorized Representative

Rule 423.560 (Definitions), Page 46841 –

The definition of an "authorized representative," as presented in Subpart M, limits who may serve in this capacity, limits the scope of their authority, and is inconsistent with the definition of who may act on behalf of a beneficiary in Subpart P (see the definition of "personal representative" in 422.772). As noted in our comments regarding Subpart A, the term *authorized representative* should be discontinued and replaced with the term *personal representative*. In addition, who may serve as a personal representative should be expanded to include appropriate entities (e.g., SPAPs) and their role should be expanded to embrace all aspects of Part D participation. Appropriate placement of this definition would be in Subpart A.

> *Recommend that CMS adopt the term "personal representative" throughout the regulations and discontinue use of the term "authorized representative." Recommend that the definition be expanded to allow appropriate entities (e.g. SPAPs) to serve as personal representatives and that the scope of authority be expanded to embrace all aspects of Part D participation. This would make the most suitable placement of the definition Subpart A, Section 423.4 (Definitions).*

General Provisions

Rule 423.562(a)(2), Page 46841 –

This provision requires a prescription drug plan to "ensure that all enrollees receive written information" about grievance and appeal procedures. It does not specify when or how the information will be disseminated.

> *Recommend that CMS add more detailed language that directs prescription drug plans to provide written information about grievance and appeal procedures upon enrollment in the plan. In addition, plans should include a reminder statement and contact telephone number on explanations of benefits and on notices concerning changes to formularies.*

General Provisions

Rule 423.562(c), Page 46841 –

This provision states that, "If an enrollee has no further liability to pay for prescription drugs furnished through a PDP, a determination regarding these items or services is not subject to appeal." This is unfair to beneficiaries who have legally reached an out-of-pocket expense limit qualifying them for 100% coverage. It gives prescription drug plans an inappropriate level of unquestionable authority to determine what is appropriate for a beneficiary. If this provision is enforced, even a prescribing physician could not appeal on behalf of a beneficiary for whom the physician believes a drug is medically necessary.

> *Recommend that this provision be deleted. The right to appeal should be available to every beneficiary regardless of coverage status. It is a right the beneficiary earns upon enrollment in a plan and it should not be subject to revocation for any reason. Furthermore, the fact that the beneficiary pays a monthly premium for coverage (regardless of whether that premium is subsidized) means that he or she has an ongoing liability even after co-pays are no longer required.*

Expedited Determinations

Rules 423.570(c)(3) and 423.570(d)(2), Pages 46842 and 46843 –

Rule 423.570(c)(3) addresses the process through which a prescription drug plan approves or denies an enrollee's request for an expedited determination. It requires the prescription drug plan to make "prompt decisions." Rule 423.570(d)(2) addresses notifying enrollees when a prescription drug plan decides to deny an enrollee's request for expedited determination. It requires plans to give enrollees "prompt oral notice." Use of the term "prompt" is open to interpretation and does not provide the parameters necessary to ensure a standardized response time among all prescription drug plans. It does not ensure that enrollees will receive immediate response in situations where an enrollee's health may be in jeopardy. Additionally, if a prescription drug plan is not also associated or affiliated with a managed care plan (or another plan that pays for medical care), the prescription drug plan would have less incentive to ensure that determinations are made in a timely manner.

> *Recommend that CMS replace the word "prompt" in each provision with a specific time frame. Rule 423.570(c)(3) should require prescription drug plans to make a decision on whether a request for an expedited determination is approved or denied within 24 hours of receipt. Rule 423.570(d)(2) should require prescription drug plans to orally inform enrollees of denials within 24 hours of receipt.*

Expedited Determinations

Rule 423.572(a), Page 46843 –

This rule gives prescription drug plans up to 72 hours to make coverage decisions upon receipt and acceptance of an expedited determination request. The actual language states that the plan must make a decision and notify the enrollee "as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request." Prescription drug plans are most likely to approve a request for an expedited determination if an enrollee's health is at risk.

Therefore, a coverage decision should subsequently be made without delay. In 72 hours, an enrollee's health could deteriorate significantly and require additional, perhaps costly medical intervention. As mentioned previously, if a prescription drug plan is not also associated or affiliated with a managed care plan (or another plan that pays for medical care), the prescription drug plan would have less incentive to ensure that determinations are made in a timely manner.

Recommend that CMS revise this provision to allow prescription drug plans no more than 48 hours to make a coverage determination. The time frame would begin upon receipt of an expedited determination request; not at the point the request is approved.

Exceptions Process
Preamble, Page 46720, Rule 423.578(a)(2), Page 46843 –
On page 46720 of the preamble, CMS proposes to require that prescription drug plans "establish a blanket rule permitting continued access to a drug at a given price when there is a mid-year change to the tiering structure." This type of provision would be advantageous to both beneficiaries and prescription drug plans since it would eliminate the need for beneficiaries to file requests for exceptions and for plans to process those exceptions. Additionally, beneficiaries who enroll in a particular plan because its formulary includes a given drug should not be penalized financially when post-enrollment changes are made. Later, if beneficiaries wish to change plans during open enrollment, they are free to do so before the new tiering structure affects them.

Recommend that CMS implement this proposal.

Exceptions Process
Preamble, Page 46720, Rule 423.578(a)(2), Page 46843 –
On page 46720 of the preamble, CMS proposes to require an enrollee, who is using a drug that is discontinued from a formulary or is no longer considered a preferred drug, to sample a preferred drug ***and experience adverse effects*** before being permitted to resume the original drug. This approach is unfair to a beneficiary who is experiencing good results from a given drug. Moreover, the practice has potential medical risks. If the beneficiary does experience adverse effects, it will negatively impact his/her life and may result in otherwise unnecessary medical intervention. If this occurs, prescription drug plans that are not affiliated with a managed care plan (or another plan that provides medical care) may not experience a financial impact. However, the responsible health plan will.

Recommend that the proposal be rejected or, as an alternative, that CMS delete the requirement that enrollees must "experience adverse effects before being permitted to resume the original drug." Instead, it would be more appropriate to use language that allows an enrollee to resume the original drug if the preferred drug is "clinically ineffective." Additionally, it would be prudent to allow exceptions to this rule when an enrollee has a history of clinical failures with the preferred drug.

Exceptions Process
Preamble, Page 46720, and Rule 423.578(a)(2)(ii), Page 46843 –
This section lists the criteria that a prescription drug plan must utilize when considering a request for an exception to the plan's tiered cost-sharing structure. Rule 423.578(a)(2)(ii) allows the plan to consider "the cost difference between the preferred drug and the requested prescription drug." Cost should not be a factor when an enrollee's physician certifies that the plan's preferred drug is "not as effective for the enrollee as the requested drug ... or that the preferred drug ... may have adverse effects for the enrollee" [per 423.578(a)(4)]. Cost considerations are addressed in the bylaws for Nevada Medicaid's Drug Utilization Review Board and its Pharmacy and Therapeutics Committee, each of which has a role in prescription drug management. The bylaws for both of these entities clearly prohibit members from taking drug costs into consideration when making utilization decisions or recommendations. Private prescription drug plans should be held to the same standards.

Recommend that CMS delete this item from the list of exception criteria.

Standard Redeterminations
Rule 423.582, Page 46845 –
This section addresses requests for standard redeterminations. It does not contain a provision that specifies who may file a request for a standard redetermination; it simply refers several times to "an enrollee."

Recommend that CMS add a provision specifying who may file a request for a standard redetermination. Recommend that the list include the enrollee, the enrollee's authorized representative, and the enrollee's prescribing physician.

Timeframes for Standard Redeterminations
Rule 423.590(a), Page 46845, and Rule 423.590(b), Page 46846 –
The timeframes for standard redetermination of a request for covered drug benefits and of a request for payment are listed as 30 days and 60 days, respectively. The rules state that these timeframes are applicable even in situations where the prescription drug plan makes a decision that is "completely favorable" to the enrollee. A "completely favorable" decision means that the plan's initial determination was incorrect and that the plan should cover and/or pay for the requested drug. As the rules are currently written, the enrollee may already have waited anywhere from three days to two weeks for the initial, incorrect decision. Imposing another 30- or 60-day wait is inappropriate.

Recommend that CMS reduce these timeframes to 14 days for covered drug benefit redeterminations [423.590(a)] and 30 days for payment redeterminations [423.590(b)].

Expedited Redeterminations
Rules 423.580, 423.584(a), and 423.586, Page 46845 –
These provisions allow only an enrollee or the enrollee's prescribing physician to request an expedited redetermination or to submit evidence in support of the disputed issue. While it may be necessary to obtain evidence from a prescribing physician, it should not be necessary to limit

those who may request an expedited determination to the enrollee or the physician. In accordance with our previous recommendations concerning the use of the term personal representative in place of authorized representative, a request from a personal representative acting on behalf of an enrollee should be sufficient to begin the process.

> *Recommend that CMS add the enrollee's personal representative to the list of those who may request an expedited determination.*

Expedited Redeterminations
Rules 423.584(c)(2) and 423.584(d)(2), Page 46845 –
Rule 423.584(c)(2) focuses on the timeframe in which a prescription drug plan may approve or deny an enrollee's request for an expedited redetermination. It requires the prescription drug plan only to make "prompt decisions." Rule 423.584(d)(2) directs prescription drug plans to provide an enrollee with "prompt oral response" when a request for an expedited redetermination is denied. As stated previously in these comments, use of the term "prompt" is open to interpretation and does not provide the parameters necessary to ensure a standardized response time among all prescription drug plans. It does not ensure that enrollees will receive immediate response in situations where an enrollee's health may be at risk. Additionally, if a prescription drug plan is not also associated or affiliated with a managed care plan (or another plan that pays for medical care), the prescription drug plan would have less incentive to ensure that redeterminations are made in a timely manner.

> *Recommend that CMS replace the word "prompt" in each provision with a specific time frame. Rule 423.584(c)(2) should require prescription drug plans to make a decision on whether a request for an expedited redetermination is approved or denied within 24 hours of receipt. Rule 423.584(d)(2) should require prescription drug plans to orally inform enrollees of denials within 24 hours of receipt.*

Independent Review Entity, Administrative Law Judge, Medicare Appeals Council
Rules 423.600 and 423.610, Page 46846, and Rule 423.612, Page 46847 –
These provisions outline an enrollee's right to request redetermination by an independent review entity, a hearing by an administrative law judge, or a review by the Medicare Appeals Council. Contrary to most other sections, these provisions do not specify who may submit a request for any of these functions. References are made only to "the enrollee."

> *Recommend that CMS practice consistency within these provisions and list who may submit requests for IRE, ALJ, and MAC determinations. Recommend that the list include the enrollee, the enrollee's authorized representative, and the enrollee's prescribing physician.*

Reopening and Revising Determinations and Decisions
Rules 423.634(a)(1) and (2), 423.634(b)(1) and (2), and 423.634(c), Page 46847 –
Section 423.634 of the proposed rule focuses on reversals of prescription drug plan decisions, including reversals issued by the plan, an independent review entity, an administrative law judge or the Medicare Appeals Council. When a plan reverses its own decision, it is allowed up to 30

days after the date the request for redetermination is received to authorize or provide the benefit under dispute, and is allowed up to 60 days after the date for request for redetermination is received to make a disputed payment. When an independent review entity reverses a plan's decision, the plan is allowed up to 72 hours after it receives notice of the reversal to *authorize* the disputed benefit and up to 14 days to *provide* the disputed benefit. Additionally, a plan is allowed up to 30 days to make payment for the previously denied coverage. If a plan's decision is reversed by an administrative law judge or another higher level of appeal, the plan has up to 60 days from the date it receives notice of the reversal to pay for, authorize or provide the disputed benefit. It seems unnecessary to allow protracted amounts of time for plans to take action after a decision is reversed. Beneficiaries and pharmacies should not be forced to wait for lengthy periods to receive a benefit or a payment that should apparently not have been denied in the first place. From a health care perspective, it is much more prudent to ensure that a beneficiary obtains a needed drug as soon as possible to ensure that his or her health is stabilized and/or improved.

> *Recommend that CMS impose one standardized time frame during which prescription drug plans must pay for, authorize and/or provide a previously disputed benefit. The time frame should match the shortest time frame currently in this section – 72 hours from the date the plan either reverses its own decision or receives notice that another entity has reversed its decision. [See 423.634(b)(1) which requires plans to authorize the benefit under dispute within 72 hours from the date it receives notice that an independent review entity has reversed the plan's decision.] This timeframe also matches that allowed when a plan reverses its coverage determination via an expedited redetermination [423.638(a)].*

Timeframes for Expedited Redeterminations or Reconsidered Determinations
Rule 423.638(c), Page 46848 –
When an administrative law judge or a higher level of appeal reverses a decision made by an independent review entity, the prescription drug plan is allowed up to 60 days from the date it receives notice of the reversal to authorize or provide the benefit. As noted previously, there is little justification for such a lengthy timeframe.

> *Recommend that CMS impose the same standardized time frame for this event as noted for Section 423.634. Recommend that CMS allow plans no more than 72 hours from the date the plan receives notice of the reversal to authorize or provide the benefit. This also matches other timeframes listed in Section 423.638.*

Coordination of Benefits

Coordination Under Part D with Other Prescription Drug Coverage (i.e., SPAPs)

Rule 423.464(e)(1)(ii) –

We have concerns about the language in 423.464(e)(1)(ii), which requires a State Pharmaceutical Assistance Program (SPAP) to provide assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls. The language does not specifically prohibit SPAPs from partnering with one or more Part D plans. However, the preamble does indicate that SPAPs may not steer beneficiaries to one plan or another through benefit design or otherwise.

> *Recommend that auto-enrollment into a Part D plan, with the ability to opt-out, not be considered steering or discrimination. For SPAPs and Part D plans to effectively coordinate and to enhance enrollment into Part D, it may be necessary to partner with one or more Part D plans. This does not mean that the SPAP would not offer equal assistance to its members that choose another plan.*

User Fees

Preamble, Page 46696, and Rule 423.464(c) and 423.464(f)(3) –

As stated in the preamble and also in the rules cited above, CMS may not charge State Pharmaceutical Assistance Programs (SPAPs) user fees for coordination of benefits, but it <u>may</u> charge user fees to other drug plans including Medicaid. Additionally, MA-PDs and PDPs may impose fees related to the cost of coordination on both SPAPs and other drug plans. Any user fees imposed on SPAPs and/or Medicaid by prescription drug plans will place an undue burden on these publicly funded programs. There are no provisions in the proposed rules that place any restrictions on the amount of money that may be charged. The sole restriction is found in 423.464(f)(3) and this states only that plans "may not impose fees on other plans that are unrelated to the cost of coordination of benefits."

> *Recommend that provisions either exempt SPAPs and Medicaid programs from paying any user fees (to neither CMS nor to Part D plans) or impose a cap on user fees for these entities.*

User Fees

Preamble, Page 466701 --

Comments are requested regarding the method that CMS should employ in imposing user fees. Should fees be paid on a monthly or quarterly basis, should fees be based on the volume of data exchanged, and should electronic payment be required?

> *Recommend that user fees be based on the actual volume of data exchanged and due no less than 30 days <u>after</u> CMS has calculated the <u>actual data exchange</u> for the month in question. (And, as stated above, user fees should not be charged to SPAP and Medicaid programs or, at minimum, limitations should be placed on user fees charged to these programs.)*

Data Exchange

Preamble, Pages 46701 and 46706 –

On page 46706 of the preamble, CMS proposes two options for tracking true out-of-pocket costs (otherwise known as TrOOP).

The first option claims to place the sole responsibility of tracking TrOOP costs on PDPs and MA-PDs. However, this is misleading. They would actually serve as individual repositories for TrOOP information only about their own enrollees. All secondary or third-party payers would have to identify the Part D plan in which the beneficiary is enrolled, establish the necessary telecommunications links, transmit enrollment information, and transmit claims payment data to the beneficiary's PDP or MA-PD each time a claim is paid. This could prove quite costly to secondary and third-party payers who may have to accomplish these tasks for many different beneficiaries enrolled in many different Part D plans. Not only would these payers have to deal with a technological nightmare of countless potentially incompatible systems, but each PDP and MA-PD would be allowed by law to impose "user fees" on the plans that access their systems.

The second option would require CMS to contract with a facilitator to establish "a single point of contact between payers." This option would create a central repository that all primary and secondary payers would be required to use and that third-party payers could voluntarily utilize. There would be far fewer problems with technological compatibility. Plus, the system could be paid for by CMS. On page 46701, CMS states that it will fund "the development and implementation of a system to assist in the coordination of benefits – if and when it is determined that our development of the system is the appropriate option." As an added bonus, SPAPs could not be charged a user fee to access the system because it would be a CMS system.

Recommend that CMS adopt Option 2 for coordination of benefits.

SPAP Issues

Preamble, Page 46701 and 46702 –

CMS requests comments on multiple SPAP issues. Below are some of the inter-related issues that surround wrap-around coverage and coordination of benefits, followed by comments concerning the important factors that must be considered as CMS develops regulations to address these issues.

- How might CMS ensure that wrap-around coverage offered by SPAPs and others does not undermine or eliminate the cost management tools established by Part D plans?
- What is the most effective way to administer the coordination of benefits provisions without creating undue administrative burden on either Part D plans or the SPAPS and other insurers that might provide wrap-around coverage?
- How will SPAPs actually coordinate with Medicare drug plans?
- Should SPAPs be required to provide feedback on how much of the remainder of the claim they have actually paid (for TrOOP)?
- CMS assumes that some SPAPs will pay Part D plans' premiums on behalf of enrollees or wrap-around coverage. For SPAPs that choose to wrap-around coverage rather than pay premiums, CMS proposes to include SPAP information in a coordination of benefits system.

Coordination of Benefits

An integral part of coordination with Medicare drug plans is communication. We stress the importance of CMS requiring Part D plans to notify the SPAPs of all activity concerning SPAP members.

The close coordination of benefits between SPAPs and Medicare drug plans is imperative. The use of one Part D enrollment card to access benefits under an SPAP, and allowing SPAP payments to count toward TrOOP, is extremely important in coordinating the benefits. However, we have concerns about what the SPAP is going to be required to do to track TrOOP expenditures. If SPAPs are prohibited from partnering with one PDP this may seriously restrict the ability to administer this provision without creating an undue administrative burden on the SPAP.

We request that CMS be cautious in requesting feedback from SPAPs about claim expenditures and remain mindful not to add to the administrative burden that Part D is imposing on SPAPs.

By choosing to contract with a facilitator to establish a "single point of contact" or clearinghouse between payers, CMS will alleviate some of the administrative burden on Part D plans, SPAPs and other insurers that provide wrap-around coverage, and CMS will provide a means for SPAPs to coordinate with Medicare drug plans. As explained by George Mills of CMS during an SPATC meeting, it will not be necessary for SPAPs to provide feedback on how much of the remainder of a claim they have paid because these payments will count toward TrOOP and it will be as though the beneficiary made the payment.

Medicare Parts A and B Issues

Preamble, Page 46703 –

- As noted on page 46703 of the preamble, a beneficiary could lose Part B benefits for a drug if the beneficiary fills the prescription at a pharmacy that does not have a Medicare supplier number. CMS wants to "encourage" Part D plans to enroll pharmacies with Medicare supplier numbers in their networks and "encourage" Part D plans to inform beneficiaries of the need to fill prescriptions at Medicare pharmacies.

  Recommend that CMS "require" (not merely "encourage") Part D plans to enroll pharmacies with Medicare supplier numbers in their networks and, if a network pharmacy does not have a Medicare supplier number, to encourage that pharmacy to apply for one. In addition, Part D plans should be required to educate beneficiaries on the value of choosing a network pharmacy that has a Medicare supplier number and provide beneficiaries with information about which of its network pharmacies has a Medicare supplier number.

- CMS is considering whether a drug denied Part B coverage because the pharmacy did not have a Medicare supplier number should become a covered Part D drug. CMS is also considering whether a drug denied Part B coverage for any other reason should become a Part D covered drug.

Recommend that CMS cover the cost of Part B drugs purchased in good faith by a Part D beneficiary at a pharmacy that does not have a Medicare supplier number. However, other valid reasons for denial should not be over-ridden by Part D.

Eligibility Issues

Preamble, Page 46706 –

CMS is considering the establishment of an eligibility query system (using HIPAA 270/271) that could be accessed by pharmacies to facilitate proper billing. To ensure that this system contains all pertinent payer information, CMS may require beneficiaries to disclose, upon enrollment in a Part D plan, any third-party payment information and to sign a HIPAA-compliant consent for release of data held by these third-party payers.

Recommend that CMS implement both of these proposals – the query system and the beneficiary disclosure requirement.

Definitions -- Dispensing Fees

Preamble, Page 46647 and 46648 (will be inserted in Rule 423.100 Definitions, Page 46815) –

In determining how to define "dispensing fee," CMS has developed three options. Option 1 would include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary. Option 2 would include the activities included in Option 1 plus amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered. Option 3 would include the activities in Options 1 and 2 plus activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist. Options 2 and 3 would eliminate current gaps in coverage relative to home-infused drugs, although CMS is concerned about double billing with regard to costs that are separately billable to Part A, Medicaid or supplemental insurance.

> *Recommend Option 3 or, at least, Option 2. Any gaps in coverage could potentially fall to Medicaid for full-dual eligibles.*

Definitions – Incurred Costs

Preamble, Pages 46650, and Rule 423.100 Definitions, Page 46815 –

On page 46650 of the preamble, CMS raises a question about whether assistance provided through indigent patient programs operated by pharmaceutical manufacturers should be counted toward incurred out-of-pocket expenses. CMS is uncertain whether assistance provided through these programs is allowable under Federal fraud and abuse laws, including the anti-kickback statute. It is important to note that these programs usually have strict limitations with relation to the duration or amount of assistance. For instance, a manufacturer may provide only a one-month supply of a particular drug or may simply provide a small discount for ongoing purchases, plus they generally do not assist individuals who have any other form of prescription coverage. Therefore, if a Part D beneficiary were to receive help from a manufacturer, it would probably be during the so-called "donut hole" when they had surpassed the initial coverage limit and had not yet reached the catastrophic coverage limit. Allowing this assistance to count toward incurred costs would be a benefit to the Part D participant, but would do little (if anything) for the manufacturer. Manufacturers typically do not widely market or advertise their indigent patient programs; they most often wait for patients to request assistance (usually after a referral by a social service provider). It would hardly be cost-effective for them to "recruit" new users through an indigent patient program so that they could later be reimbursed through Part D. Additionally, in states that do not have a State Pharmaceutical Assistance Program (SPAP) and there is limited access to charitable organizations, the manufacturers' indigent patient programs are sometimes the only payment assistance available. It would be unfair to beneficiaries who use these programs to disallow the costs.

> *Recommend that this form of assistance be counted toward incurred out-of-pocket expenses.*

Definitions – Insurance and Otherwise

Preamble, Page 46650 and 46651, and Rule 423.100 Definitions, Page 46815 –

CMS asserts that including Medicaid, SCHIP, and other government programs that assist with medical costs in its definition of "insurance or otherwise" is consistent with Sections 1860D-

2(b)(4)(C)(ii) and 1860D-24(b)(1) of the MMA. This is arguable. Section 1860D-2(b)(4)(C)(ii) gives absolutely no explanation of what constitutes "insurance or otherwise" when the reference is used in relation to incurred costs. Section 1860D-24(b)(1) lists Medicaid as a prescription payment drug resource only to ensure that the program is included in coordination of benefits requirements. There is no indication that Congress actually intended Medicaid (or any other program mentioned in this section) to be defined "insurance or otherwise."

Including Medicaid, SCHIP, and other government programs that provide medical assistance in the definition of "insurance or otherwise" has significant ramifications. For instance, it means that if a Medicaid program chooses to use state-only monies to provide wrap-around benefits for full-benefit dual eligibles (who have never before been asked to make co-payments), the expenses will not count toward incurred out-of-pocket costs. Even more disturbing is the effect on AIDS Drug Assistance Programs (ADAPs). As CMS points out on page 46651 of the preamble, Part D costs subsidized through an ADAP will not count toward incurred out-of-pocket expenses because ADAPs are funded through Federal (Title II) grants. This will put an undue financial burden on these disease-specific programs and will adversely affect their participants. These participants will essentially never become eligible for catastrophic coverage under Part D. Costs will continue to fall on the ADAP when Part D should, in all fairness, pick up catastrophic coverage costs for people with this disease in the same manner as it will for people with other diseases. CMS's approach could be viewed as discriminatory to disease-specific programs. Additionally, if provisions are made that allow ADAP participants to reach the Part D catastrophic coverage limit, ADAPs will be free to assist more individuals with AIDS who are not eligible for Part D benefits.

> *Recommend that CMS delete items (4) SCHIP and (5) Medicaid from the definition of "insurance or otherwise," and revise item (7) concerning other government-funded programs so that programs such as ADAP and their participants will not be adversely affected by restrictions surrounding incurred out-of-pocket costs.*

In addition, CMS specifically requests comments regarding whether health savings accounts should be included in the definition of "insurance or otherwise" (see bottom of page 46650 of the preamble).

> *Recommend that health savings accounts not be included in the definition of "insurance or otherwise" since these accounts are comparable to a beneficiary's own bank account.*

Definitions – Long-Term Care Facility

Preamble, Page 46648 and 46649, and Rule 423.100 Definitions, Page 46815 –

CMS has defined a "long-term care facility" to be a skilled nursing facility [per 1819(a) of the Social Security Act] or a nursing facility [per 1919(a) of the Social Security Act]. CMS wants input on whether ICF/MRs should also be included in the definition. The question relates to facilities that maintain single-source contracts with long-term care pharmacies.

Recommend adding ICF/MRs to the definition of a long-term care facility to ensure that these entities have the same protections and benefits as other long-term care facilities with relation to single-source pharmacy contracts.

Definitions – Person

Preamble, Page 46650, and Rule 423.100 Definitions, Page 46816 –

CMS proposes defining "person" to include family members and an array of organizations such as foundations, for-profit corporations, not-for-profit corporations, governments, and governmental subdivisions and agencies. This is in keeping with the definition found in 1 USC 1 and is intended to ensure that all of these entities may pay for covered Part D drug cost-sharing on behalf of a beneficiary and still have the expense count toward incurred out-of-pocket expenses (as long as conditions concerning the actual source of the funds is acceptable).

Recommend that CMS use this broad definition.

Requirements Related to Qualified Prescription Drug Coverage

Preamble, Page 46649, and Rule 423.104(b), Page 46816 –

CMS states in the preamble that PDPs must offer coverage to all Part D eligible individuals residing in the service area without restriction. The rule itself does not include the notation "without restriction." To ensure that plan sponsors are unable to identify loopholes that might allow them to deny enrollment to low-income subsidy beneficiaries, it would be prudent to tighten up the provision.

Recommend that CMS revise the language of 423.104(b) to specify that "a prescription drug plan must offer that plan, without restriction, to all Part D eligible beneficiaries residing the plan's service area, including to all low-income beneficiaries eligible for full or partial subsidy."

Annual Percentage Increase

Preamble, Page 46651, and Rule 423.104(e)(5)(iv), Page 46817 –

CMS requests comments regarding what data sources should be used to determine the annual percentage increase for deductibles, co-payments, initial coverage limit, and annual out-of-pocket threshold.

Recommend that statistical data from cost-effective programs such as Medicaid and State Pharmaceutical Assistance Programs (SPAPs) should be taken into consideration in determining the annual increases. Additionally, comparative data for Medicaid recipient and household income relative to changes in the Consumer Price Index (CPI) should be considered. The prospective impact of changes in co-payments, coverage limits, and annual out-of-pocket thresholds can then be assessed in both nominal and real terms for the recipient and for program cost projection purposes.

Establishment of PDP Service Areas *and* Access to Covered Part D Drugs
Preamble, Page 46655, and Rule 423.112(b) and 423.120(a)(1)(iii), Page 46818 –
CMS has determined that, for PDPs and MA-PDs to meet requirements for convenient access to network pharmacies, at least 70 percent of Medicare beneficiaries who reside in a rural service area must live within 15 miles of a network pharmacy. Some rural counties in Nevada are still considered frontier counties due to sparse population. It is conceivable that, in some of these areas, less than 70 percent of Medicare beneficiaries will live within 15 miles of any pharmacy (network or not). Unless special attention is paid to rural areas, the result could be that isolated beneficiaries are not adequately served or not served at all.

> *Recommend that, while establishing MA regions (which will also be used as PDP and MA-PD regions), CMS ensure that rural/frontier areas are not isolated from areas that are more densely populated. Alone, rural areas may not be cost-effective for PDPs and MA-PDs to serve. However, by grouping rural areas with suburban and urban areas, it is more likely that a greater variety of PDPs and MA-PDs will bid to serve the rural areas. Hopefully, this will give rural beneficiaries more choice and possibly greater access to network pharmacies.*

Establishment of PDP Service Areas *and* Access to Covered Part D Drugs
Preamble, Page 46656 –
CMS is requesting input on a proposed exception to the pharmacy access rules. The proposal would allow a PDP or MA-PD to count I/T/U pharmacies toward their network access requirements if the pharmacies are willing to contract with the plan and if it would be impracticable for the plan to meet rural access standards without including the I/T/U pharmacies. This exception would be acceptable only if the population in the service area is comprised almost solely of persons eligible to use the I/T/U pharmacies. Otherwise, adequate access would be denied those not eligible to use the pharmacies.

> *Recommend that, if CMS implements the proposed exception, the language of the provision is clear that the exception may only be granted if at least 95% of the population in the service area is eligible to use I/T/U pharmacies.*

Pharmacy Access Standards
Preamble, Page 46657 and 46658 –
CMS is soliciting comments on how PDPs and MA-PDs should be directed to deal with long-term care pharmacies, tribal pharmacies, and federally qualified health centers. For instance, CMS is considering whether to require plans to contract with long-term care pharmacies or encourage them to negotiate with and include long-term care pharmacies in their plans.

> *Recommend that CMS approach this matter in a way that is consistent with Medicaid requirements that health plans negotiate in good faith with essential community providers (e.g., long-term care pharmacies, ITUs, and FQHCs).*

Pharmacy Access Standards
Preamble, Page 46658 –
CMS is considering whether to require plans to contract with "a sufficient number of home infusion pharmacies to provide reasonable access for Part D enrollees." Because prescription drug plans do not offer a medical benefit, CMS is unsure that these plans would otherwise have an incentive to contract with home infusion pharmacies.

> *For the reason CMS has already cited, recommend prescription drug plans be required to contract with home infusion pharmacies.*

Access to Covered Part D Drugs
Preamble, Page 46659, and Rule 423.120(a)(5) –
Section 423.120(a)(5) allows PDPs and MA-PDs to offer lower cost-sharing to beneficiaries who use preferred network pharmacies. As discussed on page 46659 of the preamble, there is a danger that this provision will allow plans to create a within-network subset of preferred pharmacies strategically designed to discourage beneficiaries in certain areas (e.g., rural areas or inner cities) from enrolling in the plan. CMS states that they will review such designs in the bid process to ensure that the designs to do not encourage discrimination or exclusion. The rule, however, is not clear that such a design is not acceptable.

> *Recommend that CMS add the following language to 423.120(a)(5). "A plan may not design its subset of preferred pharmacies in such a way that it effectively excludes or discourages enrollment by certain classes, groups, or geographical clusters of eligible Part D beneficiaries."*

Access to Covered Part D Drugs
Preamble, Page 46659, and Rule 423.120(a)(6) –
The rule requires PDPs and MA-PDs to allow enrollees to purchase a 90-day supply of a prescription drug from a network retail pharmacy instead of from a mail-order pharmacy. The beneficiary would be responsible for any price differential. In the preamble, CMS requests input as to whether the price differential should be counted toward the beneficiary's deductible and incurred out-of-pocket costs.

> *Recommend that these price differentials count toward a beneficiary's deductible and incurred out-of-pocket costs.*

Formulary Requirements
Preamble, Page 46661 –
CMS is soliciting comments regarding whether to require plans to provide special treatment for special populations. For instance, should plans offer "certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees."

> *Recommend that CMS develop such requirements to accommodate special populations such as those in long-term care or those with mental health*

diagnoses. Additionally, formulary exceptions criteria must be flexible enough to take into account the actual circumstances of beneficiaries with special needs.

Access to Covered Part D Drugs
Preamble, Page 46663 –
CMS requests input as to whether the price differential paid by a beneficiary when using an out-of-network pharmacy (in appropriate circumstances) should be counted toward the beneficiary's incurred out-of-pocket costs.

Recommend that these price differentials count toward both the beneficiary's incurred out-of-pocket costs and the beneficiary's deductible.

Access to Covered Part D Drugs
Rule 423.120(b)(1)(ii), Page 46818 –
This provision directs each PDP and MA-PD to have a pharmacy and therapeutics committee review the organization's formulary. Section 423.120(b)(1)(ii) indicates that the committee must include "at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict with respect to the PDP sponsor and prescription drug plan or to the MA organization and MA-PD plan." The provision adds that these members must also be "experts regarding care of elderly or disabled individuals." The State of Nevada Medicaid program uses a pharmacy and therapeutics committee for purposes of developing a preferred drug list. None of the members of this committee may have any affiliation that prevents them from making independent decisions. The bylaws specifically state: "Members serving on the P&T Committee may not have a current affiliation, while serving the board/committee term, with a business or corporation that manufactures prescription drugs. This includes direct compensation through employment and contractual activities." In addition, the general rules for this committee and similar committees state that members have an ongoing duty "to submit conflicts of interest disclosure statements." These bylaws ensure that decisions made by the committee will be in the best interest of Medicaid recipient.

Recommend that CMS revise Section 423.120(b)(1)(ii) to indicate that ALL members of a pharmacy and therapeutics committee reviewing a formulary for a PDP or MA-PD must be free of conflict. The provision that the committee include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals should be separated from this provision and assigned its own number.

Access to Covered Part D Drugs
Rule 423.120(b)(6), Page 46819 –
This provision is presented as a "limitation on formulary changes" by PDPs and MA-PDs. However, it only prohibits formulary changes during a 2½ month period, from November 15th of a given year to January 31st of the following year. It allows changes during the remainder of the year, from February 1st to November 14th. Meanwhile, beginning in 2007, beneficiaries have only a month and a half to change plans – between November 15th and December 31st of a given year [see 423.36(b)(2)]. This seems unfairly weighted in favor of PDPs and MA-PDs. Conceivably, a plan could offer a certain drug to attract beneficiaries during open enrollment and

then eliminate it in February (with appropriate 30-day notice). Beneficiaries adversely affected by the change could not switch to another plan for more than eight months.

> *Recommend that CMS allow formulary changes only from October 1st to November 14th of a given year. This evens the playing field for plans and beneficiaries. Exceptions could be granted if a PDP or MA-PD submits evidence to CMS that the formulary change is essential due to unexpected and significant changes in drug availability or cost.*

Dissemination of Plan Information
Preamble, Page 46664, and Rule 423.128(d)(1), Page 46820 –
This provision directs PDPs and MA-PDs to provide a toll-free customer call center that "is open during usual business hours" and must provide customer telephone service "in accordance with standard business practices." These are rather broad directives and could be enhanced to ensure that beneficiaries have access to quality service. In fact, in the preamble, CMS is requesting input on whether plans should be required to keep their customer call centers open seven days a week, 24 hours a day. This would benefit enrollees who need answers to questions in the evening and on weekends (when prescriptions are often filled) and would ensure that plans who maintain East Coast headquarters are open to West Coast beneficiaries at appropriate times.

> *Recommend that CMS require plans to staff customer call centers seven days a week, 24 hours a day. Additionally, the second element of the provision, "in accordance with standard business practices," should be revised to encourage companies to provide "customer telephone service, including to pharmacists, that includes thorough problem-solving and referrals to alternate resources when appropriate."*

Dissemination of Plan Information
Preamble, Page 46664, and Rule 423.128(e), Page 46820 –
423.128(e) lists the required elements of an explanation of benefits. It does not include information about the beneficiary's right to appeal denials and how to do so.

> *Recommend that a provision be added to 423.128(e) requiring an explanation of benefits to include information about the beneficiary's right to appeal denials and either how to proceed with an appeal or a telephone number to call for information about how to proceed.*

Automatic Enrollment of Full-Benefit Dual Eligibles

Preamble, Pages 46638 and 46639 –

In the preamble, CMS discusses a number of options that relate to automatic enrollment of a full-benefit dual eligible into a prescription drug plan if the individual does not voluntarily enroll in a plan by the end of his/her initial enrollment period. CMS has discovered that two major issues require resolution because statutory provisions are contradictory in their requirements.

1) CMS invites comments on how to provide qualified prescription drug coverage to those full-benefit dual eligible individuals who are in MA-only plans and have failed to enroll in a PD or MA-PD plan. Section 1860D-1(b)(1)(C) of the Act seems to preclude automatic enrollment of full-benefit dual eligibles into MA-PD plans; and instead requires enrollment in a PD plan. Meanwhile, Section 1860D-1(a)(1)(B)(ii) of the Act precludes Part D eligible individuals who are enrolled in MA plans from enrolling in PDPs.

   Recommend that CMS implement its own proposal (on page 46638 of the preamble) that the reference in Section 1860D-1(b)(1)(C) of the Act to "prescription drug plans" be interpreted as including both PDPs and MA-PD plans. This will allow automatic enrollment of a full-benefit dual eligible, who is already enrolled in an MA-only plan, to be enrolled into an MA-PD plan offered by the same organization.

2) CMS invites comments on how to provide qualified prescription drug coverage to a full-benefit dual eligible enrolled in the Medicare Advantage program when the premium for the MA-PD plan(s) offered by the individual's MA organization exceed the low-income benchmark premium.

   Recommend that CMS require an existing MA plan to "grandfather" current enrollees who are full-dual eligibles into one of its own MA-PD plans that offers, at minimum, basic Part D coverage. As part of this process, the MA plan would be required to waive payment of any portion of the premium that exceeds the federal government's low-income premium subsidy benchmark. This would ensure uninterrupted service and coverage for full-dual eligibles already established with an MA plan. It would be advantageous to MA organizations as well since the loss of enrollees in medical programs would be of greater financial impact than the waiver of a few dollars per month in premiums for prescription programs.

   Another option that would resolve this problem unequivocally would be for CMS to regulate premium amounts charged by prescription drug plans to ensure that a low-income individual may enroll in ANY basic prescription drug plan and be assured of a fully subsidized premium. (This recommendation is also made in our comments on Subpart P.)

Eligibility and Enrollment

Automatic Enrollment of Full-Benefit Dual Eligibles

Preamble, Page 46639 –

CMS solicits comments on whether automatic enrollment for full-benefit dual eligibles should be handled by CMS or by States (or their contracted entities). As noted in the preamble, many Medicaid programs already have experience with random assignments and have more immediate access to changes in Medicaid eligibility. Additionally, States may receive Federal financial participation (FFP) for administrative expenses.

> *Recommend that States be allowed to conduct automatic enrollment for full-benefit dual eligibles. At each States' discretion, the function may be performed through their Medicaid or State Pharmaceutical Assistance Programs (SPAPs) or through contracted entities.*

Automatic Enrollment of Full-Benefit Dual Eligibles

Rules 423.34(d) and 423.36(a)(1), Page 46811 –

These provisions indicate that a full-benefit dual eligible will be free to voluntarily enroll in a prescription drug plan during the initial enrollment period (between November 15, 2005, and May 15, 2006). If they do not voluntarily enroll in a plan by the end of that period, they will be automatically enrolled in either a PDP or an MA-PD plan.

There are risks involved in waiting until May 16, 2006, to automatically enroll full-benefit dual eligibles who fail to voluntarily enroll in a prescription drug plan by May 15, 2006. Beginning January 1, 2006, these individuals will no longer be covered by Medicaid and, if they are also not enrolled in a Part D plan, they will have no access to pharmacy. This is a vulnerable population that cannot afford to be without the prescription medication that so often maintains their health. Not only would a lapse in drug therapy put their health at risk, but Medicaid would also face increased claims for medical treatment triggered by this potential destabilization. One option is to develop a phased-in enrollment process to allow time for the outreach and education necessary to ensure enrollment in an appropriate prescription drug plan.

> *Recommend that CMS develop a phased-in enrollment process for dual-eligibles, during which Medicaid would continue to be the primary payer and would continue to receive federal matching funds. Additionally, recommend that the phased-down state contribution (aka clawback) formula be adjusted to accommodate the delay so that States do not make duplicate payments for dual-eligibles.*

Eligibility and Enrollment

Rule 423.34, Page 46811 –

Enrollment procedures for the low-income subsidy are unclear. The MMA (Medicare Modernization Act) assigns both the Social Security Administration and State Medicaid agencies with joint responsibility for administering enrollment and periodic redetermination for the low-income subsidy.

Part D will be more confusing than the Medicare drug discount cards due to premiums, deductibles, gaps in coverage and varying co-payments. It is expected seniors will be

exponentially overwhelmed. Furthermore, the enrollment process in Part D has 2 steps: 1) applying for the subsidy and 2) enrolling in a drug plan, which is likely to only further dissuade people from enrolling.

> *Recommend that the enrollment process be made as simple as possible. A one-step enrollment process should be utilized.*

Special Enrollment Periods
Preamble, Page 46640, and Rules 423.36(c) and 423.36(c)(4), Pages 46811 and 46812 –
As set forth in the rule, an individual who is "a full-benefit dual eligible" may enroll or disenroll in a prescription drug plan "at any time." As discussed in the preamble, the intent is to allow an individual who is determined to be a full-benefit dual eligible after the initial enrollment period to enroll in a prescription drug plan at that time, and to allow a full-benefit dual eligible to change his/her prescription drug plan if he/she has been auto-enrolled in a plan that does not meet his/her needs. It is apparent that the intent is not clearly reflected in the rule. Rather, the language of the rule appears to allow full-benefit dual eligibles to enroll or disenroll at will – at any time of year and as many times as desired. If interpreted and used in this way, the rule could open a Pandora's Box of problems related to coordination of benefits and tracking of true out-of-pocket costs.

> *Recommend that CMS revise the language of 423.36(c) and 423.36(c)(4) to allow full-benefit dual eligibles to enroll or disenroll only under the intended circumstances.*

Coordination of Beneficiary Enrollment and Disenrollment through PDP's
Rule 423.42, Page 46812 –
CMS seeks comments on the best way to support options for expanding beneficiaries' drug coverage, including facilitating coverage through State Pharmaceutical Assistance Programs (SPAPs).

> *A suggested approach to facilitation that will encourage enrollment in Part D is to allow SPAPs to auto-enroll Medicare Part D eligible members into a PDP. This could be limited to those members under 150% of federal poverty level who are eligible for low-income subsidies. Members would have the option to decline enrollment. SPAPs should also be allowed to partner with one or more PDPs to provide Medicare Part D benefits to SPAP members.*
>
> *This approach may facilitate a higher rate of enrollment into Medicare Part D and shift the costs from the State to Medicare, allowing the SPAP to offer other options to enhance Medicare coverage.*

Disenrollment by the PDP
Preamble, Page 46641, and Rule 423.44(b)(2)(i), Page 46812 –
CMS solicits comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area.

Recommend that CMS ensure that regulations addressing this matter are consistent with MA rules. Additionally, the regulations must be clear about the trigger for determining when the six-month time period begins, whether the beneficiary may re-enroll and, if so, the time period when re-enrollment may occur.

Disenrollment by the PDP

Preamble, Page 46642, and Rule 423.44(d)(2), Page 46813 –

This provision addresses circumstances under which a prescription drug plan may disenroll a beneficiary based on "disruptive or threatening behavior." The preamble states that a plan electing to disenroll an individual "must do so consistent with applicable laws regarding discrimination on the basis of disability." Additionally, during a teleconference in August, CMS representatives assured participants that behaviors caused by diagnoses will not be grounds for disenrollment. However, the proposed rules do not reflect the statement found in the preamble or the statement made by CMS representatives.

Recommend that the following language be added to 423.44(d)(2): "Disruptive or threatening behavior that is a manifestation of a medical or mental diagnosis may not be used as grounds for disenrollment."

Re-Enrollment in a Prescription Drug Plan

Preamble, Page 46642 –

When an individual is disenrolled from an MA plan for nonpayment of premium or disruptive behavior and is barred from enrolling in any other MA plan, the individual may still receive medical services under original Medicare. However, if a prescription drug plan enrollee finds him/herself in the same situation, there is no fallback available. CMS requests comments regarding the applicability of prohibiting re-enrollment in a prescription drug plan.

Recommend that CMS allow re-enrollment since there is no other option for such an individual to receive prescription drug coverage. Provisions could require an individual who was disenrolled for nonpayment to have the premium automatically deducted from his/her bank account and an individual who was appropriately disenrolled for disruptive behavior to designate an authorized representative to access services on his/her behalf. To be thorough and consistent, the provisions should also address other reasons for involuntary disenrollment.

Part D Information that CMS Provides to Beneficiaries

Preamble, Page 46642 and 46643, and Rule 423.48, Page 46813 –

CMS proposes to build on its website experience with the drug discount card and provide information to beneficiaries via an online Part D price comparison. CMS also states that the same information will be available by calling 1-800-MEDICARE and that "callers can always talk to a live person."

In contrast with CMS's perspective on its website and toll-free hotline, users of these tools are not as impressed. Representatives of Nevada's Senior Health Insurance Advisory Program

(SHIP) have reported that beneficiaries, family members, advocates and volunteers have found the website confusing and, therefore, not particularly helpful in the selection of a drug discount card. Additionally, Nevada's SHIP coordinator has reported losing long-time volunteers due to the overwhelming and perplexing amount of information they must become familiar with in order to adequately assist beneficiaries. Meanwhile, individuals who have attempted to obtain information about drug discount cards through the toll-free line have not always found a "live person" readily available. Instead, they have encountered chronic busy signals or have spent long periods of time on hold. At a regional tribal consultation in Nevada this summer, tribal representatives expressed concern about relying too heavily on either of these forms of education and outreach. Many elderly beneficiaries (tribal or otherwise) do not have access to computers and/or do not have the expertise to navigate the Medicare website. One-on-one, in-person consultations are more effective for this population.

> *Outreach and education are critical components of successful Part D implementation. Therefore, recommend that CMS learn from the drug discount card experience. As suggested by CMS, the comparison and decision tools available via Medicare.gov are important, but they must not only be expanded but also simplified to ensure effectiveness. Additionally, recommend that CMS increase staffing for the toll-free hotline, provide more funding for SHIPs nationwide, and offer intensive, cost-free training to SHIP volunteers. Comprehensive written information about Part D, including price comparisons, should be published and distributed widely through State agencies, Area Agencies on Aging, SHIP volunteers, senior centers, libraries, hospitals, physicians offices, pharmacies, employee assistance programs, and other organizations or entities frequented by beneficiaries and/or their family members.*

Approval of Marketing Materials and Enrollment Forms

Rule 423.50, Page 46813 –

CMS requests comments on the advisability of allowing additional products (for example, financial services) to be provided in conjunction with the PDP services and the appropriate limitations on such activities.

> *Recommend that PDPs not be permitted to market additional products to Medicare Part D beneficiaries. The sole purpose of the PDP is to provide prescription services and not to provide a source for the PDP to market other unrelated services. CMS should not be sharing beneficiary information with PDP sponsors or MA organizations for the purpose of marketing other products. In the event CMS decides to share this information, beneficiaries should be given the ability to choose not to have their information shared with these entities. Under no circumstances should the PDPs or MAs be allowed to contact beneficiaries by telephone to market additional services. If beneficiary information is shared, it should be only at specific, scheduled times per year, not at anytime that the PDP or MA requests the data.*

Approval of Marketing Materials and Enrollment Forms
Preamble, Page 46643, and Rule 423.50, Page 46813 –
With certain exceptions, CMS intends to replicate the marketing provisions established for MA plans.

> *Recommend that these rules be consistent with comparable rules in the Balanced Budget Act.*

Procedures to Determine and Document Creditable Status of Prescription Drug Coverage
Rule 423.56, Page 46814 –
CMS invites comments on how best to ensure that beneficiaries receive timely and adequate notice of the creditable status of their prescription drug coverage without imposing a significant administrative burden.

> *Recommend that the SPAPs notice of creditable status be incorporated into material that is routinely disseminated to members instead of a separate notice. By incorporating the language into existing materials, it will reduce the expenditure of time and money for the SPAPs.*

Procedures to Determine and Document Creditable Status of Prescription Drug Coverage
Rule 423.56(c)(1), Page 46815 –
This rule states that prescription drug plans must inform Part D eligible individuals if the plan's coverage "does not meet the actuarial equivalence requirement under 423.265." This disclosure should not be necessary because every plan that participates as a Part D provider should meet the actuarial equivalence requirement. No reasonable explanation is offered that supports exceptions to this rule.

> *Recommend that CMS not allow a prescription drug plan to participate as a Part D provider if the plan does not meet the actuarial equivalence requirement.*

Acceptance of Enrollment Forms
Preamble, Page 46643 –
In MA rules, CMS is prohibiting enrollment forms from being accepted in provider offices or other places where health care is delivered. CMS is uncertain whether it is appropriate to extend the same prohibition to prescription drug plans and pharmacies. While it may prove convenient for beneficiaries to submit enrollment forms via neighborhood pharmacies, this practice presents the same risks that it poses under MA rules. For instance, it could open the door to kick-back arrangements between prescription drug plans and participating pharmacies.

> *Recommend that CMS limit and regulate the role of pharmacies in the enrollment process. Pharmacies should be allowed to display information concerning the prescription drug plans in which they participate. This will serve as an educational tool for beneficiaries who wish to enroll in plans that allow them to continue using their established pharmacy. If pharmacies are also allowed to accept enrollment forms, safeguards should be put in place to ensure that pharmacies do not ill-advisedly steer beneficiaries to one plan over another. One*

safeguard for beneficiaries would be to write an opt-out provision that allows beneficiaries to change to another plan if there is reason to believe a pharmacy has misguided them.

General Provisions

Definitions – Personal Representative and Authorized Representative

Rule 423.4, Page 46810 –

The definition of a "personal representative" does not appear in Subpart A. In fact, the definition does not appear in the regulations until Subpart P, which deals with Premiums and Cost-Sharing Subsidies for Low-Income Individuals. The definition in Subpart P, Section 423.772 is as follows:

> "*Personal representative* means – (1) Individuals who are authorized to act on behalf of the applicant; (2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or (3) An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process."

Likewise, the definition of an "authorized representative" does not appear in Subpart A. This definition appears in Subpart M, which deals with Grievances, Coverage Determinations, and Appeals. In Subpart M, Section 423.560, the definition is as follows:

> "*Authorized representative* means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter, to the extent they are appropriate, unless otherwise stated in this subpart."

The definitions, the limited scope of authority granted to these representatives, and their placement in the regulations generate several issues.

First, the regulations should be consistent in defining who is authorized to act on behalf of a beneficiary. It would simplify the matter to use only one term and one definition throughout the regulations. "*Personal representative*" is the term of choice in the Health Insurance Portability and Accountability Act [HIPAA, 45 CFR 164.502(g)]. This term, along with a somewhat modified version of the definition in Subpart P (quoted above), would best serve Part D Medicare beneficiaries and, as noted, would be consistent with other regulations related to health care.

Second, a representative should be permitted to act on behalf of a beneficiary in all aspects of Part D participation. As currently written, the regulations allow a personal representative to act on a beneficiary's behalf only with regard to applications for subsidies, and an authorized representative to act only with regard to coverage determination and appeals. The fact that personal representatives and authorized representatives are addressed in the regulations recognizes the fact that many beneficiaries need assistance in navigating complex systems. However, these representatives are not granted the latitude needed to ensure that a beneficiary receives all of the help he/she needs at all levels of Part D participation.

Third, a representative should include not only *individuals* but appropriate *entities* including, but not necessarily limited to, State Pharmaceutical Assistance Programs (SPAPs). During the prescription drug card program, CMS has allowed State Pharmaceutical Assistance Programs

(SPAPs) to serve as representatives for beneficiaries and, in that capacity, to automatically enroll beneficiaries in drug card programs. Some States have taken the extra step of adopting legislation that officially designates SPAPs as representatives with regard to the drug card program. With this as a precedent, it would be appropriate to allow SPAPs to again serve as representatives in order to conduct Part D auto-enrollment among SPAP participants. Since Part D requires auto-enrollment of full-benefit dual eligibles who do not voluntarily enroll in a prescription drug plan, the SPAP could also be allowed to conduct auto-enrollment for these individuals if the State so chooses.

Recommend that CMS adopt the term "personal representative" throughout the regulations and discontinue use of the term "authorized representative." Recommend that the definition be expanded to allow appropriate entities (e.g. SPAPs) to serve as personal representatives and that the scope of authority be expanded to embrace all aspects of Part D participation. This would make the most suitable placement of the definition Subpart A, Section 423.4 (Definitions).

KENNY C. GUINN
Governor

MICHAEL J. WILLDEN
Director

DEPARTMENT OF HUMAN RESOURCES
DIRECTOR'S OFFICE
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October 27, 2004

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

Re: CMS Proposed Rule - 4068-P

Dear Dr. McClellan:

Enclosed please find comments and recommendations regarding 42 CFR Parts 403, 411, 417, and 423, the Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule, which was released on August 3, 2004.

These comments were developed by representatives of affected divisions within the Nevada Department of Human Resources, including Medicaid, Welfare and the State Pharmaceutical Assistance Program. The Department appreciates the opportunity to review and comment on the proposed rule, and would be happy to clarify or discuss any of the following recommendations with officials from the Department of Health and Human Services. Our comments are separated into documents that each address one subpart and recommendations are listed in the same order as the proposed rule.

Thank you again for the opportunity to comment on these important regulations.

Sincerely,

Michael J. Willden

Michael J. Willden
Director

MJW:ml/jc

CMS-4068-P-729

Submitter : **Date & Time:** **10/02/2004 01:10:46**

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.

Submitter : Neal Solomon **Date & Time:** 10/02/2004 02:10:54

Organization : Consultant

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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-731

Submitter : Neal Solomon **Date & Time:** 10/02/2004 02:10:30

Organization : consultant

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Comments on Proposed Rules 1. Access Standards 2. LTC Facilities and Part D

1. Proposed definition of "rural" as it applies to New Mexico.
The proposed rules use the DoD Tricare retail pharmacy network access standards, which defines rural as less than 1,000 per square mile in a given zip code area. According to the U.S. Census Bureau, "Land Area, Population and Density for Places in New Mexico: 1990", release date May 1996, only 45 of 174 Census Designated Places (CDP) have a population density of 1,000 or more persons per square mile. Also, the total population by CDP of 1,129,773 misses quite a few people who live outside of a CDP. While there are fewer zip codes than CDPs, it is likely that far more than 70% of beneficiaries will have an actual location of housing greater than 15 miles from the nearest retail pharmacy. This is further complicated through the standard use of mailing address instead of location of housing to determine distance to retail pharmacy. Please consider modifying the standards to better assure pharmacy access in less densely populated western states.

2. Residents in areas who do not have rural addressing systems get mail mostly through post office boxes. Location of actual housing may be many miles away from mailing address. This includes Indian reservations, certain Spanish land grant communities, those living far away from established mail routes and mixed jurisdiction areas (Bureau of Land Management, military reservations, National Forest Service, etc.).

* Distance analysis to determine compliance with retail pharmacy access requirements using software such as GeoAccess can be severely skewed when significant disparities exist between location of housing and mailing addresses.

3. FR 46648-46649 requests comments regarding modifications to the definition of long-term care facility. This comment introduces a concept of "quasi-institutionalized" individuals. These are individuals are often dual eligibles and have specific needs regarding medication dispensing and administration, where institutionalization in a nursing facility is not needed, but the range of proposed pharmacy servcies may not be sufficient. These include ICF/MR; non-ambulatory non-institutionalized; limited ambulation non-institutionalized; non-institutionalized requiring medication assistance (e.g., assisted living); non-institutionalized requiring special packaging (developmentally disabled, physical deformity or compromise, etc.)

The types additional servcies needed include:

* Keeping in regular inventory or extemporaneously compounding of special dosage forms to accommodate swallowing disorders (e.g., liquid, chewable, transdermal). Dysphagia is a serious medical condition that is best served by pharmacists who can determine how to modify drug therapy regimens to accommodate the disorder. Such expertise can be provided through the PDPs and such be included as a requirement.

* Special packaging needs, including compliance aids, such as blister packaging. Various medical conditions necessitate compliance packaging including:

* Cognitive impairment, difficulty remembering when to take medication. Various types of compliance packaging is used to create graphic layout of when to take medication.

* Compliance monitoring packaging so that a family member or visiting nurse can make a rapid visual assessment of adherence to medication regimen.

CONCLUDING RECOMMENDATIONS

* Special packaging needs of beneficiaries should be included as requirements for PDPs.

* All PDPs should be required to provide appropriate access guarantees by comparing differences between mailing address with location of

housing.

Submitter : Mrs. Melinda Andel **Date & Time:** 10/02/2004 03:10:15

Organization : Mrs. Melinda Andel

Category : Nurse

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Vital medical supplies associated with the administration of insulin have been excluded under the proposed definition of Covered Part D Drugs. Just as important as the proper administration of insulin, is the proper disposal of used needles. Proper disposal of used needles is not only of vital importance to the patient, but to others who might come in contact with improperly disposed needles. Contaminated needles also pose a grave threat to the environment. More than three billion needles are used annually in the home. While patients are instructed to place contaminated needles in a plastic container for disposal, many used needles are thrown into the trash unprotected. Used needles properly placed in a plastic container still pose the threat of contamination as a needle can easily be pushed through the plastic with any amount of force. Members of both the House and Senate, and 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 an inevitable function of insulin administration and, thus, medically necessary. I urge you to seriously consider the necessity of proper needle disposal.

Submitter : Mr. Dennis Callihan **Date & Time:** 10/02/2004 03:10:36

Organization : Mr. Dennis Callihan

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern,

Thank you for recognizing that pharmacist's can make a valuable contribution to patient care through Medication Therapy Management. I hope that you will recognize the value of independent practitioners in this endeavor. While some organizations currently provide this limited service to there clients, there is often preconceived bias built into the system, which, through your efforts of recognizing individual/group providers of MTM services would help to eliminiate
Thank you again for you consideration of this matter.

Very Truly Yours,

Dennis E. Callihan

CMS-4068-P-734

Submitter : Dale Schmidt **Date & Time:** 10/02/2004 03:10:28

Organization : Owen Withee Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacy owner, I am grateful for your allowing me to express 3 concerns I have with CMS-4068-P. I will be to the point in as few of words as possible.
>I find it very important that the plan sponsors allow as many providers as possible into the Part D benefit. THe access standards that will be applied should be applied at a level no greater than a county to insure that patients have ready access to a provider. Plan sponsors should also be required to provide reimbursement that at a minimum covers the costs associated with the dispensing of prescription drugs.
>Patients should not be economically coerced into using one pharmacy over another, such as mail order, or to pharmacies in which the plan sponsor has ownership interest.
>CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Sponsors could provide additional MTM services, beyond the minimum required, but must meet the CMS minimum requirements. Likewise, if a pharmacy receives a order for an MTM service, the plan sponsors should be directed to allow for the pharmacy to provide that service.
All prescibers who are eligible for payment under Medicares should be allowed to refer patients in need of MTM services to a provider of MTM services. AT A MIMIMUM, each plan should be required to pay for MTM services ordered by a prescriber.

In closing, pharmaces can be an intergral component of the new Medicare benefit. Recipients often rely on their pharmacist for advice and counsel. Interested pharmacies should be able to participate equally and fully and they should receive adequate payment for the services they provide.
Thank you for allowing me to comment.
Sincerely,
Dale Schmidt

CMS-4068-P-735

Submitter : Dr. Robert McNeese **Date & Time:** 10/02/2004 03:10:54

Organization : Corley's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I am thankful that pharmacists are being recognized for the services we provide rather than only the product dispensed. It is a well known fact that the elderly are a very non-compliant group of citizens in this country when it comes to medication management. I would like to see pharmacists reimbursed for the time and effort put forth to help with compliance issues. I think the drug benefit should provide for medication managment programs to include fees for pharmacists dispensing medications in "bubble pack" such as those used with the Medicine-On-Time prescription managment system. Overall, if these patients are more compliant with their medication regimens, everyone wins!

CMS-4068-P-736

Submitter : **Date & Time:** 10/02/2004 03:10:00

Organization :

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I would like to thank you for the opportunity to comment on this very important issue. As we know the older population continues to grow and they are the biggest consumer of prescription drugs. Adverse effects from drugs are among the top 5 health threats to seniors. Most of these problems are predictable, and therefore preventable. Millions of dollars in hospital ER visits, hospital admissions and nursing home admissions could be avoided by the proper use of medication. There is a shortage of Doctors who have the training to treat the special needs of seniors. Seniors are distinctly different in their reactions to medications. Pharmacists are the 'medication experts' and the 'Certified Geriatric Pharmacist' credential is setting apart pharmacists that specialize in the unique differences in seniors. MTMS should not allow just anyone to provide these services, senior care pharmacists are the ideal providers. I don't believe that a specific or 'preferred' pharmacy should be forced to provide these services, but the beneficiary should be able to choose, the same as they have the freedom to choose their own doctors. They must be comfortable with the person that is going to help them manage something as personal as their health.
Not every medicare beneficiary need be eligible for MTMS, but target high risk individuals - such as those with chronic disease states, take multiple medications, or have frequent hospital/Doctor visits to name a few. I believe that there are multiple members of the community who are able to refer an individual for MTMS. Because different members of the team see different aspects of the clients lifestyle, a physician, social worker, home care nurse, geriatric case manager or community pharmacist would be an appropriate source of referals for medication management. The goverment has mandated a pharmacist review for nursing home residents for some time and it has been shown they can decrease drug costs. Seniors in the community have the same chronic diseases, take as many or more medications than nursing home residents and also see multiple doctors or use multiple pharmacies which put them at an even greater risk - who is watching out for these seniors and their medications? I urge CMS to allow reimbursement for MTMS and geriatric pharmacists are an ideal candidate to provide these services to our elderly population.

CMS-4068-P-737

Submitter : Miss. Christina Bradshaw **Date & Time:** 10/02/2004 04:10:49

Organization : UNC School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I am a third-year pharmacy student at UNC School of Pharmacy, so this regulation is of great importance to me, especially since I will be out in the community practicing in fewer than two years. Medication Therapy Management Services should not be a privilege solely for "targeted beneficiaries, but for others who may not quality for MTMS under their plan as well. I would not want to turn any patient that desires MTMS away for any reason. In those cases where "non-targeted beneficiaries" receive MTMS, pharmacists should be able to bill those patients directly for those services. Those that do qualify for MTMS should include individuals with multiple chronic diseases AND those taking two or more drugs. As this often changes, CMS should notify any new patients that qualify for MTMS on a monthly basis. These services should be available to them for one full year at a pharmacy of their choice. CMS should also notify pharmacists of those targeted beneficiaries. Optimal providers of MTMS would be pharmacists who can interact with and decide upon what type of service each patient needs. As this will differ depending on their individual need, the initial assessment should always be face-to-face. In doing so, the pharmacist can build rapport with patients and ensure that they receive a complete evaluation. Also, all plans should pay the same fee to those who provide MTMS. I fully support the MTMS Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004.

CMS-4068-P-738

Submitter : **Date & Time:** **10/02/2004 05:10:28**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please ensure that there is a fair opportunity for all community pharmacies and that mail order pharmacies are not favored by certain third party plans by not allowing the use of local pharmacies. Community pharmacists are the best option for face to face medication management for people. Denying this benefit in favor of strictly mail order prescription service would be denying the patron's right to choose which is the best method of consultation for their drug therapy. Please ensure that local pharmacies are given the same level playing field as mail order services.

Submitter : Mr. Mark Jinkins **Date & Time:** 10/02/2004 09:10:50

Organization : None

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As an insulin dependent diabetic, please define supplies associated with the administration of insulin tp include needle disposal supplies & devices if you have not done so; otherwise needles not properly disposed of may pose a health risk to society.

Submitter : Mr. William Hubert **Date & Time:** 10/02/2004 12:10:01

Organization : Mr. William Hubert

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for allowing me to air my particular views on the proposed regulation to implement the new Medicare prescription drug benefit.

Subpart C needs to be changed, however. It MUST show the importance of community pharmacies and allow for local access, not a general access. There are too many patients turned away every day due to the insistence of their insurance plan that they avoid community pharmacies and instead use mail order or receive no benefits at all.

Concerning Subpart D:
Community pharmacies and pharmacists must be able to dispense Medication Therapy Management (MTM) services to beneficiaries. Community pharmacists are the ideal health care professionals to provide these valuable services to patients on a one-to-one basis, not via telephone to a pharmacist that they have never met (and never will).

Thank you for taking to time to consider your Medicare patients in these matters.

CMS-4068-P-741

Submitter : Ms. Ellen Leiserson **Date & Time:** 10/02/2004 01:10:50

Organization : Maryland Citizen

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

CMS-4068-P-741-Attach-1.doc

10/2/2004

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

Dear CMS:

Thank you for the opportunity to 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 loIr 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 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 Ieks (from November 15th the beginning of the enrollment period to January 1, 2006), I request that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. 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. This may require a legislative change and I hope that CMS will actively support such legislation in the current session of Congress.

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

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

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

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

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

Ellen Leiserson
6507 Sherwood Road
Baltimore, MD 21239
410-377-0806

Submitter : Dr. RICHARD LOGAN **Date & Time:** 10/02/2004 01:10:19

Organization : L & S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

While many provisions of this proposed rule are beneficial to my patients and are deserving of praise, the provision Sec. 423.120(a)(5) is troubling.

It gives the authority to usurp any willing provider rules in states, and will allow PBMs, the bane of the patient care industry, to push patients into their own mail order pharmacy plans. This is not compatable with quality patient care. Patients neither want nor benefit from mail order.

I ask that CMS withdraw the provision entitling the plan sponsor to have the sole determination of true, active pharmacy praticipants in a region.
PLEASE WITHDRAW Sec. 423.120(a)(5)

Submitter : Mrs. Kathy Spain **Date & Time:** 10/02/2004 01:10:16

Organization : Omni Diabetes, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

As a diabetes educator and mother of a child with diabetes I was concerned that the proposed definition of Covered Part-D Drugs - medical supplies associated with the administration of insulin, does not include provisions for the safe disposal of insulin needles. Safe disposal is not only crucial for the safety of the patient, but for others as well. Safe needle disposal is an important societal, environmental, and public health issue as well. This issue is supported by organizations such as the American Medical Association, American Association of Diabetes Educators, and the American Pharmaceutical Association as well as many members of both the House and Senate.
It is estimated that over 3 billion insulin needles are used annually in the home. Supplies and/or devices to ensure proper needle disposal should be included as part of the "medical supplies associated with the administration of insulin."
Thank you

CMS-4068-P-744

Submitter : Ms. Elaine Buchsbaum **Date & Time:** 10/02/2004 01:10:06

Organization : Ms. Elaine Buchsbaum

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about the proposed rules of the recently released Medicare Prescription Drug Improvement and Modernization Action of 2003 which fail to provide adequate safeguards to ensure that beneficiaries with disabilities have access to medications they need.

My son is 28 years old and has autism, retardation and a seizure disorder. He has dual eligibility for Medicare and Medicaid. The lack of needed protections under these proposed rules will fall heavily upon him and others like him since their drug coverage will shift from Medicaid to Medicare in 2006.

Specifically, I worry about the Formularies and about affordability of the drugs. His seizure disorder is controlled by a delicate balance of SPECIFIC drugs. Substituting other drugs for those he is on, or changing the combination of drugs in any way, would have a big impact on his health. I worry that he will need to continue use of the drugs he is presently on, but will have to pay much more for them. His income is extremely low. He would be forced to go off the drugs that have proven effective.
Additionally, I feel that a workable grievance and appeals process is necessary and I object to anything less.
Thank you for the opportunity to address these issues.
Elaine Buchsbaum
126 Bowne Station Road
Stockton, NJ 08559

Submitter : Mr. Peter Tyczkowski **Date & Time:** 10/02/2004 01:10:57

Organization : Self

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

September30, 2004

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

To Whom It May Concern:

I am sending this letter express my concerns on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.

My primary concern lies in the proposed Medication Therapy Management Program. In no way should bulk mailings of printed material or hurried phone center calls become an acceptable means to assist fragile seniors. The best resource for this important service is face-to-face contact with a pharmacist.

I also believe there needs to be a number of improvements regarding selection of who is eligible for these services, how they are identified, and how patients and providers are informed. My other suggestions are as follows:

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

Patients with a chronic disease that leads to other health issues should also qualify for MTMS (for example, patients with diabetes).

Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.

Eligibility for MTMS can change as impacted by a patients health status, so plans should be required to identify new eligible beneficiaries on a monthly basis. Pharmacists and physicians should also be able to identify eligible beneficiaries.

Plans should be required to inform patients, pharmacists and other providers when a patient becomes eligible for MTMS. The plans also must be required to inform patients about their choices (including their local pharmacy) for obtaining MTMS and cover MTMS even if the patient reaches the ?donut hole.?

Finally, Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries and CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.
Thank you for your time and consideration of my concerns.

Sincerely,
Peter Tyczkowski, MBA, R.Ph.
Peter Tyczkowski, MBA, R.Ph.
ptyczkowski@snet.net
(860) 205-7987

CMS-4068-P-746

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I am a third-year pharmacy student at the UNC School of Pharmacy and will be graduating in less than two years. More than likely, I will be working in community pharmacy, so this regulation will have a direct impact on my career. First of all, I believe that ALL plan beneficiaries should have access to a local pharmacy. Congress made a promise that plans would provide all patients with convenient access to their pharmacy and it is the duty of CMS to keep that promise. Thus, plans should be required to fully meet pharmacy access standards, not just "on average." In doing so, pharmacies will be more willing to take part in the plan's pharmacy network. I want to be sure that all my patients get the care they need and the service they deserve. Furthermore, I think CMS should reconsider the concept of "preferred" and "non-preferred" pharmacy providers. I want to build rapport and engender trust among patients. This idea of preferred/non-preferred would conflict with my objectives and disrupt any existing pharmacist-patient relationships if patients were driven away to a particular pharmacy. Beneficiaries should have their choice of pharmacy and pharmacist, just as Congress specified. I don't think beneficiaries should have to pay more for going elsewhere. Also, my patients should not have to bear the burden of higher costs when they get an extended supply of medication at my pharmacy. This would also coerce them to seek alternate pharmacy services. However, if plans do allow community pharmacists to charge more for extended quantities of medications, CMS should clarify that the difference in price is due to service costs and not to higher drug cost.

Submitter : Dr. Mary Bowlin **Date & Time:** 10/02/2004 02:10:21

Organization : Dr. Mary Bowlin

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C, please update the pharmacy access standards to require that plans meet the TRICARE pharmacy access requirements on a local (zip code) level, not on the plan's regional level. This is the only way to ensure that all beneficiaries have access to the local pharmacy of their choice. Congress' intent to provide a level playing field for community pharmacies is important and must be followed. We must be sure that plans can't favor mail order pharmacies by inappropriate use of "preferred" networks.

Additionally, under Subpart D, please make sure 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-748

Submitter : Mrs. Shauna Peterson **Date & Time:** 10/02/2004 02:10:22

Organization : Mrs. Shauna Peterson

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-749

Submitter : Dr. Karen Hoang **Date & Time:** 10/02/2004 02:10:21

Organization : Arrow/Familymeds Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I would like to express my concerns on the proposed regulation to implement the Medicare prescription drug benefit.

Firstly, I am concerned about how reimbursement will be determined. The cost of dispensing in CT is estimated to be over $9 per prescription, and current reimbursements are inadequate. This may be acceptable at large chains where the sheer volume of prescriptions is able to keep the pharmacy running, but smaller community pharmacies are struggling. These corner drugsores are the places that aren't open 24 hours, where pharmacists have the time to answer questions and teach patients how to use a drug correctly (without getting paid for this service,might I add), and where patients can count on seeing the same pharmacist each day.

The proposed regulation to allow plans to establish 'preferred' and 'non-preferred' pharmacies is also a concern of mine. If Congress really believes that patients have the right to choose which pharmacy they go to, there should be no 'preferred network'. This is another aspect of the plan that will place smaller pharmacies at a disadvantage since they are not able to negotiate a contract like the national chains will. This is a shame because I truly believe the smaller 'corner drugstores' are the model pharmacies where pharmacists have time to sit down with patients, go over their medications in detail, and provide the optimal drug therapy. Oftentimes I see elderly patients on at least 10 different medications because they go to an ophthamologist for glaucoma, a cardiologist, a pulmonary specialist, and their family physician, and each doctor prescribes 2-3 medications. These doctors don't talk to each other, and it's up to the pharmacist to find the drug interactions. If the interaction is corrected at the pharmacy level, before the patient goes home, thousands in hospital bills could be prevented when the patient doesn't break a hip from low blood pressure or cardiac arrhythmias because one drug increased the effect of another.

I believe that the value of the pharmacist is highly understimated in the eyes of the government. Pharmacists are the most accessible healthcare professional. Try reaching your child's pediatrician at 8pm the next time your child complains of a stomachache.

Pharmacists have a lot to offer to the community, and they need to remain accessible to the community.

Thank you for taking the time to read my letter.

Sincerely,
Karen Hoang, PharmD
Arrow/FamilyMeds Pharmacy
400 Saybrook Rd
Middletown CT 06457

cc: Senator Christopher Dodd
Senator Joseph Lieberman

Submitter : Mr. **Date & Time:** 10/02/2004 03:10:00

Organization : Mr.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please revise the pharmacy access standards to ensure that the plans meet the TRICARE pharmacy access requirements on a local zip code level. This is the only way to ensure that beneficiaries have access to a local pharmacy of their choice. CMS should insure that Congress provide a level playing field for community pharmacies and that plans can't favor mail order by inappropriate use of preferred networks.

Also, please ensure that plans are required to include community pharmacists and pharmacies in the delivery of Medication Therapy Management Services.

Thanks.

Submitter : Dr. Jean Hall **Date & Time:** 10/02/2004 04:10:20

Organization : University of Kansas

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I am writing as the Principal Investigator for the evaluation of the Kansas Medicaid Buy-In for employed people with disabilities. The great majority of people enrolled in this program are dually-eligible for Medicare & Medicaid and currently depend on their Medicaid coverage for prescription drug purchases.

Buy-In participants who are dually eligible have repeatedly & overwhelmingly shared that they are better able to get prescription meds because of enrollment in the Buy-In. If the law is implemented as written, disabled people who have both Medicare & Medicaid coverage will no longer be able to access prescription drugs through Medicaid. Because Medicare beneficiaries w/disabilities are different from the most beneficiaries with regard to their prescription drug use & costs, they may be disproportionately & negatively affected by the legislation.

The White House Nat'l Economic Council/Domestic Policy Council (2002) released a report on ?Disability, Medicare, & Prescription Drugs.? A key finding is that, compared to Medicare beneficiaries in general, those w/disabilities require a greater number of prescription drugs & the drugs are more expensive. Specifically, the average beneficiary with a disability had 28 prescriptions filled per year compared to the overall Medicare beneficiary average of 20/year. In addition, people w/ disabilities spent 50% more on drugs due not only to having more prescriptions, but also because the drugs they need are more expensive.

The Kaiser Commission on Medicaid & the Uninsured recently published the following information about dual-eligibles & the coming changes to Medicare:
*As of 1/1/06, states cannot provide federally-financed prescription coverage to dual-eligibles even if those individuals are not enrolled in a Medicare Part D plan. By the same token, dual-eligibles do not have the choice to remain with their current Medicaid coverage.
*Under Part D, people w/ dual Medicare/Medicaid eligibility will pay drug co-pays that are higher than their Medicaid co-pays. After 2006, the co-pays will increase each year.
*The current Medicaid rule prohibiting providers from denying prescriptions to people who cannot meet a co-payment will not apply to dual-eligibles enrolled in Part D plans. Thus, if a dual-eligible is unable to meet a Part D co-payment, he or she can be denied the prescription until the co-payment is met.
*The array of drugs covered by Part D plans may fall short of those covered under Medicaid. This is likely to be particularly true of the Part D plans in which dual-eligibles can afford to enroll given that they receive a premium subsidy only for the cost of plans with average or below-average premiums. While Medicaid programs generally are required to cover all medically necessary drugs, Part D plans have far more flexibility to limit the array of drugs that they will cover.

Thus, a general comment on the law & its regulations is that they discriminate against people w/ disabilities. Moreover, the law NEGATES one of the biggest INCENTIVES to work under the Ticket to Work/Work Incentive Improvement Act. Given these concerns, my comments focus on beneficiary protections, especially for this population that is often targeted for exclusion by insurance plans.
*Better address adequate processes to allow for coverage of clinically appropriate off-label uses of medications. People with disabilities such as MS, lupus, & some mental illnesses are more likely than most older adults to depend on off-label medication usage to control their conditions.
*Strengthen processes to ensure non-discrimination by plans; people with disabilities are more expensive to cover & are most at risk of being denied the coverage they need.
*Add meaningful formulary exception/protections for populations with special medication needs.
*Improve out-of-network access standards to ensure emergency access to needed medications.

Jean P. Hall
Asst. Research Prof.
Univ. of KS
jhall@ku.edu

CMS-4068-P-752

Submitter : Mr. Matthew Svejk **Date & Time:** 10/02/2004 03:10:13

Organization : Cardinal Health

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I would like to express my concerns on the proposed regulation to implement the Medicare prescription drug benefit.

Firstly, I am concerned about how reimbursement will be determined. I am very disappointed that CMS did not provide for pharmacists' fees as they do for other healthcare providers. The cost of dispensing in CT is estimated to be over $9 per prescription, and current reimbursements are inadequate - patient care is being challenged. Plans should pay pharmacists for the cost of goods + true cost of dispensing + a percent profit.

Secondly, I am also concerned about the proposed regulation to allow plans to establish 'preferred' and 'non-preferred' pharmacies. This could allow plans to distinguish between pharmacies based on cost production. This could place smaller pharmacies at a disadvantage since they are not able to negotiate a contract like the national chains. Patients will not be able to go to the 'corner drugstore' that they have been going to for the past 30 years. Even if smaller pharmacies are allowed access, the fees that the larger corporations negotiate could be so low that the smaller pharmacies couldn't afford to participate.

I believe that the value of the pharmacist is highly understimated in the eyes of the government. Pharmacists are highly trusted and are the most accessible healthcare professional. I hope they remain accessible.

Thank you for taking the time to read my letter.

Sincerely,
Matthew Svejk, RPh
Cardinal Health
628 Hebron Ave
Glastonbury CT 06033

CMS-4068-P-753

Submitter : Mr. Dennis O'Dell **Date & Time:** 10/02/2004 04:10:36

Organization : Mr. Dennis O'Dell

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Please require the PDP's and MAPDP's (Plans) to meet the Tricare standards as Congress intended rather than permitting restricted or limited networks of pharmacies through regional "averaging" or through establishment of "preferred" networks that will not provide equal access to all beneficiaries. Beneficiaries should also be protected against reduced "choice" of their pharmacy by prohibiting the Plans from steering beneficiaries to mail order through unequal copayment designs or through other cost shifting mechanisms.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

In order to provide real-time prescription service to beneficiaries at their local pharmacy, please develop (or require the Plans to develop) a real-time centralized claims and TrOOP processing system that coordinates real-time adjudication and coordination of benefits between PDP's, MAPDP's and all other plans that may pay a portion of the cost of a prescription for a beneficiary. This "centralized" system should not require the pharmacy to transmit information to multiple plans for a prescription when secondary paying plans (SPAPs, etc.)pay a portion of the claim. The centralized processor should receive the initial claim information from the pharmacy and then do all of the claim and TrOOP coordination between all of the involved plans behind the scenes, real-time, and then return the final claim payment information to the pharmacy for appropriate collection of the beneficiaries copayment. Please see NACDS comments for details of how this real-time, "point of care" system(SPOCS)can be in place by 1/1/06 to prevent patients from being delayed in receiving their needed medication while a pharmacy tries to figure out what plans are involved in paying for a recipient's medication.

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

Plans should be required to utilize community pharmacists and community pharmacies to develop AND DELIVER Medication Therapy Management (MTM) programs. Standard program requirements and payments for services should be developed to insure consistent beneficiary outcomes.

CMS-4068-P-754

Submitter : **Date & Time:** **10/02/2004 04:10:08**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C, please look to reword the pharmacy access standards so that plans meet the TRICARE pharmacy access requirements locally for my area (ZIP 97132), not on a general regional level. To assure that all beneficiaries have access to the local pharmacy of their choosing, the plan should meet the standard on a local level. 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.
Under subpart D, please make changes so that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management services to patients. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, in-person, to beneficiaries.

Submitter : Ms. Juanita Taylor **Date & Time:** 10/02/2004 04:10:56

Organization : Matters of the Heart Ministries, Inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I believe that it is vitally important that each individual on Medicare have every opportunity to maintain quality/quantity of life utilizing every medicinal options available. There should be no limits on the combinations. I understand that this can be costly, but who can put a fee on persons life?

CMS-4068-P-756

Submitter : Dr. William Scales **Date & Time:** 10/02/2004 05:10:56

Organization : Dr. William Scales

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. Colin Fitzgerrel **Date & Time:** 10/02/2004 05:10:20

Organization : Mr. Colin Fitzgerrel

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to first thank you for allowing me to comment on the proposed regulation to implement the Medicare prescription drug benefit and for taking the time to review my opinion.

Subpart C: Benefits & Beneficiary Protections
As far as the Any Willing Provider proposal, it leaves loopholes for insurance providers to fall through. By letting them set up preferred and non-preferred pharmacies, plans could coerce patients to use a pharmacy they normally would not just because it yields significantly lower copays. This would contradict the benefit of the access standards. Also, this could damage established patient-pharmacist relationships and really inconvenience each patient, as well as hurt business for the deemed non-preferred pharmacies. Access is not truly access if a patient is forced to use other pharmacies.

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I appreciate CMS recognition of the fact that different beneficiaries require different medication therapy management services such as an overall health assessment, a drug therapy plan, and monitoring services. I also appreciate the recognition that pharmacists will most likely be the primary providers for MTM services. However, I am concerned with this in that leaving the decision to the plans may allow them to choose less qualified providers for the services.

Pharmacists are the ideal health care professionals to provide medication therapy management services and determine which services each patient needs and sometimes to determine which patient is in need of this help the most. I observe this every day as the pharmacist I work under provides MTM services at CVS/pharmacy. I am a pharmacy student and I realize the importance and potential impact of this service. Insurance plans should be encouraged to utilize our knowledge. With our help, patients can see the best outcomes from their medication therapies. Our expertise should be recognized as comparable to other health care professionals. In this, we should be provided financial benefit in the same manner. Insurance plans should be required to pay the same fee to all MTMS providers.

In conclusion, I urge CMS to revise the regulation on plan setup of preferred versus non-preferred providers as well as strengthen the setup of MTM service fees for pharmacists.

Thank you for your time and consideration.

Sincerely,
Colin Fitzgerrel, Doctor of Pharmacy Candidate

cefitzge@purdue.edu
218 West Lutz Ave
West Lafayette, IN 47906

CMS-4068-P-758

Submitter : Mr. John Roska **Date & Time:** 10/02/2004 05:10:55

Organization : Mr. John Roska

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-4068-P
To Whom It May Concern:
I write today to offer comments regarding the proposed Medicare Part D rules. As an employee of Shopko 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 receive adequate payment for services.

CMS-4068-P-759

Submitter : **Date & Time:** **10/02/2004 06:10:19**

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 (zipcode) 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-760

Submitter : Natasha Polster **Date & Time:** 10/02/2004 06:10:34

Organization : Natasha Polster

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C, please revise the pharmacy access standards so that plans meet the TRICARE pharmacy access requirements on a local level, not on the plan's regional or "average" overall level. If it is required that a plan meets the standard on a local level, it's 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 make changes so that plans are required to include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to Medicare patients. Community pharmacists are the ideal health care professionals to provide these valuable services conveniently, face-to-face, to beneficiaries.

Thank you for making the changes, they are needed to help the people eligible for Medicare.

CMS-4068-P-761

Submitter : Mr. Carl Stein **Date & Time:** 10/02/2004 06:10:38

Organization : Owen Medical Group

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

I am responding to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit.

CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

I treat many patients with HIV disease. It is frustrating to know that although I have treatments available to help them, the patients may not be able to access the treatments due to government policy. Please ensure that all patients with HIV have equal access at all times to all necessary treatments.

Thank you for considering my comments as you finalize the regulations.

Carl Stein, MHS, PAC
Physician Assistant
AAHIVM HIV Specialist
Owen Medical Group
45 Castro Street #402
San Francisco, CA 94114
415-861-2400

Submitter : **Date & Time:** 10/02/2004 07:10:42

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I believe the use of e-prescribing will only allow for advancement in the field of pharmacy as we enter into the twenty-first century. As is a common fact among pharmacists, it can be quite difficult to decipher a doctor?s handwriting due to their haste in writing prescriptions, but e-prescribing will solve this dilemma. Since there will be no more guess work by a pharmacist or technician in reading a paper prescription, there will be less of a chance of a medication error to occur. With this error rate drastically dropping, liability will also change. Currently, if a medication error is made in filling a prescription, the blame is placed on the pharmacist. And because of this blame, a pharmacist could possibly be sued and enter into the legal system, spending a large sum of money on legal counsel and malpractice insurance. Pharmacy malpractice suits will be less common if e-prescribing becomes an accepted means of communication between health care professionals. This could also possibly lead to a reduced price on malpractice insurance.

Benefits of e-prescribing will be seen by all health care professionals. With information regarding the patient?s plan?s formulary will provide the necessary information to reduce the number of calls to physicians. When the physician prescribes a medication, he/she is able to check the formulary to see which drugs are covered and which are not. This will eliminate the need for a pharmacist to call a patient?s doctor to have a non-covered medication changed to one that is covered. This will reduce the unnecessary time spent on the phone and increase the time needed to counseling patients.
The use of e-prescribing will become increasing easy to assimilate into the younger generations of health care workers due to their advanced technological skills. With the growing sale rates of palm pilots, e-prescribing will be at the new health care professional?s fingertips. If the importance of e-prescribing is stressed during formal education it will soon become second nature. But concerning the immediate use of e-prescribing, the older and less computer friendly health care professionals must be taken into consideration. The skeptics of e-prescribing are mostly unaware of the details of the process. With some one-on-one training and a little adjustment, I believe the health care system will be revised and converted to a more technologically advanced approach. It goes without saying that people will not do something without it directly benefiting them, so incentives are necessary for the start of the widespread use of e-prescribing.

Possible enticements could include:
*Providing of the equipment needed to operate a system with e-prescribing (new computers or hand-held devices) either free of charge or with a minimal fee to health care professionals whom have signed a contract to use the method.
*Providing monetary incentives to those whom agree to use e-prescribing (a bonus given for every prescription written by e-prescribing).
*Provide the training necessary to manage e-prescribing and allow those whom choose the option to count the training as Continuing Education credits.
*Provide graduating students of health care professions a hand-held computer or palm pilot for professional purposes such as e-prescribing.
*Offer discounted prices

CMS-4068-P-763

Submitter : **Date & Time:** 10/02/2004 07:10:52

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-764

Submitter : Mr. Jeffrey Trombley **Date & Time:** 10/02/2004 07:10:39

Organization : Henry Ford Health System

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Dispensing fee- I would like to see Option #3 for the definition. Pharmacist's need to be better compensated for dispensing and clinical monitoring of drug therapy. The current dispensing fee's are too low in comparison to our expert knowledge on medications. If anything, pay a higher dispensing fee just to keep up with inflation.

Standard contract should be made available as long as a pharmacy can negotiate different terms and conditions to pay pharmacist's for couceling services.

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

Comment on MTMPs- Pharmacist's are unique providers of MTMPs and should be the only professionals doing this. We need to have provider status like other healthcare workers. Components of MTMPs should vary with disease state. Pharmacist's provide MTM on a daily basis and should be compensated for it. I think there should be tiered reimbursement depending on the severity of disease and time spent counceling. Example- Generel pharmacist counceling-level 1 reimbursement, or if a pharmacist is certified in a certain disease state, leve2 higher reimbursement, and finally if pharmacist is cridentialed like a Certified Diabetic Educator, level 3 reimbursement at even higher rate.

Also, when reimbursing pharmacist's for MTMPs, pay us enough and we will promote ourselves and get the message out to beneficiaries to use our services. The most effective steps to make valuable, proven, MTMP services available to improve health care quality is to pay pharmacists a health sum to provide these services.

All enrollees should qualify for some form of MTMS on different levels wether it's general drug counceling on proper use of medication to more complex education for more serious diseases(ex. Diabetes, Asthma, CVD, etc). Let the pharmacist decide the level of MTM for each patient. Bottom line, pay pharmacists for MTMS.

CMS-4068-P-765

Submitter : Frank Clark **Date & Time:** 10/02/2004 07:10:03

Organization : Garden State Pharmacy Owners

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The mismanagement of our nation's prescription program continues! When will our legislators learn that they cannot put the "fox in charge of the hen house!"? By allowing pharmacy benefit managers (PBMs) to manage the Medicare prescription plan we are allowing them to manage their profits. This would not be so bad if they had a conscience, cared for their patients like they were friends and family or had a history of saving lives and money but they don't...we pharmacists do! With the PBM's, dividends replace conscience, they care only about their profit and they will cost more money than they "save" in the long run because their ultimate aim is to herd our patients into mail order. Even if mail order offered a savings empirically (and evidence is coming that they don't), the truth of the matter is that the short-term "savings" of mail order pale in comparison with the long-term implications and complications of a patient population that has lost timely, consistent, quality face-to-face contact with their selected, historical, trusted health professional (patients see their pharmacist 4 times more frequently than their doctors).
Nothing can replace the value of patient contact! The more familiar and knowledgeable that contact...the better! We community pharmacists know our patients, care for them and they for us. Allowing these patients the freedom to choose their caregivers not only allows them to make those caregivers the best choice for themselves but puts their caregivers on notice that they had better measure up. By allowing PBM's to control which pharmacies are "in" or "out" of the exclusive subset networks of the Medicare prescription program you are allowing them to deny patients their right to choose and fostering an apathetic caregiver marketplace. Many communities will loose their community pharmacies and the exclusive benefits those CHOSEN pharmacies provided.
The worst part is that the long-term consequences are exactly that...long-term. We won't see the damaging effects of this ill-managed benefit until significant damage has already been done.
I urge our leadership to allow freedom to choose, any willing provider and NO mandatory mail order!
Thank You!

CMS-4068-P-766

Submitter : Mr. Doug Cornelius **Date & Time:** 10/02/2004 07:10:38

Organization : Mr. Doug Cornelius

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The pharmacy Access standards appear appropriate. Dispensing fees should include delivery charges other than mail options, especially in poor urban and in rural areas. Seniors would still be given care by their local pharmacists. This is an important medication safety issue. If I can deliver my medications to my patient if/when they are home-bound, they will not have some prescriptions on file from me and some on file at a mail order center. I can then ensure EVERY prescription is safe and appropriate in regards to other medications my patient is taking.

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

Any willing provider clauses are a must. This provision will set a basic level contract. It is in the interest of the country's finances to allow plans and pharmacies to negotiate lower prices, but ALL providers must be able to "dance" with the plans.

Generics must be madatory with up to FOUR branded products available to any beneficiary. Those four branded products must go through a "prior authorization" review. Otherwise, prescribers and pharmacies must work together to come up with therapeutice plans using availabel generics. Drug Therapy Quality Assuarnce programs should be seperated from Medication Therapy Management Quality Assurance programs, but could be used in tandem to evaluate the qualioty of care from a provider.

Unless the federal government can set precedent and over-ride state consumer safety rules, error rates should not be collected and used as quality assurance. Most pharmacies have policies and procedures in place to protect the public. Compelling pharmacists, physicians, nurses, etc to report errors to the government will kill any reporting procedures in place due to the risk of discovery. Error reporting must be left for the use of peer review.

In the provision of MTMS, we need to be aware that many people, including seniors use over-the-counter medications, herbal remedies, and other "wares" hocked on television. Limiting MTMs to PART D covered drugs only will limit the true care for the patient. ALL Part beneficiaries should be eligible for a basic medication review every 6 months, and this should include any non-prescribed agents they are using. Patients with multiple PArt D-covered drugs should be eligible for a second tier of care, offered by any trained pharmacy provider. This would include lipid management, diabetes care, COPD/Asthma, osteoarthritis and others. A third tier should be used for Part D recipients with therapy involving drugs with small therapeutic windows, injectables (including insulin) OR with advance chronic illnesses with multiple co-morbidities (ESRD, DM with nerve or kidney damage, others) This third teire should also include covering specialists such as dieticians.

All 3 tiers should have enough flexibility to assure the patient has enough time with their pharmacist without opening the door for abuse of the system. Several programs and pilots exist today that would provide CMS with resonable standards of care and fee structures. The colleges of pharmacy, American Pharmacist Association, and the City of Asheville, NC are great resources.

ELIGIBILITY, ELECTION, AND ENROLLMENT

These seem appropriate

CMS-4068-P-767

Submitter : Mr. howard feder **Date & Time:** 10/02/2004 07:10:38

Organization : v.g.h.pharmacy inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

this website is so hard to use that it's no wonder that the entire system is so screwed up

CMS-4068-P-768

Submitter : **Bonnie Burns** **Date & Time:** **10/02/2004 07:10:00**

Organization : **California Health Advocates**

Category : **Consumer Group**

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

Attached comments address this area and others.

CMS-4068-P-768-Attach-1.doc

CALIFORNIA HEALTH ADVOCATES
The California HICAP Association

October 1, 2004

Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: COMMENTS on Proposed Rules

File Code [CMS 4068-P]

Medicare Program; Medicare Prescription Drug Benefit

Introduction

California Health Advocates (CHA), established in 1997, is a nonprofit 501c (3) organization dedicated to timely, accurate, and responsive education and advocacy efforts for California Medicare beneficiaries, their families, and the pre-retirement population.

CHA promotes the work of the state-administered Health Insurance Counseling and Advocacy Program (HICAP) projects serving over four million Medicare beneficiaries of all ages throughout California. HICAP is the State Health Insurance Assistance Program (SHIP). In addition, CHA provides high-quality statewide community education and professional training opportunities, including the web site www.calmedicare.org addressing Medicare, related health care coverage, and long-term care insurance in support of the HICAP network and others working on behalf of Medicare beneficiaries and their families.

These comments are endorsed by the **World Institute of Disability** (WID). WID is a nonprofit research, training, and public policy center promoting the civil rights and the full societal inclusion of people with disabilities.

Preamble Subpart S. Special Rules for States

Section 4(c)iv of the Preamble

Medicare Supplement Policies

Page 46760 Medigap Disclosure Notice

California Health Advocates served as co-chair for consumer group representatives appointed to the Statutory Working Group of the NAIC Senior Issues Task Force charged with making conforming changes to the NAIC Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act as required by MMA. California Health Advocates also previously served on the Advisory Committee to the NAIC for standardization of Medigap policies required by the Omnibus Budget Reconciliation Act (OBRA) of 1990.

Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible. The disclosure notice submitted by the NAIC Statutory Working Group to the Senior Issues Task Force, which appears in the preamble to the Regulation, has been modified by CMS. The CMS Notice is longer, and varies substantially from the one agreed upon by members of the Statutory Working Group and adopted by the NAIC.

CMS has introduced information about Medicare Part D at the beginning of the disclosure notice that is unnecessary and adds to the complexity and length of the notice. We are certain that information about the new Medicare drug benefit will be readily available from a variety of sources including CMS. Introducing it in this disclosure notice detracts from important information consumers must have to understand and exercise their rights concerning their Medigap coverage.

CMS has introduced editorial comments about the value of Part D benefits that may or may not be accurate for certain individuals. The added language introduces Part D information before consumers will understand they have important decisions to make about their Medigap coverage.

CMS has deleted important contact information from the earliest part of the disclosure notice that would direct beneficiaries to 1-800-Medicare for help understanding the disclosure notice.

CMS has modified and added repetitive information about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. This defeats the goal of keeping the disclosure notice as short and as simple as possible. There are many other ways for CMS to let consumers know that they must inform the issuer when they enroll in Part D without complicating this disclosure notice.

CMS has further complicated the notice by adding language that delves into enrollment issues about Medicare Part D. This additional language dilutes critical information about Medigap coverage, the actions that need to taken, and notice of rights to other coverage. The additional language is unrelated information that will be readily available through many other sources.

We urge CMS to accept the NAIC notice as it was drafted without the modification and if CMS believes that further modification is required to refer it back to the NAIC to make those changes

Other Disclosure Notices of Creditable Coverage

The specific information people will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, a rider to a Medigap policy, or an innovative benefit attached to a Medigap or Medicare Select plan.

We urge CMS to develop a different notice for people who will have creditable coverage and to delegate this task to the NAIC Statutory Working Group that has the expertise to develop accurate notices about insurance and the issues consumer need to take into consideration when exercising their rights.

Subpart B – Eligibility and Enrollment

Section 423.46 Late enrollment penalty

We urge CMS to delay implementation of this section for all enrollees for two years.

The drug benefit is a new and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. Many may not understand the changes to their Medigap policies and what is meant by "creditable coverage." Six months may be insufficient time to understand the Part D program, understand how Part D coordinates with other drug coverage they may have, and to then choose the drug plan that is right for them or to retain their Medigap policies H, I, and J with drug coverage. Based from experience with the Medicare-approved prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 credit available to them. Medicare beneficiaries find the program too complex and confusing. Beneficiaries should not be penalized and have to pay more when they delay enrollment because they were given inadequate, incomplete, incorrect or no information.

We urge CMS to create a special enrollment period, with no late penalty imposed, if a Medigap issuer or other entity providing drug coverage to

Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage.

Subpart B

Section 423.48, Information about Part D.

General Concern: Funding for the State Health Insurance Assistance Programs (SHIPs).

When Medicare beneficiaries need help with individual decisions about their Medicare benefits they turn to an existing network of one-on-one counseling and assistance available through the State Health Insurance Assistance Programs (SHIP). We believe beneficiaries will need significant amounts of information and individualized assistance to make informed decisions about their heath care choices under MMA. Our experience with the discount card and eligibility for transitional assistance proves that reaching beneficiaries and helping them understand new choices will not be easy, and will be further complicated by a condensed time frame in which to make decisions. SHIPs are already engaged in understanding this massive new program and training their volunteer counselors. These counselors will be guiding clients through complex new choices and related decision-making about the new prescription drug benefit, including new ways of getting their Medicare benefits. The SHIPs are seriously under funded for the workload that will be generated by these historic changes to the Medicare program. While the Senate version of MMA included funding for the SHIPs of $1 per Medicare beneficiary, that funding was not included in the final version of MMA. It is irrational to expect that 1-800-medicare can provide the individualized assistance Medicare beneficiaries will need, and that the SHIPs can absorb the increased demand resulting from these historic changes within their current funding.

We urge CMS to increase funding to the SHIPs to meet the massive new challenge of helping beneficiaries to make individualized, informed choices about their new benefits.

Section 423.58 Procedures to determine and document creditable coverage

The discussion in the Preamble to the proposed regulation makes reference to the difficulty of determining creditable coverage and the inability to make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of Medigap policies they have issued in single states, multiple states, nationally, or to affinity groups. In addition we expect confusion by both companies and our clients because CMS has expanded the definition of a Medicare Supplement (Medigap) policy to include riders and freestanding benefits for prescription drugs. Medicare beneficiaries may lose the right to replace their supplemental benefits as a result of mistakes on the part of issuers, when a retiree plan no longer provides creditable coverage, or when dual eligible beneficiaries lose their eligibility for Medicaid.

Medigap guaranteed issue rights: The NAIC Model Regulation to Implement the Medicare Supplement Insurance Minimum Standards Act in Section 12 B 2(e), Guaranteed Issue for Eligible Persons, includes the authority of the Secretary to identify "other such exceptional conditions as the Secretary may provide" that trigger the right to a guaranteed issue Medigap policy. Beneficiaries should be entitled to the same choices they would have had if their coverage had not been creditable.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Guarantee Issue Rights for Individuals with Retiree Plans: In addition to the mistakes we expect to see in the Medigap market, employers may also make changes to their prescription drug benefits on or after the implementation date of Part D. They may drop or reduce prescription drug benefits as many have done with retiree medical benefits. The NAIC Model Regulation incorporates the Balanced Budget Act (BBA) of 1997 protections that include a small remedy in Section 12 B (1) for retirees who lose *all* the benefits supplementing Medicare. However there is no protection available to retirees when a single benefit, or multiple benefits, are reduced or dropped as long as some benefits remain. A retiree could lose just their prescription drug benefit when an employer defaults to Medicare Part D in 2006, or they could lose that benefit later if an employer changes the plan.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Guaranteed Issue Rights for Individuals Who Lose Medicaid Eligibility Income and resources can change for a variety of reasons and people and do lose their eligibility to Medicaid. Often they are unable to buy a Medigap policy even when they or their family can afford to pay for one. Issuers medically underwrite this population, who are often sicker, and refuse to issue them coverage.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Guaranteed issue rights would allow these groups of Medicare beneficiaries to choose the greater flexibility of original Medicare. Without that choice older and sicker individuals are much more likely to be forced into a Medicare Advantage plan because issuers can refuse to sell them a Medigap policy due to their existing health conditions.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Overarching Concerns Regarding Various Sections And Subsections Of The Regulations.

General Concern: Information, education and outreach about Part D.

Materials used to communicate with Medicare beneficiaries must be accurate, timely and available in different languages and alternative formats from both CMS and from the plans. Medicare beneficiaries must be able to clearly understand the range of new choices, decisions they must make, and the consequences of those decisions. Requirements and standards for materials the plans use should not be in guidance to the plans, but in the final regulation where they will be enforceable. Simply adding more information to the price comparison website is inadequate for the vast majority of Medicare beneficiaries. Written information needs to be widely available with referral to trusted sources for individualized assistance. At a minimum, beneficiaries will need to understand their choices, the cost of each choice including premiums and out of pocket costs, providers who will supply covered services, be able to determine which choices best meet their needs, and know the rights they have and how to exercise them. Without clear, accurate, and detailed information beneficiaries will be unable to make choices that meet their needs.

We urge CMS to require clear, accurate, and timely disclosure of all pertinent information about benefits, costs, and providers, initially and with each change that occurs.

General Concern: The needs of Dual Eligibles

We urge CMS to delay termination of Medicaid prescription drug benefits for dual eligible beneficiaries for at least one year.

After extensive review of the proposed rule, most reviewers we work with have found it impossible to understand how dual eligibles will access seamless drug coverage. We are particularly concerned for those Social Security SSDI beneficiaries who are in a return to work stage of their lives, and how these new MMA rules will integrate with existing Social Security work rules. Delaying the rule for duals until these issues are clarified would support the President's New Freedom Initiative that encourages these beneficiaries to seek employment. CMS faces a daunting challenge just finding and enrolling all duals, regardless of their work status, before their drug benefits under Medicaid end December 31, 2004. Once reached, duals will need extensive, comprehensive one-on-one help understanding the transfer of their benefits from Medicaid to Medicare and how these benefits affect their work status.

Duals and low-income beneficiaries are an especially difficult population to reach. They are much less likely to use the Internet, and some cannot even be reached by phone. Many duals, particularly those with cognitive impairment or mental illness, are therefore likely to have a break in benefits when they will not be covered by either Medicare or Medicaid.

If duals are auto enrolled into a drug plan to ensure continuation of their drug benefits they may still fail to understand the switch or how to use their new benefits. Given the dismal experience reaching and enrolling Medicare beneficiaries who are eligible for the discount card transitional assistance, and the long-standing difficulty of reaching people eligible for benefits under the QMB and SLMB programs, we believe the duals cannot be reached and successfully transitioned to Medicare in less than two years.

We urge CMS to delay the transition from Medicaid prescription drug benefits to Medicare for dual eligible beneficiaries.

General Concerns About Access to Medications and Continuity of Care

Congress and the Administration have promised that the dual eligible Medicare beneficiaries will be better off under the Part D prescription drug benefit than they are under Medicaid's drug coverage. If CMS is to keep that promise, duals and others with serious medical conditions or mental illness must be able to get their medications and maintain their continuity of care. Drug plans must not be able to force duals to switch medications to stay within the formulary of a particular plan or tier. The exception process and appeals and grievance process described in the proposed regulation will be very difficult for duals and others with mental illness or cognitive impairment to navigate without substantial and individual assistance. Duals and others could be denied medications for weeks during the appeals process with no requirement that the plan provide an emergency supply. Duals and others who are unable to negotiate these systems may go without essential medications.

We urge CMS to ensure that continuity of care will be maintained for all Medicare beneficiaries enrolling in a drug plan.

Concerns Regarding Involuntary Disenrollment Standards

We are particularly concerned with the standards for involuntary disenrollment in the proposed regulation. Allowing involuntary disenrollment for disruptive, unruly, abusive, uncooperative, or threatening behavior is a lower threshold than in the Medicare + Choice standards and could lead to discrimination against duals and others with mental illness or cognitive impairments. Changes in drug regimens can produce unexpected reactions, whether the change is to a new or different drug for clinical reasons, or to comply with the requirements of a formulary. Duals and others who might be involuntarily disenrolled under this lower threshold would then be left without access to any prescription drugs. They would have no way to ensure enrollment in another plan until the following coordinated annual enrollment period and would incur a late enrollment penalty as well. In addition, Medicare beneficiaries in any of these situations could not be expected to manage their own re-enrollment in another plan later without substantial individual assistance.

CMS must develop specific procedures and protections plans are required to follow that meet the special needs of this population to ensure that they are not subject to discriminatory practices by the plans.

We urge CMS to provide at a minimum the same protections in the M+C program regulations.

California Health Advocates and the World Institute of Disability appreciate the opportunity to comment on the proposed regulations.

Bonnie Burns
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www.wid.org

CMS-4068-P-769

Submitter : **Bonnie Burns** **Date & Time:** **10/02/2004 08:10:54**

Organization : **California Health Advocates**

Category : **Consumer Group**

Issue Areas/Comments

Issues 11-20

SPECIAL RULES FOR STATES

Attached comments address the disclosure notice in Subpart S

CMS-4068-P-769-Attach-1.doc

Comments of the Consumer Group Members of the NAIC Statutory Working Group

September 30, 2004

The U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Comments on Proposed Regulations
File Code [CMS-4068-P]
42 CFR Part 423, Subpart T (4)

Introduction

California Health Advocates, the Medicare Advocacy Project, Inc., Consumers Union, the SHIP Steering Committee, the Medicare Rights Center, and the Health Assistance Partnership served on the Statutory Working Group of the NAIC Senior Issues Task Force charged with making conforming changes to the NAIC Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act as required by MMA. California Health Advocates and Consumers Union also previously served on the Advisory Committee to the NAIC for standardization of Medigap policies required by the Omnibus Budget Reconciliation Act (OBRA) of 1990. As consumer group members of the NAIC Statutory Working Group we are submitting comments on issues related to our work incorporating changes to Medicare Supplement Insurance as required by the MMA.

Preamble Subpart S. Special Rules for States

Section 4(c)iv of the Preamble

Medicare Supplement Policies

Page 46760 Medigap Disclosure Notice

The first task of the NAIC Statutory Working Group was to draft a Disclosure Form that must be sent by issuers of Medigap insurance to individuals who have a Medigap policy with benefits for prescription drugs that are not creditable coverage under the Medicare Modernization Act.

The working group submitted a simple two-page form to the Seniors Issues Task Force that regulators, industry and consumer groups agreed contained adequate information and notice of the steps consumers needed to take in regards to their Medigap policy. NAIC submitted the agreed upon form to CMS. Disclosure notices advising consumers of their statutory rights must be short, simple, easy to understand, and address as few issues as possible.

The disclosure notice submitted by the NAIC Senior Issues Task Force, which appears in the preamble to the proposed regulation, has been modified by CMS. The notice is now longer, and varies substantially from the one agreed upon by members of the Statutory Working Group and adopted by the NAIC.

CMS has introduced information about Medicare Part D at the beginning of the disclosure notice that the working group believed was unnecessary and would add to the complexity and length of the notice. The working group specifically rejected comments intended to publicize the value of Medicare Part D. We are certain that information about the new Medicare drug benefit will be readily available from a variety of sources including CMS. Introducing it in this disclosure notice detracts from important information consumers must have to understand and exercise their rights concerning their Medigap coverage.

CMS has introduced editorial comments about the value of Part D benefits that may or may not be accurate for certain individuals. The added language introduces Part D information before consumers will understand they have important decisions to make about their Medigap coverage.

CMS has deleted important contact information from the earliest part of the disclosure notice that would direct beneficiaries to 1-800-medicare for help understanding the disclosure notice.

CMS has modified and added repetitive information about the need to notify the Medigap issuer if a person later enrolls in Medicare Part D. The working group agreed that multiple statements were unnecessary and would defeat the goal of keeping the disclosure notice as short and as simple as possible. Consumer group members agreed that there are many other ways for the industry and for CMS to let consumers know that they must inform the issuer when they enroll in Part D.

CMS has further complicated the notice by adding language that delves into enrollment issues about Medicare Part D. This additional language dilutes critical information about Medigap coverage, the actions that need to taken, and notice of rights to other coverage. The additional language is unrelated information that will be readily available through many other sources.

Regulators, industry and consumer groups consulted with the NAIC as required by law, and in the process came to mutual agreement about the language and construction of the disclosure notice to help consumers make important decisions about their Medigap coverage. We believe CMS should accept the NAIC notice as it was drafted without the modification. If CMS believes that further modification is required the disclosure notice should be referred back to the NAIC to make those changes.

We encourage CMS to develop a different notice for people who will have creditable coverage. The specific information people will need about their creditable coverage, and any required action, will vary depending on whether their coverage is employer sponsored retiree coverage, a Medigap Plan J, a pre-standard Medigap plan, a rider to a Medigap policy, or an innovative benefit attached to a Medigap or Medicare Select plan. We encourage CMS to delegate this task to the NAIC Statutory Working Group that has the expertise to develop accurate notices about insurance and the issues consumer need to take into consideration when exercising their rights.

Subpart B – Eligibility and Enrollment

Section 423.46 Late Enrollment Penalty

We urge CMS to delay implementation of this section for all enrollees for two years. The drug benefit is a new and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. Many may not understand the changes to their Medigap policies and what is meant by "creditable coverage." Six months may be insufficient time to understand the Part D program, understand how Part D coordinates with other drug coverage they may have, and to then choose the drug plan that is right for them or to retain their Medigap policies H, I, and J with drug coverage. Experience with the Medicare-endorsed prescription drug discount card shows that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 credit available to them. Our clients find the program too complex and confusing.

We further ask CMS to create a special enrollment period, with no late penalty imposed, if a Medigap issuer or other entity providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage. Beneficiaries should not be penalized and have to pay more when they delay enrollment because they were given inadequate, incomplete, incorrect or no information.

Subpart B Eligibility and Enrollment

Section 423.58 Procedures to determine and document creditable coverage

The discussion in the Preamble to the Regulation references the difficulty of determining creditable coverage and the inability to make that determination in advance of a final rule to implement Part D. We expect there will be confusion on this issue and that mistakes may be made by issuers in applying an actuarial test to groups of Medigap policies they have issued in single states, multiple states, nationally, or to affinity groups. In addition we expect confusion by both companies and our clients because CMS has expanded the definition of a Medicare Supplement (Medigap) policy to include riders and freestanding benefits for prescription drugs. Medicare beneficiaries may lose the right to replace their supplemental benefits as a result of mistakes on the part of issuers, when a retiree plan no longer provides creditable coverage, or when Dual Eligibles lose their eligibility for Medicaid.

Medigap guaranteed issue rights: The NAIC Model Regulation to Implement the Medicare Supplement Insurance Minimum Standards Act in Section 12 B 2(e), Guaranteed Issue for Eligible Persons, includes the authority of the Secretary to identify "other such exceptional conditions as the Secretary may provide" that trigger the right to a guaranteed issue Medigap policy. We urge CMS to add guaranteed issue rights for Medicare beneficiaries who lose creditable coverage. They should be entitled to the same choices they would have had if their coverage had not been creditable.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Guarantee Issue Rights for Individuals with Retiree Plans: In addition to the mistakes we expect to see in the Medigap market, employers may also make changes to their prescription drug benefits on or after the implementation date of Part D. They may drop or reduce prescription drug benefits as many have done with retiree medical benefits. The NAIC Model Regulation incorporates the Balanced Budget Act (BBA) of 1997 protections that include a small remedy in Section 12 B (1) for retirees who lose *all* the benefits supplementing Medicare. However there is no protection available to retirees when a single benefit, or multiple benefits, are reduced or dropped as long as some benefits remain. A retiree could lose just their prescription drug benefit when an employer defaults to Medicare Part D in 2006, or they could lose that benefit later if an employer changes the plan.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Guaranteed Issue Rights for Individuals Who Lose Medicaid Eligibility Income and resources can change for a variety of reasons and people and do lose their eligibility to Medicaid. Often they are unable to buy a Medigap policy even when they or their family can afford to pay for one. Issuers medically underwrite this population, who are often sicker, and refuse to issue them coverage. We urge CMS to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

We urge CMS to use its existing authority to identify this situation as one that will trigger the right to guaranteed issue of a Medigap policy.

Guaranteed issue rights would allow these groups of Medicare beneficiaries to choose the greater flexibility of original Medicare. Without that choice older and sicker individuals are much more likely to be forced into a Medicare Advantage plan because issuers can refuse to sell them a Medigap policy due to their existing health conditions.

These comments are respectfully submitted by the following consumer organizations,

Bonnie Burns, Training and Policy Specialist
California Health Advocates

Vickie Gottlich, Attorney
Center for Medicare Advocacy

Gail Shearer, Director Health Policy Analysis
Washington Office, Consumers Union

Carla Obiol, North Carolina SHIP Director
SHIP Steering Committee

Kevin Simpson, Director
Health Assistance Partnership

Diane Archer, Founder and Special Counsel
Medicare Rights Center

Submitter : Dr. Joanne Antonopoulos **Date & Time:** 10/02/2004 09:10:09

Organization : Aspirus Wausau Hospital

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

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

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As a clinical hospital pharmacist, I am deeply concerned with the rules as they are currently proposed.

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

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

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

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

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

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

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerely

Joanne Antonopoulos

Submitter : Mrs. Carole Sherman **Date & Time:** 10/02/2004 09:10:50

Organization : Mother and Father

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

GENERAL

GENERAL

September 29, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21224-8014

Re: Medicare Part D proposed regulations -
69 Fed. Reg. 46632 (Aug. 3, 2004)

Ladies and Gentlemen:

We write to express our deep concern regarding language in the captioned sections. We have over thirty-five years first-hand experience with persons with developmental disabilities, in particular severe mental retardation. We have over twenty years experience with intermediate care facilities for persons with mental retardation (ICFs/MR). We are intimately familiar with the population receiving critical services at such facilities. In addition, we have four years of first-hand experience with 'skilled nursing facilities,' which are serving and supporting our mothers.

ICFs/MR should remain in the agency's definition of 'long term care facilities.' The nation's ICFs/MR provide services to individuals whose complex behaviors and medical conditions are, in our opinion, equivalent to and in many instances more severe than persons residing in nursing homes. ICF/MR residents are in general the most vulnerable in the DD population. These citizens' conditions are life-long and irreversible - their licensed treatment facilities most certainly should be included in your definition of 'long term care' facilities.

Definition of the term 'institutionalized' should not be restricted to Medicaid-eligible individuals residing in nursing facilities but should include all individuals eligible for ICF/MR placement, current residents, home and community-based services (HCBS) waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

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

We appreciate the opportunity to comment.

Sincerely,

Carole L. Sherman & William F. Sherman
450 Midland Street
Little Rock, AR 72205

Mother & Father of John, aged 35, a long time resident of the Arkadelphia, AR HDC
(a licensed ICF/MR),
and prior to that, the beneficiary of out-reach/respite services
from the Conway, AR HDC (also a licensed ICF/MR);

Daughter and Son of aged mothers living in skilled nursing facilities;

Members of Families and Friends of Care Facility Residents (FF/CFR) and

Members of Voice of the Retarded (VOR)

cc: Arkansas Congressional Delegation

CMS-4068-P-772

Submitter : Mr. W.J. Francis **Date & Time:** 10/02/2004 09:10:46

Organization : Public Policy Network

Category : Individual

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Dear Sirs: here is a comment on subparts I and K.

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

Dear Sirs: here is a comment on subparts I and K.

CMS-4068-P-772-Attach-1.doc

CMS-4068-P-772-Attach-1.doc

Subparts I Preemption and K Contracts with Medicare PDP Sponsors
Comment on CMS-4068-P; Proposed rule for establishment of the Medicare Prescription Drug Benefit
October 2, 2004

Dear Sirs:

This is comment applies to the proposed subparts I (preemption) and the subpart K (contracts), and any other related requirements that I have not identified that present similar problems of regulatory excess. I propose that subpart K's "requirements of other laws" and "Federal and State standards" subsections be removed in their entirety. I have submitted a similar comment on the proposed MA regulation.

Your proposed rule retains verbatim a subsection from the Medicare+Choice regulation that would require PDP plans to comply with "all Federal, State, and local laws and regulations" (as explained in your preamble language describing how your proposed Title I regulations simply copy those of Title II). This subsection's regulatory text requires compliance with "all other applicable laws and regulations" and is retained from the existing M+C regulation. You would also retain verbatim a subsection requiring a compliance plan dealing with all Federal, State, and local laws. On its face, these requirements would make denial of PDP contract eligibility an enforcement sanction for potential violations of thousands of Federal laws and regulations as well as thousands of State and local laws and regulations. The retained regulatory text makes no exception for State insurance laws, and hence HHS seems to be proposing to retain all existing State insurance standards as PDP standards.

However, Section 232 of the MMA specifically preempts State law and regulations (and local law, which is necessarily authorized by State law). It says that the standards established under the MMA "shall supersede any State law or regulation … with respect to MA plans which are offered by MA organizations under this part." In another section of the MMA, this preemption is extended to PDP plans.

Accordingly, your proposed retention of 422.502(h)(1)(vi), and 422.501(b)(3)(vi)(A) [existing CFR numbering system] in 423.504 [proposed PDP regulatory text], requiring that a PDP plan agrees to comply with "all other applicable laws and rules" and has a compliance plan including "written policies, procedures, and standards of conduct … to comply with all applicable Federal and State standards" are in direct contradiction of the MMA preemption clauses and Congressional intent. This is clearly an area where you should have revised existing regulatory language to reduce potential burden and confusion on PDP and MA plans.

The proper fix is to eliminate these subsections in their entirety. Nothing in the MMA authorizes you to impose any State requirements (other than licensure and solvency) on PDP or MA plans. Nor is there any reason for HHS to seek to impose on PDP or MA plans an enforcement requirement for all State laws other than those that apply to health

insurance. What a bizarre policy decision that would be—all State laws other than those related to health insurance as such would be enforced by HHS.

The States can enforce their own laws without any help from HHS, and you should be ashamed of not having eliminated these ridiculous regulatory provisions in your proposed rule.

In this respect, has the Congress appropriated a dime to fund HHS enforcement of Federal, State, and local laws not under the direct jurisdiction of HHS, and assigned by statute to other agencies? Has HHS ever requested an appropriation for this purpose? This looks like bureaucratic and legal empire building on a massive scale. What savings might be possible if HHS eliminated its enforcement of Federal, State, and local laws under the existing M+C program? What budgetary excess is proposed for the PDP program to enforce these clauses? Alternatively, if there are no potential savings because HHS plans to spend nothing enforcing these provisions, they would appear to be pure regulatory bloat and bloviation.

Were you to retain these subsections you would be in apparent violation of laws and Executive Orders dealing with Federalism, which require you to respect States' primacy in enforcement of their own laws, except for those validly preempted. Nothing in your preamble suggests that you gave the slightest thought to the radical proposition that HHS might enforce State zoning, criminal, labor, property tax, automotive, and other laws, and nothing in your preamble provides the legally requisite justification.

I have sent a copy of this comment to OMB, because of the serious regulatory policy and burden issues that it raises under EO 13132 on Federalism.

Sincerely, W.J. Francis
Public Policy Network
703-278-0041

CMS-4068-P-773

Submitter : **Date & Time:** **10/02/2004 09:10:48**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

CMS-4068-P-773-Attach-1.doc

October 2, 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 appreciate the opportunity to comment on the proposed Medicare prescription drug benefit regulation. I would like to offer the following comments for consideration before the proposed regulations are implemented.

Subpart C: Benefits & Beneficiary Protections

As the regulation stands, there are three different defined areas of access. While I think that CMS is on the right track, I think there will still be a sufficient number of potential beneficiaries that will fall through the cracks. If plans are required to meet the standard at the local level then this is an appropriate way to ensure that nearly all beneficiaries have easy access to a local pharmacy and preferably the one of their choice.

The proposed regulation is sound in the fact that it will permit any pharmacy, willing to accept a plan's terms and conditions, to participate in their pharmacy network. However, I am concerned about the consequences that will be associated with allowing plans to make distinctions and designate pharmacies within their network as "preferred" or "non-preferred." If plans are able to make these designations then it is likely that a good number of patients will be coerced into obtaining services from other providers than the one of their choice. Congress wanted to ensure that patients could see the pharmacist of their choice and if the regulation is implemented as written then the outcome will be different from what was originally intended.

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

There are certain beneficiaries that should be targeted for medication therapy management services. I think this is the case because a main focus of this area should be prevention of further illness that could be associated with the improper use of prescription medications. As time passes different people may become appropriate candidates for this type of therapy so it will be imperative for plans to assess and identify new targeted beneficiaries in a timely basis; perhaps once per month should be the baseline for this procedure. The plans should be required to inform network pharmacists of patients who are eligible for the therapy. Pharmacists and physicians should also be able to identify these beneficiaries as well.

Once a beneficiary becomes eligible, the plans should be required to inform the beneficiary of their status and the options that are available to them. Also, once they are eligible, they should remain eligible for the entire year.

CMS should also clarify that plans are not allowed to prohibit pharmacists from providing services to non-targeted beneficiaries. If a patient (whether a beneficiary or not) is not covered by a particular plan for MTMS then the pharmacist should be able to bill them directly for services.

Pharmacists are the health care professionals most capable of providing MTMS.

It needs to be clarified by CMS that plans cannot require or encourage beneficiaries to obtain services from a specific provider.

All providers should receive the same fee for providing MTMS. All pharmacies should receive the same fee for providing identical services.

Once again, thank you for considering my views on these matters.

Christopher R. Dennis
First Year Pharmacy School Student
Campbell University School of Pharmacy

CMS-4068-P-774

Submitter : Dr. Charles Downs **Date & Time:** 10/02/2004 10:10:21

Organization : Washington County Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I firmly believe that patients should be able to obtain prescriptions from local pharmacies and that PMB's should not be allowed to charge a lower co-payment for mail order versus the co-payment when using a local pharmacy. In my opinion, mail order is one of the worse things to happen to the process of medication management because there is virtually no counseling, often a delay in patient's obtaining refills and in some instances gaps in therapy due to this, questions or temperature ranges during shipping, lack of proper interaction checking for acute need prescriptions (since the community pharmacist does not have the complete patient profile, and finally inconvenience for the patient since they often don't know what must be obtained via mail order until they present their prescription to the community pharmacy.

I also ask that you revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan's overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use the local pharmacy where I am employed. Anything less than this is unacceptable as well as bad for the patients' wellbeing.

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

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

As stated previously, all plans should be open to the any willing provider concept. Otherwise, the plans will use whatever is cheapest and not necessarily the best medication therapy management as well as other services. Their goal will be the bottom line, whereas providers outside of the plan will have the patient's wellbeing as the most important thing on their minds

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

I appreciate that CMS recognizes that different beneficiaries will require different medication therapy monitoring services such as health assessment, a meication 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 provicers to provide medication therapy management services.

I also believe that as a pharmacist that I am the most qualified individual to monitor patient therapy. As a clinical pharmacist, I am often amazed that nurse practitioners and PA's are currently allowed to prescribe and monitor medications, yet I am not. One would not believe how many errors are made by these prescribers that pharmacists have to make calls on along with questionable therapy. Pharmacists have the best training of any health professsional to manage medication. If we are reimbursed at a fair rate for our services, I see pharmacists moving from the drugstore to the doctor's office and become prime movers in providing the most cost effective therapy, not only because we will use the most efficatious medications, but also because we will eliminate unnecessary ones and use the most cost effective medications without being swayed by the drug industry sales force. Currently, we are so overtrained for what we allowed to do in our practices; we need to able to do what we were trained to do, and having pharmacists at the forefront of therapy management will maximize this.

I have already seen heard that PMB's will use nurses for medication therapy management in order to do it at the cheapest rate possible. The

majority of nurses are not qualified for this; they just don't have the training. Only physicians and pharmacists should be reimbursed for medication therapy management.

Pharmacists are the ideal health care professionals to provide medication therapy management services and determine which services each beneficiary needs. As a clinical pharmacist in a hospital setting, I continually make recommendations to physicians regarding antibiotics, diabetes medications, cardiac medications, and most everything else. Planse shoud be encouraged to use my services to let me help my patients make the best use of their medications in a primary setting as well as in an institution

The formulary needs to be more restrictive. There are many minimally necessary medications such as nasally inhaled steriods, non-sedating antihistamines, etc. Also, patients should be made to try less expensive alternatives first, such as a regular NSAID before a COX2 inhibitor, ACEI before an ARB, etc.

PAYMENTS TO PDP AND MA-PD PLANS

Payment should be equitable and reflect the education involved in becoming a drug expert. Numerous studies have shown a high return for effective medication therapy managment done by pharmacists. I have seen studies showing 2-3 dollars savings for every dollar spent in this area.

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

The government should also place these medications out for bid the same as is done with the VA system. There would be significant savings through this process. I resent the fact that PHARMA has such an impact on our political process to eliminate the bidding process.

CMS-4068-P-775

Submitter : Mrs. Ellen Garcia **Date & Time:** 10/02/2004 10:10:21

Organization : Providence ElderPlace Seattle

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I would like to express my support for the National PACE Association's comment on the proposed Medicare Part D rule. In developing NPA's comment, NPA staff actively consulted the NPA Board of Directors of which I am Chair. In reviewing the proposed rule and NPA's response, I am supportive of the comments put forth by NPA in an effort to maintain PACE organizations' achievements in meeting the prescription drug needs of their enrollees and to reconcile PACE and Part D requirements. Providence ElderPlace Seattle currently serves a very diverse population of 235 frail elders through our broad range of comprehensive PACE services. We are concerned that any regulations finalized take into consideration the unique needs of smaller PACE programs which will be challenged if costly, difficult requirements are imposed through this regulatory process.

Thank you for your consideration of our comments.

Submitter : Mrs. Diane Bungum **Date & Time:** 10/02/2004 11:10:42

Organization : Arc of the Mid-Columbia

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I support the comments submitted by the Oregon Dept. of Human Services, Senior and People with Disabilities and the Arc of the United States concerning these benefits.

Submitter : Dr. Brianne Fairchild **Date & Time:** 10/02/2004 11:10:33

Organization : Dr. Brianne Fairchild

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

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

I am concerned that leaving plans to decide 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 when services each beneficiary needs. I currently provide the folooowing MTM services in my practice: diabetes, cholesterol, blood pressure, and anti-coagulation monitoring. Plans should be encouraged to use my services - to let me help my patients make the best use of their medications.

CMS-4068-P-778

Submitter : Miss. Tamika Leftwich **Date & Time:** 10/02/2004 11:10:44

Organization : APhA-ASP, University of Pittsburgh

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-778-Attach-1.doc

October 2, 2004

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

Re: CMS-4068-P

Dear Sir or Madam,

I appreciate the chance to comment on the proposed regulation to implement the Medicare prescription drug benefit. I would like to offer the following comment for consideration as CMS develops the final regulation.

In regards to practitioner incentives for electronic prescriptions, I feel that would be very beneficial to pharmacies. By providing incentives, there will also be the following positive outcomes:

- Timelier service
- Less error
- More opportunities for counseling

In conclusion, I urge the CMS to continue developing methods to provide practitioner incentives for using electronic prescriptions due to the positive results it would bring. Thank you for considering my view.

Sincerely,
Tamika Leftwich, Pharm D candidate for 2006
Spin Coordinator for the University of Pittsburgh ASP chapter

CMS-4068-P-779

Submitter : Dr. Molly Mieska **Date & Time:** 10/03/2004 12:10:19

Organization : Froedtert Lutheran Memorial Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

To Whom it May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As a clinical pharmacist I am deeply concerned about the rules as they are currently propsed.

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

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

CMS should require all plan sponsors to provides at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum requitred, 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 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. 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 must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists praticing 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 plan sponsors otherwise many of the nation's foremost pharmacy practices may not even be included in the various programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the servies they provide to the recipients of the program.

Thank you for your consideration,

Molly Mieska, PharmD
Froedtert Memorial Lutheran Hospital
Anticoagulation Clinic

CMS-4068-P-780

Submitter : Dr. Ronny Chiu **Date & Time:** 10/03/2004 01:10:12

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern,
Under Subpart C, the TRICARE pharmacy access requirements that is based on a local (zip code) level and not on the plan's regional or 'average' overall level should be the standard. This is the only remedy to make sure that patient's have access to pharmacies of their choice. In addition, this standard will also make sure taht plan do not favor mail order pharmacies who usually contracts out with their 'preferred networks' of pharmacies. As a result of this practice, mail order pharmacies does not give patients' the option of choosing a pharmacy of their choice who can provide a higher standard of service.

Under Subpart D, it is important that plans include community pharmacists and community pharmacies in the delivery of Medication Therapy Management (MTM) services to patients. Community pharmacists not only can provide a higher standard of quality care to the patient by providing consulations and face to face contacts but can also help save money by avoiding unnecessary hospitalizations or emergency room visits by intervening and checking the appropriateness of the patients' drug therapy.
Thank you for the opportunity to express my concern.
Ronny Chiu

CMS-4068-P-781

Submitter : Mrs. Constance Seligman **Date & Time:** 10/03/2004 01:10:40

Organization : Constance Seligman, LCSW

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I am writing to register my strong concern that the proposed bill to switch medicaid prescription drug coverage to the new Medicare Drug coverage represents severe risk to mental health consumers. Often psychiatrists must try several medications before one is found which keeps patients stable without side effects that discourage medication compliance. The current proposal for fail first, restrictive formularies and substitution of generics for brand names seriously compromises the efforts of mental health practitionners to maintain the stability of their clients. This will ultimately cost the taxpayer more,not less, as these clients require repeated hospitalizations to fix something that had been working under the present arrangement.

The mentally ill are among the most vulnerable persons in the medical community, because not only are they maintaining themselves out of the hospital with great difficulty but they cannot advocate for themselves. If this legislation passes it will be at tremendous cost to society, because individuals who have been stabilized due to careful balancing of medication will be back in the hospital or worse, creating problems to society such as increased homelessness and vagrancy. If mental health patients and their doctors do not have appropriate medications available to them, the long term cost to society in terms of long term unemployment will be horrific.

Particularly threatening is the plan to disenroll consumers who are "disruptive." "disruptiveness" is not defined; who will be the arbitrer? If a representative is having a bad day, does she have permission to disenfranchise the complaining client? The constitutionality of this threat is very much in question. Do we have enough medicaid dollars to throw away in the courts defending this patently unjust proposal?

Surely there are less questionable methods to economize than a legistlated "put up or shut up" policy such as the one you've advanced.

CMS-4068-P-782

Submitter : Mrs. Barbara K. Rhodes **Date & Time:** 10/03/2004 01:10:10

Organization : Mrs. Barbara K. Rhodes

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As a parent of a young woman with disabilities and a volunteer advocate who deals with dozens of families every year, I want to express my concern over the proposed new Medicare plan that will impact those with dual eligibility for Medicare and Medicaid.

Although my daughter is not one of those involved, I am hearing from multiple families who are concerned that this new proposed plan will change how these individuals receive prescription medications. Currently, all of the prescriptions needed by this population are paid for by Medicaid. I am very concerned about the federal government's plans for the Medicare formulary, which will restrict access to medications that have worked successfully in the past. Most of these individuals have gone through years of trial and error to find the correct medications and if these specific meds are not on the new formulary, the patient ends up in a medical crises as they cannot afford to simply purchase the medications that are most effective.

Another factor is co-pay which does not exist, currently, under the Medicaid plan. People with developmental disabilities and those with the most critical need of specific medications, do not have funds to pay for medications or any co-pays. Many of these individuals live on an extremely meager income.

I know it is not the intent of congress to create hardship for those families and individuals who deal with complex issues around developmental disabilities. Each case must be considered on an individual basis and the needs met without undue delay and expense.

Please reconsider the current plan. Speak to families and individuals who will be most seriously affected by the changes that have been proposed.

Thanks you,
Barbara K. Rhodes
8 Pinecrest Court
Deptford, NJ 08096

856/853-8177 - home
609/330-2540 - cell

Submitter : Mr. Sandor Flitter **Date & Time:** 10/03/2004 02:10:49

Organization : Consumer Satisfaction Team

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

10/2/04

To: The Center for Medicaid and Medicare Services .

As a person who works in the Philadelphia Behavioral Health System and has lived with a mental illness for 16 years, I have some feelings about the recently proposed rules for implementing the new Medicare prescription drug benefit program.

Access to psychiatric medications is very important for those suffering from a mental illness and I feel that it would be beneficial for those in need of psychiatric medications to have at least six extra months to make the change from Medicaid to Medicare in order to allow adequate time to enroll, educate and locate the consumers in order to ensure that they get the medications they need.

People with a mental illness need their medications to be accessible. Without access to the current medications a mental health consumer might have to switch to something different and very possibly not as effective. Changing psychiatric medications can be detrimental and possibly cause serious adverse drug reactions and interactions. Also, a mental health consumer who has enjoyed many years of mental stability, having a productive and meaningful life might relapse because of a change in their much needed mind- freeing pills.

One particular issue that I wanted to comment on was the involuntary disenrollment of members for disruptive behavior. This does not make sense to me as the medications are actually what might just help a mental health consumer to be less or minimally aggressive or disruptive. Sometimes a person with a mental illness may not be able to control their behaviors until they have found the right combination of medications.

I can not comment on all the issues related to the upcoming changes but please remember that people suffering from a mental illness are not to blame for what has happened to them as their brain chemistry is not under voluntary control.

Thank you for your time,

Sandor Flitter

Submitter : Miss. Kimberly Fuller **Date & Time:** 10/03/2004 02:10:13

Organization : University of Tennessee College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please refer to attached document

CMS-4068-P-785

Submitter : Dr. America Jones **Date & Time:** 10/03/2004 02:10:51

Organization : TPA

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I appreciate that CMSrecognizes that different beneficiaries will require different Medication Therapy Management 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 a wide variations in te types of MTM services that will be offered, even within palns in the same region. I recommend CMS define a minimum standard package of MTM services thata plan has to offer.
In addition, the proposed regulation does not incule specific eligibility creteria for MTM services.

ELIGIBILITY, ELECTION, AND ENROLLMENT

I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug beenfit plan is allowed to apply the Dept of defense"s TRICARE standards on average for each region. I recommend the CMS require plans to meet the TRICARE standards on the local level rather than in the average in a regional service plan.
T address the sitaution where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level, the regulation should require that the access standard be greater of the TRICARE standard or the access equal to that avaialble to a member of the general public living in that zip code.
Requiring palns to meet the standard on a local level is the only way ti ensure patients equal and convenient access ti their chosen pharmacies.

PAYMENTS TO PDP AND MA-PD PLANS

The proposed regulation offers 3 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 the dispensing services provided in various pharmacy enviorments such as home infusion.

CMS-4068-P-786

Submitter : Dr. Barry Bates **Date & Time:** 10/03/2004 03:10:28

Organization : Dr. Barry Bates

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I recommend that cms require plans to meet the tricare standards on the local zip code level rather than "on average" in a service area. I also believe that any willing pharmacy provider should be able to provide the same co-pays to the patient population. Also retail & mail order co-pays & days supply should be the exact same to each provider. barry bates d.ph.

Submitter : Mr. Matthew Wilson **Date & Time:** 10/03/2004 04:10:27

Organization : TPA/ASP

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 2, 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 (38103) level rather than ?on average? in a regional service area.

To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.

Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.

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

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

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

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

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

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower

co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient populat

CMS-4068-P-788

Submitter : Mr. Evan Tong **Date & Time:** 10/03/2004 04:10:00

Organization : Mr. Evan Tong

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for taking the time to read my comments and for the opportunity to discuss the proposed regulations to implement the Medicare Prescription Drug Benefit.

The proposed regulations allow plans to distinguish pharmacies as "preferred" and "non-preferred." This could reduce a beneficiary's co-pay at "preferred" pharmacies and thus provide an unfair advantage to what should be level competition. If pharmacies accept business terms to their pharmacy networks, they should be allowed to participate fairly. This does not provide fair access because patients are being coerced to use pharmacies they do not necessarily wish to go to within the network. A standard contract should be offered to all pharmacies.

Community pharmacies should be allowed a level playing field with mail order pharmacy in terms of patient benefits. Historically, patients who desire 90-day supplies of medications can only obtain them through mail order. Their plans will not allow such a benefit to be available through their community pharmacy, even if the patient is willing to pay proportionally more for an extended supply. In the future, if plans charge more for this extended supply from community pharmacy, this difference should be directly related to the difference in service costs and not the cost of the drug product.

As a student pharmacist approaching my last year, I am eager to apply the clinical knowledge I have obtained. I appreciate that CMS recognizes pharmacists as the ideal health care professionals to provide MTM services. I currently provide many such services to my patients in community practice, but it is often difficult to have the time and means to do so. I only hope that this new plan will finally encourage my services and allow me to better assist my patients.

Thank you for your consideration.

Sincerely,

Evan Tong
Duquesne University Pharmacy Student
SPIN Coordinator 2004-2005
Tong518@duq.edu

CMS-4068-P-788-Attach-1.doc

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for taking the time to read my comments and for the opportunity to discuss the proposed regulations to implement the Medicare Prescription Drug Benefit.

The proposed regulations allow plans to distinguish pharmacies as "preferred" and "non-preferred." This could reduce a beneficiary's co-pay at "preferred" pharmacies and thus provide an unfair advantage to what should be level competition. If pharmacies accept business terms to their pharmacy networks, they should be allowed to participate fairly. This does not provide fair access because patients are being coerced to use pharmacies they do not necessarily wish to go to within the network. A standard contract should be offered to all pharmacies.

Community pharmacies should be allowed a level playing field with mail order pharmacy in terms of patient benefits. Historically, patients who desire 90-day supplies of medications can only obtain them through mail order. Their plans will not allow such a benefit to be available through their community pharmacy, even if the patient is willing to pay proportionally more for an extended supply. In the future, if plans charge more for this extended supply from community pharmacy, this difference should be directly related to the difference in service costs and not the cost of the drug product.

As a student pharmacist approaching my last year, I am eager to apply the clinical knowledge I have obtained. I appreciate that CMS recognizes pharmacists as the ideal health care professionals to provide MTM services. I currently provide many such services to my patients in community practice, but it is often difficult to have the time and means to do so. I only hope that this new plan will finally encourage my services and allow me to better assist my patients.

Thank you for your consideration.

Sincerely,

Evan Tong
Duquesne University Pharmacy Student
SPIN Coordinator 2004-2005
Tong518@duq.edu

CMS-4068-P-789

Submitter : Ms. Ashley Blankenship **Date & Time:** 10/03/2004 04:10:50

Organization : Campbell School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-789-Attach-1.doc

October 2, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2068-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

Pharmacy Access Standards

North Carolina has many urban areas along with several high populated areas. In all the state, 98% of the counties have pharmacies. By the current regulations, the people living in the various urban areas have a chance of not being near a pharmacy qualified by the TRICARE principles. It is vital to apply the TRICARE standards more locally, reducing them at least to a county level. Since an "average" is obtained, it is clear that some people in the rural communities and their pharmacies are at an extreme disadvantage.

Any Willing Provider

It makes no sense for the proposed rules to contain both preferred and non-preferred pharmacies. These regulations seem to contradict the title itself, plainly abandoning the "any willing provider" stipulation. This system could cause people to have to drive long distances from their home to an actual preferred pharmacy, leaving their trusted pharmacist. Forcing a customer to switch from a pharmacist who they trust and admire to another pharmacist can be compared to someone switching from their trusted family doctor.

Level Playing Field

The existing regulations cause a problem in extended medication supply. The policy states that plans are allowed to charge a higher price for extended supply (more than a thirty day supply) at a community pharmacy. It is these community pharmacies that are at a disadvantage trying to provide adequate service to their costumers. The regulations should clarify the difference must be directly linked to the service cost and not the actual cost of the drug products.

In conclusion, I urge CMS to revise the regulation:

1) to require plans to meet the TRICARE requirements at a local level;
2) to not allow a plan to have both preferred and non-preferred pharmacy providers;

3) to only allow differences in prices for providing an extended drug supply based on cost of service and not on the differentials in drug costs.

Thank you for considering my view.

Ashley Blankenship
Campbell School of Pharmacy Student (P1)

CMS-4068-P-790

Submitter : Mr. Dana Sato **Date & Time:** 10/03/2004 08:10:57

Organization : Mr. Dana Sato

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

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

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

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

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

CMS-4068-P-791

Submitter : Sandra Justice **Date & Time:** 10/03/2004 01:10:20

Organization : Sandra Justice

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Research results are available from the American Pharmacists Association that prove the value of a pharmacist managing a patient's drug therapy....value to the patient and to the payor. I encourage you to include payment for these valuable services in the Medicare Prescription Drug Benefit.

CMS-4068-P-792

Submitter : Dr. Gary Gijsbers **Date & Time:** 10/03/2004 02:10:17

Organization : McKesson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

My understanding is that the prescription drug benefit will be applicable only to certain, or select, pharmacists with special training or skills. I believe that not including all pharmacists in the wording of the document would be a major mistake! One, the knowledge base has increased tremendously for pharmacists with all schools now adding 1-2 years additional training for the Doctor of Pharmacy degree and secondly, please do your homework by reviewing the medical and pharmaceutical literature, there are literally hundreds and hundreds of studies that document the tremendous cost-effectiveness that all pharmacists (not just those with special training or certification) bring to patients as well as the health care system overall. Therefore, I hope the Medicare Prescription Drug Benefit-wording will not be short-sighted when finalizing the draft of this very important benefit, and will take into consideration the above points which will affect potentially all patients in the U.S.
Thank you for your consideration.
Regards--Dr. Gary J. Gijsbers

CMS-4068-P-793

Submitter : **Roma Netherton** **Date & Time:** **10/03/2004 02:10:12**

Organization : **The Advocacy Network, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Proposed Medicare Drug-Program Rules
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.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 loss
access to drug coverage. The chronically ill do not have a cure.
We strongley believe that the concerns discussed must be addressed
in order to ensure access to mental health medications under Part D
drug benefit for the many medicare beneficiaries who need them.
Your attention regarding this matter will be appreciated.

Submitter : Ms. Marsha Jonas **Date & Time:** 10/03/2004 03:10:08

Organization : Benzoprotracted

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:

As a former Benzodiazepine user and member of an International Benzodiazepine Withdrawal Support Group, I would like to voice my concerns over the current proposed changes to Medicare Part D concerning Benzodiazepines. I am very concerned about the immense deleterious ramifications that these changes could cause to current Medicare recipient, long-term users of these drugs which would be affected by these changes.

I?m writing you to inform all of you that you will be making a very grave mistake concerning the exclusion of Benzodiazepines by Medicare Part D. By excluding the Benzodiapines, you will be seriously risking the lives of long-term users of said medications. Medicare-recipients are most unlikely to pay out-of-pocket for this medication considering that many of them are on a fixed, low income; therefore, they may abruptly stop this medication which could cause seizures that can possibly lead to a coma and/or a lengthy, severe, painful, sometimes extremely intolerable withdrawal that may or may not leave them with permanent withdrawal symptoms. Additionally, this may actually cause them to take their own lives in order to escape its horrors. Also, there are virtually no remedies to this withdrawal once it starts aside from reinstatement or the tincture of time. Many of these former Benzodiazepine users will not know that they are even experiencing withdrawal from these drugs and will seek out costly, fruitless remedies in order to find a way to stop it. All of this is more likely to cost Medicare far more money in the long run. For many and perhaps most patients currently on Benzodiazepines, this may have been their only viable form of treatment and should not be taken away from them due to their new found inability to pay for their prescription. For many other long term Benzodiazepine users who may want to consider trying to get off, a lengthy tapering process should absolutely be utilized for which adequate time may not be allowed to carry this objective out per the proposed changes to Medicare Part D. Still yet, after a careful slow taper, they could still go on to experience long-term, debilitating withdrawal
symptoms and will then not be able to reinstate due to, once again, their lack of financial means to pay for their prescription. The ramifications are almost too numerous to list.

In essence, it is prudent that Medicare find a way to cover Benzodiazepines not only because it is more humane to the patient that is taking it long term, but also because it is just much more cost effective in the long run for Medicare.

Sincerely,

Marsha A. Jonas

CMS-4068-P-795

Submitter : Betsy Bizarro **Date & Time:** 10/03/2004 04:10:17

Organization : Betsy Bizarro

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-795-Attach-1.doc

Date 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:

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

CMS-4068-P-796

Submitter : Ms. Tracey McCutcheon **Date & Time:** 10/03/2004 05:10:06

Organization : CMS

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

TEST - No address for fedexed or hand-carried comments is provided in the NPRM.

CMS-4068-P-797

Submitter : Ms. Tracey McCutcheon **Date & Time:** 10/03/2004 05:10:43

Organization : CMS

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

TEST - There is no issue box for subpart R - Retiree Drug Subsidy

Submitter : Mr. Louis Hutchison **Date & Time:** 10/03/2004 05:10:42

Organization : HealthTrans

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

BACKGROUND

HealthTrans has commented on several areas of the drug benefit in our attached letter. Our comments also include recommendations in each area.

In particular, HealthTrans wishes to recommend and encourage CMS to take into specific account the work and value of the National Council for Prescription Drug Programs as an organization that has worked with a variety of interests in setting and establishing workable standards adopted by the private sector. Given the clear interest that CMS has in establishing strong private sector participation and continued interest in this new, risk-sharing benefit as well as in getting companies to participate as PDP?s under the MMA, we believe that CMS would be well served to look at private sector practices in such complex areas as rebate management, formulary management, network administration, and electronic claims adjudication procedures. To that end, NCPDP has enjoyed the wide support of a variety of parties playing a role in the management of prescription drug programs. We believe attention to private sector practices and standards will serve CMS well given what we believe is their desire to encourage contractors that show an interest in participating in benefit administration longer term. We also believe that this will provide CMS with further assurance that the objective of establishing superior quality and service to beneficiaries and providing access to pharmaceuticals in an affordable, well-managed setting are achieved.

Further, while we recognize that CMS plans to outline the proposed regions at a later date, we would use the reference in this section of the proposed rule to provide a comment in this area. Given that the Medicare drug benefit will require interest parties to take risk and that there is a limited amount of data regarding utilization and anticipated senior participation in the program, we believe CMS would be well served once again to look beyond existing Medicare regions and recognize that a regional plan based on existing health plans may better serve to reassure potential bidders?some of whom may be able to use their regional experience as they consider the issues associated with risk in the new benefit. As CMS undoubtedly is aware, many health plans as well as most pharmacy benefit managers are not in the risk business today in the specific area of senior citizen pharmacy usage. However, many of these same health plans and pharmacy benefit managers do have some measure of experience in senior citizen pharmacy utilization through the services they provide in administering and managing employer group retiree benefits.

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

HealthTrans believes CMS should provide further guidance in its final rule that provides beneficiaries with the same benefits related to spotting and reducing medication errors regardless of whether they select a health plan or a stand-alone PDP. Further, with respect to medical error reporting and medication recalls, HealthTrans recommends that CMS carefully examine the current practices of the pharmacy benefit management and administration community and the retail and mail pharmacy communities so as to learn about their current coordination and ability to issue medication alerts and assist with various FDA driven recalls. With regard to medical error reporting, given current use of the pharmacy management technology in place, either further advancements are necessary or coordination with other aspects of the healthcare delivery will be required.

With respect to Medication Therapy Management Programs, HealthTrans recommends that CMS provide further guidance on the types of programs it would like to see and in so doing, provide wide latitude for companies that provide pharmacy management and administration services to coordinate with the plans that may also be serving a beneficiary?s needs in the hospital and physician areas of healthcare. Such latitude would allow health plans to access skills and knowledge in the pharmacy benefit administration field and join such skills and knowledge with their own clinical expertise.

With respect to fraud, abuse and waste, HealthTrans believes CMS should be made aware that for some time pharmacy administration and benefit management companies have used a variety of tools to target areas of possible fraud, abuse and waste. Given the advanced on-line technology that is available to adjudicate claims and the data generated during the process, pharmacy management and administrative practices allow for screening and alerts related to a wide range of potential fraud, abuse and waste practices. This screening together with appropriate follow through with all the ?touch points? of patient, physician, pharmacist and sound internal audit practices has provided a significant protection against fraud and abuse. Other pharmacy and drug-related government agencies are well aware of the sophistication that can be employed in screening for potentially

fraudulent or abusive situations. HealthTrans recommends that CMS explore this area further with a variety of private sector companies and would be happy to talk further with CMS about these practices.

CMS-4068-P-798-Attach-1.pdf

CMS-4068-P-798-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:

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

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

Submitter : Mr. Michael Campbell **Date & Time:** 10/03/2004 05:10:03

Organization : Pennsylvania Health Law Project

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

October 1, 2004

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

Re: Comments to Medicare Part D Prescription Drug Regulations
File Code: CMS-4068-P

Dear Sir/Madam:

Enclosed please find comments on the Proposed Medicare Part D Prescription Drug Regulations, submitted by the Pennsylvania Health Law Project, on behalf of the Consumer Health Coalition, the Philadelphia Welfare Rights Organization, the Clarion County Welfare Rights Organization, and the Armstrong County Low Income Rights Organization.

We will also be providing a copy of these comments via overnight mail. Any questions or problems regarding these comments may be directed to Leonardo Cuello at (215) 625-3896. We appreciate your attention to these comments.

Sincerely,

Michael Campbell
Executive Director

Cc:
Consumer Health Coalition
Philadelphia Welfare Rights Organization
Clarion County Welfare Rights Organization
Armstrong County Low Income Rights Organization.

CMS-4068-P-799-Attach-1.doc

File Code: CMS-4068-P

Comments to the Proposed Medicare Prescription Drug Regulations: 42 CFR Part 423

**Prepared by the Pennsylvania Health Law Project
on behalf of the Consumer Health Coalition,
Philadelphia Welfare Rights Organization,
Clarion County Welfare Rights Organization, and
Armstrong County Low Income Rights Organization.**

Subpart A—General Provisions

Whether through examples or more descriptive language, the definition of actuarial equivalence in Section 423.4 must be refined. The proposed definition of actuarial equivalence simply says that something is actuarially equivalent if "generally accepted actuarial principles" make it so. Because this concept is so critical to whether a consumer has creditable coverage (Subpart B) and whether an alternative prescription drug plan (Subpart D) is comparable to a standard prescription drug plan, the definition must be more descriptive and more tangible to the consumer.

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

Overarching Concerns Regarding the Enrollment Process

We are very concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries, beneficiaries with mental illness, and other populations with special needs. More attention must be given to developing materials and education and

enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness and cognitive impairments, and those with other special needs about the new drug benefit and helping them to enroll in the best plan available.

For example, in the conference report for the Medicare Modernization Act, Congress directed that "the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated [sic] access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes." [Report No. 108-391, pp. 769-770.] Experience implementing Medicaid managed care programs over past 10 years shows that to successfully enroll individuals with mental illness, cognitive impairments (like Alzheimer's) and disabilities, outreach, education, and enrollment opportunities must be incorporated at multiple points within the health communities.

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

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

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

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.

We are pleased to see 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. Coupled with the prohibition on de jure or de facto discrimination against any disability or group, this piece will be a critical protection for our consumers with disabilities. We believe enforcement of this provision will be essential and offer comments throughout the following sections that urge clarification to insure that this intent is clear.

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.

Auto-enrollment of dual eligibles into PDPs as proposed in Section 423.34(d) should occur on November 15, 2005, not May 15, 2006. While we understand that the initial enrollment period runs from November 15, 2005 to May 15, 2006, we are gravely concerned about full dual eligibles who will lose Medicaid prescription drug covered on January 1, 2006. Dual eligibles should be auto-enrolled immediately to insure that they maintain access to drug coverage. 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.

This auto-enrollment process is an additional and considerable burden on the states and the structure of the program with its "clawback" provision builds in a financial disincentive for states to maximize enrollment in Part D. Under the law, the "clawback payment" will be based on the number of dual eligibles enrolled in the new Part D benefit: the fewer enrolled, the smaller the giveback to the Federal government. To blunt that disincentive and to maximize enrollment, administrative payments to the states for autoenrollment must be adequate and must be sufficient to counter the built in financial disincentives inherent in the "clawback" provision. We urge CMS to reimburse the states for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.

With regard to CMS's request for comment on how to auto-enroll dual eligibles who are in MA-only plans, we suggest 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. We suggest adding "but no later than the 1st day of the second calendar month following the month of the request for the enrollment change" to the end of Section 423.38(c).**

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.

We suggest several ways that CMS can better address this issue:

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

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

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

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

We 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. For example, a consumer knows she has creditable coverage but that it is ending in December when she leaves her job. The person does not disclose it because her PDP enrollment effective date is January 1 by which time the creditable coverage was to have ended. Instead, the employer decides not to terminate the creditable coverage until January 31st. In such a case, the consumer should be allowed to cure and obtain payments from their other coverage, or make out-

of-pocket payments to the PDP to remain in her plan. This person should not be disenrolled and it is insult to injury to deny this person a SEP if she is disenrolled.

There is an error in Section 423.44(b)(1). The provision referring to the disenrollment of an individual who has engaged in disruptive behavior should be cited as Sec. 423.44(b)(1)(ii) rather than Sec. 423.44(b)(1)(i) because 423.44(b)(1)(i) refers to disenrolling an individual when any monthly premium is not paid on a timely basis.

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 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. We are 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 final regulations for Section 423.44 must set forth a process for appealing disenrollment decisions and denials of reenrollment. Our clients' experience with human and technological errors evidences a critical need for a process to appeal disenrollment decisions and denials of reenrollment.

Sec. 423.46 Late enrollment penalty.

General concerns/comment on this section.

We urge CMS to delay implementation of this section for all enrollees for two years. The drug benefit is a new program and particularly complex program. Many beneficiaries will be confused about their enrollment opportunities and obligations, or not understand that they must choose a plan and enroll. We see from the Medicare-endorsed prescription drug discount card that, even with significant outreach, the majority of individuals eligible for the low-income subsidy have not yet taken advantage of the $600 subsidy available to them.

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

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

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

Omissions in this section.

Beyond that general comment, we have several more specific concerns regarding omissions in this section.

- **Add appeals opportunity.** There should be an opportunity for enrollees to appeal late enrollment penalties. This should be noted in this section and should be incorporated as part of the general system for appeals outlined in Subpart M.

- **Coordinate with "special enrollment periods."** Late enrollment penalties should be coordinated with "special enrollment periods" to ensure that individuals who take advantage of the special enrollment periods do not face late penalties. The exemption of time during special enrollment periods from late penalties should be stated in this section.

- **Exemption for individuals involuntarily disenrolled.** Unless CMS adds special enrollment opportunities for individuals who are involuntarily disenrolled—as strongly recommended under our comments on section 423.36(c)—those who are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period. At that point, they may be subject to a late penalty and increased premiums. This is patently unfair, especially since it may be based on an arbitrary and unjustified decision by the plan to 'get rid of' high cost patients. The disruptive behavior may have resulted from denial of access to needed medications. The late enrollment penalty should be waived for these individuals as well.

- **Late enrollment penalties and people with disabilities**. CMS should incorporate an enrollment "grace period" for individuals with disabilities. The rationale for requiring "creditable coverage" with a gap of no more than 63 days is to encourage healthier individuals to maintain coverage and thus to minimize adverse selection for Part D. This rationale does not apply to beneficiaries with disabilities, and these beneficiaries might well require additional time to make a selection and complete the enrollment process. Therefore, CMS should incorporate a late enrollment "grace period" for this population.

- **Special enrollment opportunities/no penalties for incorrect notice of change in coverage status (see also Section 423.56).** If an employer or other entity providing drug coverage to Medicare beneficiaries fails to provide adequate or correct notice of the creditable status of that coverage or a change in status of that coverage, and that coverage is not creditable, beneficiaries should not face late enrollment penalties.

Sec. 423.48 Information about Part D.

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

Information plans must provide.

This section states that "each PDP and MA-PDP plan must provide…information necessary" to enable CMS to assist eligible individuals to make informed decisions among Part D plans available to them. It notes CMS may provide guidance regarding format and standard terminology to be used by plans. This is insufficient. Medicare beneficiaries can only exercise an informed choice about their drug plan if they have adequate information about drug plan options available to them. The information should be provided annually, in writing, and include details about the plan benefit structure, cost-sharing and tiers, formulary, pharmacy network, and appeals and exception process. In order to assure that beneficiaries have the required information, the standards should be included in regulations that are binding and enforceable, and not in guidance.

In addition, CMS needs to require plans to make information available in alternative formats for people with disabilities and in languages other than English to reflect the languages spoken in a plan's service area.

CMS's proposal to extend the price comparison website only helps the limited number of beneficiaries who have access to the Internet. CMS should continue to make the information available upon written request and through 1-800-Medicare. We urge CMS to continue to work to improve these information sources, as they sometimes are difficult to use by consumers.

Minimal information plans should be required to provide.

While the information that CMS may need from plans may change from time to time as CMS gains experience with Part D, there is a minimal amount of information on the benefit itself that potential enrollees will need in order to make a choice among plans. That should be specified in this section. Specifically, beneficiaries will need to understand:

- Premium information, including whether individuals who receive the low-income subsidy will have to pay a part of the premium and, if so, the amount they will have to pay;

- The benefits structure and comparative value of the plans available to them;

- The coinsurance or copay they will need to pay for each covered Part D drug on the formulary;

- The specific negotiated drug prices upon which coinsurance calculations will be based and that will be available to beneficiaries if they confront the gap in coverage;

- Formulary structure, the actual drugs on the formulary, and how the formulary can change during the plan year.

- Participating pharmacies, mail order options, out-of-service options.

- Appeals and grievance processes.

- General information on plan performance. (As experience is gained with plans, information should be available on formulary change rate, number of grievances filed and outcomes, number and type of appeals and outcomes.)

It is essential that plans provide information to CMS that will allow CMS to present the items outlined above to potential enrollees in a clear manner that will allow them to easily compare plans. Plans should also be required to provide this information to potential enrollees (see comments on section 423.50, below). Therefore, we urge that CMS specify the minimal information that plans will need to provide. As noted, guidance is insufficient.

Specifically, we urge CMS to require plans to provide information on negotiated prices in an easily accessible format. This is critical for potential enrollees who will have high coinsurance and may confront a gap in coverage where the only benefit available to them is the negotiated price. We urge CMS to require plans to publish, as part of their marketing materials, price information. This could be provided in a manageable format.

For example, CMS could determine the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries and require all plans to publish in a standardized format, and post on the Internet, their negotiated price for each of those drugs. Such a list would be easy to prepare and take only about one page in marketing materials.

CMS should include more specific requirements under Section 423.50(c) about the benefit information plans must provide in their marketing materials. It will be important that beneficiaries have comprehensive information on plan benefits and drug prices, since the drug co-pays, coinsurance and donut hole costs they might have to pay could be substantial. We recommend that CMS add to this list the requirement that plans make available the following information on benefits and benefits structure, in written format and on the Internet:

- **Information on the formulary**: What the formulary is; information on the fact that the formulary might change; what notice that will be provided if there is a formulary change; and, at the least, formulary and cost-share tier information for the 25 to 50 drugs most frequently prescribed to Medicare beneficiaries (see section 423.48, above).

- **Information on drug prices.** A description of the "negotiated price," and a list of the negotiated price for 25 to 50 most frequently prescribed drugs (again, see section 423.48, above).

- **Premium information**. Information on plan benefits and the premium (for the basic benefit and any other benefits offered). If a plan offers multiple benefits, marketing material should include a side-by-side comparison of those benefits. For each benefit offered, plans should be required to note, clearly and conspicuously, whether individuals qualifying for the low-income subsidy will have to pay a premium and, if so, the amount that will have to be paid.

This information will be critical if beneficiaries are to make informed choices among plans. It should be part of standard marketing materials; potential enrollees should not have to request this basic information.

It is unacceptable that, under Section 423.50, a plan's marketing materials are deemed approved if CMS fails to approve them within a certain time period. Even worse, these same marketing materials from one region are then deemed approved in all other regions in which the plan operates, except for state specific information. Many of the Medicare beneficiaries to whom the Part D plans will be marketing are frail elderly, consumers with cognitive or memory impairments, persons with limited education or who have LEP. In short, they are persons who may have difficulty

understanding a complicated program like Part D, and who may be easily taken advantage of. It is critical that the marketing materials being sent out contain clear information as well as information that will not mislead or misrepresent the Part D program or the plan's product. We have seen letters sent out by Medicare+Choice plans that had been approved in Region II, which contained what could arguably be considered generic information, except that the rules for the program described were different for Pennsylvania. CMS should either craft model forms that, if used unaltered, could be deemed approved within 10 days or it must review and actively approve all materials before they go out.

The proposed regulations in Section 423.50 fail to require enrollment forms, marketing materials, and notices to be provided in alternative languages and alternative formats. The proposed regulations in Section 423.50 also fail to indicate that plans must have, and make available to consumers, interpreters and alternative communication methods. The only mention of any alternatives we found is that "For markets with a significant non-English speaking population, provide materials in the language of these individuals." This is not adequate. Again, a Subpart devoted entirely to notice requirements should be developed and should address these issues.

The restrictions on PDP marketing under Section 423.50(e) must be greatly expanded.

Prohibit telemarketing. Telemarketing should expressly be prohibited. Door-to-door solicitation is prohibited under this section and telemarketing presents many of the same dangers. There have been numerous reports of telemarketing fraud under the Medicare Drug Discount Program. The Part D benefit is susceptible to even more fraudulent business practices. The regulations should specifically prohibit prescription drug plans from initiating telephone or e-mail contact with potential enrollees, unless the potential enrollee requests contact through such means in response to a direct mail or other advertisement.

Prohibit marketing of other services. In the Preamble, CMS asked for comments on whether it would be advisable to permit prescription drug plan sponsors to market and provide additional products (such as financial services, long term care insurance, credit cards) in conjunction with Medicare prescription drug plan services. CMS seems to believe that this would encourage entities such as financial services firms to participate as prescription drug plans. CMS should not allow plans to market other services, nor should it seek to encourage other entities, such as financial institutions, to participate as PDPs. This would be unadvisable for several reasons:

- Having plans offer added services would create a great deal of confusion among beneficiaries. Beneficiaries might believe that CMS had approved the additional services being offered in conjunction with the "Medicare approved card"; the

difficult task of comparing plans would become even more complex for potential enrollees; beneficiaries might mistakenly believe that they need to take an entire package of offered services when they sign up for the drug plan. This section prohibits marketing activities that could "mislead or confuse." Allowing plan sponsors to market added services is so apt to create situations that confuse and mislead beneficiaries that it is in direct conflict with the provisions of this section.

- Financial institutions are exempt from the HIPAA Privacy Rule; CMS should not encourage entities exempt from HIPAA to participate as PDPs. The potential for abuse—both cherry picking of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals—is enormous.

Prohibit single-contract pharmacies from marketing.

CMS asked for comment on the applicability of MMA marketing requirements for PDP marketing. We recommend that PDP marketing be much more severely constrained. There is the potential for pharmacies to market certain PDPs more aggressively, regardless of whether or not that PDP is the best for the beneficiary. We can easily foresee that occurring if a pharmacy has a contract with only one PDP or has more favorable contract terms with a specific PDP. Providers with relationships with a PDP plan might market that plan more heavily. We urge CMS to consider the potential for provider and pharmacy-based marketing to steer beneficiaries into inappropriate PDPs and to make marketing requirements more protective of consumers than those for the Medicare Discount Card and also to specify marketing limits in the regulations.

At the very least, pharmacies with only one PDP contract should not be allowed to market the program; other pharmacies (those with multiple contracts) should be required to provide equal space to materials from all PDPs with which they contract.

Do not allow plans to use Medicare discount card enrollee and applicant information. The regulations should prohibit prescription drug plans from obtaining and using Medicare Drug Discount Card enrollee and applicant information, and information collected from any other card programs the company might sponsor.

It is foreseeable that many Discount Card sponsors will apply to be prescription drug plans. As Discount Card plans, these entities will have beneficiary-level information on drug use, creating the potential for prescription drug plans to use Discount Card information to target marketing to low-cost beneficiaries, either directly or through marketing firms.

Section 423.50(e)(2) prohibits drug plans from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." The regulations should:

- Specifically prohibit prescription drug plans from obtaining or using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor.

- Prohibit others from using individually identifiable health information collected or maintained by a Medicare Discount Card Sponsor to market on behalf of a prescription drug plan sponsor.

Specify whether and how the Secretary can provide information to prescription drug plans. The MMA added section 1860D-1(b)(4)(A) to the Social Security Act. This permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."

The proposed rule does not contain any provision governing whether and how this information will be provided and in the Preamble, CMS seeks comments on a number of operational issues as well as on the provision in general.

The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair information practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. There may be some marginal benefit in the Secretary's providing information to prescription drug plans if the plans send information to eligible individuals information that would actually be useful in determining which plan to select. We recommend the following in the disclosure of identifiable information:

- If the Secretary provides information to prescription drug plans, the information provided should be limited to the minimal amount necessary: the potential enrollee's name and address. No health or financial information should be disclosed.

- The Secretary should disclose identifiable information to prescription drug plans to facilitate marketing or enrollment only if the plan's marketing materials contain formulary and drug pricing information or are accompanied by an application form. This approach could help balance privacy concerns with the need for beneficiaries to obtain important plan information.

- The Secretary should not disclose telephone numbers. Telemarketing should be prohibited; there is not need for plans to have beneficiary phone numbers unless provided by the beneficiary.

Beneficiaries should be given the choice of whether they want this information disclosed. We suggest that an opt-in approach be used to ensure that beneficiaries do, in fact, want their information disclosed. The op-in notice should be clear; written with the Medicare population in mind; state what will be shared; and clearly state that even if a beneficiary elects to opt-out, they can still enroll in the benefit, they will still receive information about the benefit from CMS, and they can still request information directly from plans.

Sec 423.56 Procedures to determine and document creditable status of prescription drug coverage.

Notices of Creditable Coverage must be sent to consumers several times a year, and in multiple formats, by Creditable Coverage entities between June 2005 and December 2006. Section 423.56 requires insurers to send consumers notices of creditable prescription drug coverage. The section does not require that these be sent out repeatedly. Distinct Notices of Creditable Coverage should be sent out quarterly during this time period and statements about coverage being creditable or not should be included on other mailings.

CMS should craft standard notices for both creditable and non-creditable coverage that include information explaining the relevance of whether prescription drug coverage is creditable or not and how that impacts Part D enrollment. These notices should be similar to standard notices and language required by Medigap insurers as noted in the preamble for Subpart S.

We also support the CMS idea that "given the importance of knowing whether coverage constitutes 'creditable coverage'" health plan sponsors should provide information to their enrollees about the value of the benefit, the annual premium, and the amount that the beneficiary will be required to pay. More information to consumers will help them understand how their coverage compares and whether they may want to seek Medicare coverage.

In cases where individuals are not 'adequately informed' by an employer or other entity that their coverage is not creditable, CMS should take action on behalf of all the individuals of that employer or other entity to provide a special enrollment period (SEP). In other words, each individual adversely impacted by the failure of the employer or other entity to adequately inform should not have to apply or appeal for a SEP.

CMS should publish annual notices of actuarial equivalence for entities to utilize in assessing whether their coverage is creditable.

Subpart C—Benefits and Beneficiary Protections

Sec. 423.100 Definitions.

The final regulations should include a definition of "dispensing fee" to permit coverage of home infusion-related services. We recommend that the final rule include a definition of "dispensing fee" that is broadly framed, in order to permit the payment of costs associated with home infusion therapy. Of the options provided in the preamble to the proposed rule, we support option 3. We do not believe that a narrowly crafted definition of dispensing fee is appropriate because the conference report at §1860D-2(d)(1)(B) references negotiated prices in a manner that indicates that Congress intends to define negotiated prices in a way that arrives at the most accurate prices when considering a variety of both concessions and fees. Since the antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin and other drugs that are administered through home infusion are indisputably covered Part D drugs, and equipment, supplies and services are integral to the administration of home infusion therapies, costs associated with such administration should be included in the definition of dispensing fee, in order to arrive at the most accurate determination of the negotiated price.

We do not support option 1 for the definition of "dispensing fee" because we believe it makes an arbitrary and inappropriate distinction between costs associated with dispensing a covered Part D drug and associated costs for the delivery and administration of a covered Part D drug, and we do not support option 2 because we do not believe that the definition captures all of the true costs associated with the dispensing of a covered Part D drug.

The final definition of "long-term care facility" in the final regulations should be expanded to explicitly include ICF/MRs and assisted living facilities. We recommend that the final rule include a definition of "long-term care facility" that explicitly includes intermediate care facilities for persons with mental retardation and related conditions (ICF/MRs) and assisted living facilities. We believe that many mid

to large size ICF/MRs and some assisted living facilities operate exclusive contracts with long-term care pharmacies.

We recommend that the final rule define "usual and customary price" to be, "the maximum price that a pharmacy would charge a customer who is a Medicare beneficiary participating in an in-network Part D plan."

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.

Treatment of Health Savings Accounts (HSAs) as group health plans. We recommend that the final rule clearly state that health saving accounts (HSAs) meet the definition of employment-based retiree health coverage in Sec. 1860D-22 and the "insurance or otherwise" provision in Sec. 1860D-24 of the MMA. The law precludes contributions from employer sponsored health plans from being counted as incurred costs and counting toward the deductible or out of pocket limit. We do not believe that contributions from one employer-sponsored benefit should receive differential treatment over contributions from another type of employer-sponsored benefit. Therefore, the final rule must not preferentially treat contributions from HSAs, HRAs, and FSAs by counting them as incurred costs when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) do not count as incurred costs. The proposed regulations state that contributions made by an AIDS Drug Assistance Program (ADAP) on behalf of a beneficiary will not count towards the beneficiary's true out-of-pocket costs, which is necessary to reach the catastrophic limit. We strongly recommend that the final rule count cost-sharing subsidies from AIDS Drug Assistance Programs (ADAPs) as incurred costs. If a state ADAP program decides to provide cost-sharing subsidies, these subsidies must be counted as incurred costs. ADAPs are an integral component of the safety net for people living with HIV/AIDS in this country and have a long history of filling in gaps left by other federal programs, including Medicaid and Medicare.

Federal funds for ADAP programs are appropriated by Congress on a discretionary basis. Notwithstanding the decision by a state to use ADAP funds to subsidize Part D cost-sharing, federal costs do not increase. Further, ADAP funding has not kept pace with growing need over the past decade, and this has led to increases in the number of individuals on waiting lists for ADAP services, as well as restrictions and limitations in ADAP formularies. In this environment, should a state prioritize providing Part D cost-sharing subsidies, federal policy should not create a disincentive for states to make the most prudent resource allocation decisions. Furthermore, the populations served by ADAPs are predominately low-income and often take multiple prescription drugs. Therefore, even Medicare subsidized cost-sharing for low-income Medicare Part D enrollees could provide a significant barrier to accessing prescription drugs. This has grave implications both for the medical management of HIV/AIDS in the affected individual, but also public health implications resulting from increased risk of the development of resistance to currently available HIV-related antiretroviral medications and therefore an increased risk of transmission. Discouraging ADAPs from subsidizing beneficiary cost sharing by not counting as incurred expenses ADAP expenses spent on premiums, deductibles, cost-sharing or the amount spent filling in the donut hole, could leave people living with HIV/AIDS who receive Medicare benefits vulnerable to fall through the cracks.

The regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS and not allow them to count as incurred costs, while at the same time allowing state dollars to be used for State Pharmaceutical Assistance Programs' (SPAPs) expenditures on behalf of a beneficiary. Under the proposed regulations, SPAPs are allowed to wrap-around in a way that all costs spent on behalf of a beneficiary count as incurred costs. States should have the flexibility to provide prescription drugs to a variety of populations, including people living with HIV/AIDS, with appropriated state dollars. It is inexcusable to exempt people living with HIV/AIDS from receiving this type of help from their state, while allowing people with other medical conditions to benefit from their state dollars.

Maximizing savings for people needing HIV/AIDS medications under the 340B program. The regulations encourage state ADAPs to move toward the model of purchasing their drugs directly, under the 340B program, instead of using a rebate model. We feel it is completely inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by the Health Resources and Services Administration (HRSA), the federal agency that oversees the Ryan White CARE Act and the 340B Program.

As mentioned, there are several states that use a rebate option model available to ADAPs under 340B to purchase drugs instead of the direct purchase model. These states, including California and New York, the two largest ADAPs, have carefully analyzed the cost benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study which demonstrated that after calculating rebates, they receive prices for HIV pharmaceuticals comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms.

Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size and geography and demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen. ADAPs have and will continue to use every mechanism available to receive the best prices for their HIV-related drugs, including negotiating for supplemental rebates and discounts.

Coordinating between ADAPs and Medicare Part D benefits. Any coordination between ADAPs and the Medicare Part D PDPs is, under the proposed rules, completely voluntary on the part of the PDPs. There are several issues that would inhibit the coordination of benefits between ADAPs and PDPs. Most importantly, since ADAPs' expenditures for beneficiaries would not count as incurred costs and thereby not allowing many of the HIV-positive beneficiaries' living with HIV/AIDS to reach the catastrophic limit, ADAPs would have no strong incentive to collaborate with private drug plans. Furthermore, PDPs could charge ADAPs for any coordination between the two entities. The proposed coordination would not result in any significant amount of cost savings and would not be cost-effective for the ADAPs. Finally, it could potentially be very difficult for ADAPs to coordinate with multiple PDPs participating in the Medicare program in a given area. Under these proposed rules, it is not feasible for ADAPs to coordinate with PDPs. However, if CMS would allow payments made by ADAPs to count as incurred costs, coordination between ADAPs and PDPs could result

in substantial costs savings and therefore provide incentive for ADAPs to collaborate with PDPs.

We are interested in exploring methods of collaboration between ADAPs and PDPs that could allow beneficiaries living with HIV/AIDS to benefit from the 340B pricing. We understand that several 340B entities have begun entering into partnerships with various state and local government programs to provide more individuals access to 340B pricing. However, there are so many complexities and unknowns about the Medicare Part D prescription drug program and its effects on ADAPs that we are not prepared to comment on the details of any such collaboration.

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. Given that the MMA adopts a consumer choice model, it is imperative that the final rule ensure that elderly beneficiaries and people with disabilities have access to plans with benefit designs that are sufficiently standardized to permit an objective comparison among plan options. 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.

The MMA permits tiered cost-sharing so that Part D plans are permitted to incentivize the use of preferred drugs within a class, when it is clinically appropriate. By placing no limits on the use of tiered cost-sharing, the proposed rule undermines the balance achieved by the Congress between permitting plans to use formularies with numerous provisions (including the P&T committee requirements and the exceptions process) that seek to ensure that individuals receive all of the covered Part D drugs they need when medically necessary. In another section, we also comment on what we view as a wholly inadequate exceptions process.

The absence of reasonable limits on cost-sharing tiers combined with an inadequate and unworkable exceptions process would provide Medicare Part D enrollees with a catch-22. Permitting unlimited cost-sharing tiers could permit a Part D plan to effectively bar access to clinically necessary covered Part D drugs because cost-sharing is unaffordable and the exceptions process does not include adequate

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

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. 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. Even the lowest income consumers who qualify for the full subsidy may have difficulty paying their copayments, especially if they take a high number of medications. In addition, this could be especially problematic for consumers who are unable to get an exception to have a non-preferred drug covered at the preferred drug co-pay and who may be unable to afford the higher level of cost sharing.

The provisions of Sec. 423.104(g) that allow plans to offer basic alternative benefit designs that go beyond actuarially equivalent standard coverage must be revisited. We are strongly opposed to the provisions of § 423.104(g). We recommend that the final rule exclude provisions for "enhanced alternative coverage". The MMA provides for standard prescription drug coverage and alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices.

We believe that the proposed provisions at § 423.104(g) exceed the authority of the statute and defeat the purpose of the Act, which is to provide meaningful choice of prescription drug plans by eligible Part D beneficiaries. The different options make it virtually impossible to compare plans, and thus make it nearly impossible for older people and people with disabilities to make an informed choice of private plan options.

Sec. 423.120 Access to covered Part D drugs.

We are pleased to see the provision in Sec. 423.120(a) requiring pharmacy access standards for each local service area. We support the inclusion in the final rule of a provision in the proposed rule that requires pharmacy access standards must be met in each local service area, rather than by permitting plans to apply them across a multi-region or national service area. A key principle of the MMA is that Medicare beneficiaries will have convenient access to a local pharmacy. By permitting plans to meet the access standards across more than one local service area could only lead to individuals in some local service areas to not have convenient access to a local

pharmacy. However, as noted below, we believe that the access standards should be based on travel time rather than mileage.

We also support the provision in Sec. 423.120(a) that plans can only count retail pharmacies as part of their networks for the purpose of meeting access standards. We support the inclusion in the final rule of the provision in the proposed rule that only counts retail pharmacies for the purpose of meeting pharmacy access standards. Because of the principle that Medicare beneficiaries will have convenient access to a local pharmacy, it would undermine this principle if the access standards could be met by counting pharmacies that serve only specific populations and which are not available to all parts of the general public.

Pharmacy access standards in Section 423.120(a)(1) should be based on travel time and not on mileage. In urban areas, for example, 2 miles can take two hours on public transportation. Such travel times would be unreasonably burdensome for lower-income or frail individuals. We suggest that plans be required to follow access standards based on time such that pharmacies must be within 10 minutes travel time of 90% of the consumers in an urban area, within 20 minutes travel time of 90% of the consumers in a suburban area, and within 30 minutes travel time of 75% of the consumers in a rural area. Time based standards have worked well in Pennsylvania's Medicaid mandatory managed care program, "HealthChoices." Additionally, we recommend that all PDPs and MA-PDs be required to contract with pharmacies that offer home delivery service. A same-day or next day need for medications makes mail-order an impracticable solution for urgent or emergent situations.

We support the addition of a provision in the final rule that requires prescription drug plans and MA-PD plans to offer their standard pharmacy contracts to some or all long-term care pharmacies in their service areas. The preamble to this subpart includes a discussion of access to long-term care pharmacies for Part D enrollees, specifically about using authority under section 1860D-4(b)(1)(C)(iv) of the Act to require prescription drug plans and MA-PD plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their plans' standard pharmacy contracts. We recommend that the final rule require prescription drug plans to offer to contract with all LTC pharmacies and make available a standard contract. Over 80% of nursing home beds are in facilities that require the resident to use a long-term care pharmacy. Should the final rule not contain this requirement and in situations where a LTC pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

In addition, the preamble notes that CMS is seeking comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA. We believe that there are

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

We recommend that the final regulations include a provision requiring prescription drug plans to offer to contract with all FQHC and rural pharmacies and make available a standard contract as a way to assure Part D enrollees' access to these types of pharmacies. Federally qualified health centers (FQHCs) and rural health centers play a critical role in bringing doctors, basic health services and facilities into the nation's neediest and most isolated communities. Should the final rule not contain this requirement and in situations where an FQHC or rural pharmacy is not part of a plan's network, then plan enrollees should be exempted from differential cost-sharing requirements for accessing an out-of-network pharmacy.

We believe that the final regulations must include participation standards for pharmacies. If the access standards are to be meaningful, those pharmacies can be counted toward meeting them must stock all drugs on the PDP's formulary. Our experience in Pennsylvania is that without minimum standards, some pharmacies stock only those items which generate what they deem to be an acceptable profit. Similarly, all pharmacies must be expected to provide a standard response in the event that a prescription is not authorized by the PDP. For example, a pharmacy should be required to make direct contact with the prescriber to determine if substitution of a formulary drug is appropriate or if the physician believes that the off-formulary drug is necessary. Likewise, in situations where an interim supply is warranted, the pharmacy must be required to provide the prescription. In Pennsylvania, we have found that whether a consumer successfully comes away from a pharmacy with any medicine depends on the pharmacist's willingness to cooperate and assist. The goal must be that no member leaves a pharmacy empty handed.

The final regulations for Sec. 423.120 (a)(4) should require PDP sponsors and MA organizations to make available a standard contract for participation in their plan's network. Section 1860D-4(b) of the MMA requires plans to permit the participation of any willing pharmacy, and also requires prescription drug plans to provide for convenient access for network pharmacies. We believe that these requirements are best achieved by requiring plans to make available a standard contract for participation in their plan's network. We also believe that this also has other important advantages in terms of ease of administration and expanded beneficiary access.

The final regulations for Sec. 423.120 (a)(5) permitting lower cost-sharing for preferred pharmacies through higher cost-sharing for non-preferred pharmacies or as

alternative prescription drug coverage should be clarified. We recommend that the final rule permit lower cost sharing for preferred pharmacies only when the plan's network of pharmacies exceeds the minimum regulatory requirements for network adequacy. In addition, as recommended previously, enrollees who are required or who have specialized needs that make it desirable to use specialized pharmacies, including LTC pharmacies, FQHC, and rural pharmacies, should not be penalized by having to pay higher cost-sharing.

The final regulations for Sec. 423.120(a)(6) must permit the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy (vs. a network mail-order pharmacy) to count as an incurred cost. We recommend that the final rule ensure that beneficiary costs paid out-of-pocket used for the purchase of covered Part D drugs count as incurred costs. A key principle of the MMA is that Medicare beneficiaries will have convenient access to a local pharmacy. We believe that this principle is undermined by permitting plans to charge beneficiaries the cost differential for receiving an extended supply of a covered Part D drug through a network retail pharmacy versus a network mail order pharmacy. Notwithstanding this objection, the final rule should permit the cost differential charged to beneficiaries to count as an incurred cost.

All plans should be required to have a P&T committee and those committees should be required to be involved in formulary development, review, and implementation as well as involvement in the development, review, and implementation 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 implementation of the formulary as well as the development, review, and implementation of tiering structures is a critical consumer protection.

The final regulations for Sec. 423.120(b)(1) should include a charge for P&T committees to, "ensure that the interests of enrollees, taking into account the unique needs and co-morbidities commonly associated with aging populations and people with disabilities served by Medicare, are protected by all formulary and benefit design decisions made by the Part D plan." In all cases, the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs. The final rule should also include provisions for sanctions against P&T committee members when P&T committee decisions are in gross violation of this charge.

The final regulations for Sec. 423.120(b)(1) must require P&T committees to develop formularies and make benefit design decisions in a way that is transparent

to plan enrollees and the public. The final rule should require P&T committees to hold public hearings and receive input from the public prior to the adoption of or revision to plan formularies. The final rule should specify that meetings of the P&T committee should be open to the public. Further, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations, and a diverse range of disabled populations

The final regulations for Sec. 423.120(b)(1) must require P&T committees to meet at least quarterly, and have processes for making formulary revisions between regularly scheduled meetings when new clinical information or FDA approval of medications occurs that could be used for the treatment of life threatening conditions.

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 existence of P&T committees, whose purpose is to consider existing scientific knowledge and clinical experience in designing formularies, would be dramatically undermined and would run counter to the statute, unless P&T committee decisions are binding on plans.

We also believe that Congress intended for P&T committee decisions to be binding on plans. If P&T committee decisions were intended to be merely advisory, then the provisions requiring independent physician and pharmacist participation would be unnecessary. In other comments, we will make clear that we have serious concerns about the independence and integrity of P&T committee decision making. The final rule must take greater steps to shield P&T committee decisions from plan financial considerations and it must reinforce the independence and broad-based clinical expertise of P&T committees.

The final regulations for Sec. 423.120(b)(1)(ii) must require that the composition of independent members on a plan's P&T Committee be proportionate and not a precise number. Two independent members of a P&T Committee comprised of 40 people are insignificant. We suggest one half representation by independent individuals.

We also recommend that the final regulations for Sec. 423.120(b)(1) requiring certain P&T Committee members to be "independent and free of conflict with respect to the sponsor and plan" to also apply to pharmaceutical manufacturers. The essential function of the P&T committee is to ensure that formulary and benefit design decisions are based on existing scientific knowledge and clinical experience. This function cannot be adequately performed when P&T committees consist of a majority of members who are not independent. As with plan employees, employees of

pharmaceutical manufacturers have a conflict and cannot be relied upon to give an impartial and fair view of existing scientific knowledge and clinical evidence.

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 final regulations must also standardize the process for how new medications will be classified under a plans therapeutic class and category structure. Leaving this up to each plan to decide will lead to disparities and disparities lead to access barriers. We encourage the use of the USP for classifying new medications.

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. The review standards developed by CMS must be published as legally-enforceable regulations, and not as guidelines. Moreover, the standards for public comment on these critical standards must meet the requirements of the Administrative Procedures Act.

The proposed regulations at Sec. 423.120(b)(4) must be clarified to include minimum timeframes for periodic evaluation and analysis of protocols and procedures related to plan formularies. We recommend that the final rule require plans to evaluate and analyze their protocols and procedures related to plan formularies at least quarterly. For many conditions, every month brings significant advances in the clinical management of disease making it essential that the final rule require regular ongoing and timely review of their formulary protocols and procedures.

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. Notifying enrollees about formulary changes primarily through a website

is simply inadequate. Too many elderly and disabled individuals 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 inform the beneficiary about the right to request an exception and appeal a plan's decision to drop a specific covered Part D drug from their formulary and include information about the exception and appeals processes.

The proposed regulations at Sec. 423.120(b)(6) regarding limitations on formulary changes prior to the beginning of a contract year must be strengthened and clarified in the final regulations. We recommend that the final rule place strict limits on mid-year formulary changes, requiring plans to justify a decision to remove drugs from a formulary. Permitted reasons for discontinuing coverage would include the availability of new clinical evidence indicating that a particular covered Part D drug is unsafe or contraindicated for a specific use or when all manufacturers discontinue supplying a particular covered Part D drug in the United States.

Should the final rule fail to effect such a restriction, we strongly recommend that plans be required to continue dispensing all discontinued drugs for all persons currently taking a discontinued drug as part of an ongoing treatment regimen, until completion of the course of treatment.

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 4 distinct 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.

The proposed regulation at Sec. 423.124(a) is insufficient to provide for emergency access to covered Part D drugs. We support inclusion in the final rule provisions in the proposed rule that establish out-of-network access standards. Nonetheless, this requirement is insufficient to provide for emergency access to covered Part D drugs. The final rule must establish requirements on plans to dispense a temporary supply of a drug (wherever a prescription is presented, irrespective of whether it is at a network pharmacy) in cases of emergency. If the emergency situation involves a coverage dispute, the plan must dispense refills until such time as the prescription expires or the coverage dispute is resolved, through either a plan decision to provide coverage for the drug or through completion of the appeal process. This requirement must also specify that a temporary supply must be dispensed even in cases where beneficiaries are unable to pay applicable cost-sharing.

We recommend that the final rule for Sec. 423.124(b) limit out-of-network cost-sharing to no more than the difference between the maximum price charged to any in-network Part D plan that in which the pharmacy participates and the in-network price. While we recommend that this limitation apply in all circumstances, at a minimum, it must be applied through the final rule, to the scenarios described in the preamble to the proposed rule:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;

- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;

- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her plan's pharmacy network; and

- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail order pharmacies.

The final regulations for Sec. 423.124(b) must include a provision to count the cost differential for receiving a covered Part D drug at an out-of-network pharmacy at the usual and customary price (vs. a network pharmacy) as an incurred cost. We

recommend that the final rule ensure that all beneficiary costs used for the purchase of covered Part D drugs count as incurred costs. Therefore, if the final rule permits Part D participants to be charged the cost differential for receiving a covered Part D drug at an out-of-network pharmacy versus at a network pharmacy, then the rule must require that this differential is counted as an incurred cost.

The final regulations for Sec. 423.124(b) should include proposed payment rules at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy. We recommend that out-of-network pharmacies that are outside of an individual Medicare beneficiary's local service area be required to charge beneficiaries no more than the maximum charged to any in-network plan that they participate in. Further, we recommend that pharmacies be permitted to charge out-of-network customers who are out of their local service area prices as low as the deepest discounted price for in-network participants in any Part D plan accepted by the pharmacy.

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.

CMS must proscribe a uniform format for plans to list available drugs. In our experience in Pennsylvania, consumers find it impossible to compare among the participating drug plan formularies, and prescribers cannot efficiently utilize the formularies because they are presented in widely disparate formats. Formularies and updates should be required to be posted on-line in real time.

Requiring all PDP sponsors and MA organizations to provide 24-hours-a-day/7-days-a-week access to their toll-free customer call centers is essential and must be included in the final regulations at Sec. 423.128(d). The management of the Part D prescription drug benefit is a serious issue that necessitates timely assistance and resolution of coverage issues. The implications of delayed access are potentially very serious. For this reason, notwithstanding concerns about the cost of making round-the-clock access available to their enrollees, this must be considered part of the cost of participating in the Part D program. This is a critical requirement that must be included in the final rule.

Required information in the explanation of benefits must be expanded in the final regulations for Sec. 423.128(e). We support the inclusion in the final rule of

provisions in the proposed rule regarding elements of the explanation of benefits. These elements, however, must be supplemented by:

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

- **Access to formulary information:** Plans should be required to provide information to all Part D eligible individuals, and not just plan enrollees, about the plan formulary. Moreover, while we are supportive of the provision in the proposed rule that requires plans to make available access to the plan's formulary. In isolation, however, this is insufficient. Beneficiaries need precise and detailed information about the formulary both to make an informed choice about enrollment and then to minimize their out-of-pocket costs once enrolled in a plan. Simply giving beneficiaries a description of how they can obtain information about the formulary is insufficient to further the goals of the statute. Plan descriptions should include a detailed formulary, in a uniform format proscribed by CMS, listing not only all the drugs but the tier and amount of co-payment upon which each drug is placed, especially if plans will be allowed to require beneficiaries to pay 100% of the cost of certain formulary drugs.

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

The provision at Sec. 423.128(e)(6) requiring that an explanation of benefits be provided at least monthly for individuals utilizing their prescription drug benefits in a given month must be retained. The explanation of benefits should include the drugs the plan paid for, the beneficiary cost sharing, whether the deductible has been met, and how much remains to b e met in out-of-pocket costs before stop-loss coverage begins. The notice should also tell people how to appeal or to request an exception.

The proposed regulations in Sec. 423.132 require that in general a person be told about the lowest cost generic available under a plan at the time they pick it up at a network pharmacy (or receive it in the mail). The Secretary is given discretion to waive that disclosure requirement, and the Preamble discusses (p. 46665) whether such information should be given to long term care residents, given the special ways in

which medicines are delivered in nursing homes. We believe that many nursing home residents, their families, or their representatives would like to know if savings are possible, and we urge that such information be made available.

The proposed regulations in Section 423.132 require that pharmacies inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that drug available at that pharmacy. For mail-order pharmacies, this notice would be provided at the time of delivery of the drug. We would recommend that this notice occur at the time of order (to the extent that this is possible) so that a consumer can modify their order before delivery occurs if they choose to do so.

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.

The requirement in Section 423.153 that plans include medication therapy management program (MTMP) raises many concerns. Requiring plans to engage in this managed care activity would seem to go well beyond the capabilities of a stand-alone drug plan PDPs would be unlikely to have the appropriate specialists and counselors in their "network" needed to fulfill this requirement. Additionally, this requirement interferes with consumers' freedom of choice of provider to manage their healthcare. Dual eligibles, for example, might end up with discrete care management from their Medicare doctor, their Medicaid managed care plan, and their PDPs. This introduces unnecessary confusion. Offering a MTMP should be optional for plans and taking advantage of such a service must be optional for consumers within the plans.

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.

The final regulations in Section 423.153 should require all plans to operate quality assurance programs and specify which elements quality assurance programs must include. In the preamble, CMS lists the elements that are "desirable" for quality assurance programs (electronic prescribing, clinical decision support systems, educational interventions, bar codes, adverse event reporting systems, and provider and patient education.) but then says "We do not expect PDPs and MA-PD plans to adopt all of these elements." This is insufficient. We recommend that the final rule require all plans to operate quality assurance programs with the elements described above as well as clinical decision support systems and educational interventions

The preamble notes that "In the future, we may require quality reporting that includes error rates." This is a key quality indicator that should shape consumer selection of plans. We urge that data on plan error rates, even if just a sampling in 2006, be made public in the first year of the program and all in future years.

We support the development and use of consumer satisfaction surveys to gather comparative data on the plans (Section 423.156). **Consumers must be included in the survey design process and we recommend that the surveys be sent, and the results analyzed by CMS, prior to CMS's annual (May) notification to plans whether or not their contracts will be renewed.** We urge that the first surveys be conducted starting in 2006 with the results available before the fall 2006 open season. The preamble and the proposed rule do not describe an effective date.

We support and commend CMS's efforts to expedite, in every way possible, the development and widespread use of e-prescribing (Section 423.159). The life-saving safety and quality improvements from such a system will be enormous.

We do not support the proposed deeming requirements in the proposed regulations and strongly recommend that the final rule delete the provisions in Section 423.165. **We believe that deeming compliance significantly diminishes the beneficiary protections in the MMA and serves only to protect certain organizations from having to comply with key provisions of the statute.**

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)). Subpart C touches on this with regard to formulary development and review by CMS, but the review standards and criteria should be clearly defined.

The eligibility requirements for an entity to bid to become a PDP sponsor or an MA-PD under Section 423.265 (a) should be tightened. There is nothing in paragraph (a) that precludes a prescription drug plan (PDP) from being owned by or affiliated with a drug manufacturer. The recent history of drug manufacturer and drug delivery firm cooperation shows that this type of relationship invariably leads to the products of the manufacturer being promoted, regardless of whether they are the best product, or the lowest cost. It will be nearly impossible for CMS to prevent such abuses of beneficiaries, and therefore we urge that the regulations prevent groups affiliated with manufacturers from providing the Part D benefit. As the Preamble states in the discussion of fallback plan negotiations, CMS "would also ensure that there is no conflict of interest leading to higher bids." Banning financial relationships between manufacturers and PDPs is the best way to prevent such a conflict.

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. We urge that the regulation drop the word 'substantially.' Any cherry picking is an abuse of beneficiaries, the Medicare program, and taxpayers in general.

We hope that the USP model becomes more detailed and offers more classes and subclasses. But assuming that the USP model does not become less granular (less detailed) and stays approximately as it is, then CMS should make it known that it will not approve any plan application which develops its own formulary that has fewer classes and categories than the USP model. Any plan which spends money and P&T effort to develop its own formulary that is likely to cover fewer essential, high technology medicines should be presumed to be trying to avoid HIV/AIDS, mental health, complex cancer, and other cases. The potential for abuse of the program by cherry-picking is so enormous that CMS needs to be much stronger in its advice in this subsection.

Subpart G—Payments to PDP Sponsors and MA Organizations

No comments to CMS.

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

No comments to CMS.

Subpart J—Coordination Under Part D With Other Prescription Drug Coverage

Sec 423.464 Coordination of Benefits with Other Providers of Prescription Drug Coverage.

We urge that AIDS Drug Assistance Programs (ADAPs) be recognized as State Pharmacy Assistance Programs and be allowed to wrap around the Medicare Part D drug benefit and that ADAP expenditures be counted as true out-of-pocket costs. We see nothing in the law that prohibits ADAPs as being designated as SPAPs and they certainly serve the same function and purpose as traditional SPAPs, for the low income HIV/AIDS population.

We are pleased to see specific provisions in Section 423.464 (e) dealing with Coordination with State Pharmaceutical Assistance Programs. We are hopeful that existing SPAPs and new SPAPs will be able to help beneficiaries 'fill in the donut,' and we appreciate CMS's efforts to coordinate this assistance.

In order to assure that beneficiaries are receiving seamless coverage and not facing undue out of pocket expenses, an exchange of data between the PDP and the SPAP is necessary. This should include (but not be limited to) an exchange of eligibility files, exchange of claims payment and information about the drugs on the PDPs formulary and any changes to it.

We strongly encourage CMS to develop a centralized data coordination system to track benefits and TrOOP for all consumers. While it seems logical that plans should track the information about who pays and what counts as an incurred expense in terms of calculating TrOOP, having a central repository of this information is critical to protecting consumers from overpayments because of inaccurate TrOOP tracking or problems in terms of sharing data between plans, especially when a consumer changes Part D plans mid-year. In addition, CMS seems to be leaning toward a voluntary system of reporting all payment information from any plan involved in the payment of a Part D drug, whereas reporting and tracking absolutely must be required of all PDPs and MA-PDs. This is vital to ensuring the accurate tracking of TrOOP (again to protect consumers from paying too much out of their pocket). In addition, this would assure consistency across the plans in determining what costs do or do not count toward TrOOP.

Consumers should receive quarterly notice detailing their out of pocket costs. Additionally, there should be a procedure in place for consumers who dispute the amount of out of pocket cost recorded to challenge and correct the amount. Given the importance of out of pocket costs for the beneficiaries, there should be very clear guidelines regarding how these costs are tracked.

Subpart K – Application Procedures and Contracts with PDP sponsors

Sec. 423.502 Application requirements.

PDP sponsor applicants should not be allowed to have their PDP sponsor application wholly exempt from FOIA disclosures. We recommend that PDP sponsors be permitted to petition to have distinct portions of their application exempt, but there is no reason to exempt the complete application. Additionally, CMS must set forth clear standards for when and why exemptions would be approved.

An annual audit should be added to the protections against fraud and beneficiary protections of Section 423.504(d). While we strongly support the strong new anti-fraud provisions in this section, we also hope that CMS will make it clear that this program **will**—not "may"—be subject to extensive annual audit. The history of providers in this sector (for example, the $1.1 million settlement of Omnicare of Maine with the State of Maine announced August 25 as a penalty for switching patients from lower cost forms of a generic to a more expensive form), coupled with the billions of dollars at stake, make this a very high risk program.

We are concerned about Section 423.507, which would require a PDP that is not renewing its contract to inform consumers of other PDP and MA-PD options and benefits in the same region. It is unclear how this obligation will materialize in terms of how a departing PDP will know the information about other plans in the PDP region, especially if other plans are changing or pulling out at the same time.

The proposed regulations in Section 423.507(b) require CMS to decide each year after only four months whether to renew a PDP's contract and this is too little time. It is unclear how CMS could gather adequate information on a plan's performance in time to render a decision not to renew by May 1. The date should be pushed to at least July 1.

Provisions for the timely transfer of files and data should be incorporated into 423.507(a)(2) and (a)(3). In light of the MedPAC's June, 2004 report to Congress on the importance of long-lead times in transferring files, we believe the timeframes in this section are too short and should be lengthened if at all possible. We also note that MedPAC reported cases where one provider refused to cooperate with another provider in file and data transfer. As a condition of participation in the program or recovery of surety bonds, PDPs and MA-PDs should be required to cooperate in a timely manner in all file and data transfers, including in cases where the PDP is leaving the market.

Subpart L— Effect of Change of Ownership or Leasing of Facilities

The final regulations for Section 423.552 must require notices to a PDPs enrollees if there is a change of ownership and these notices must include details about what impact, if any, the change will have on their access to care.

The proposed regulation at Section 423.552 on novations fails to explain what happens to beneficiaries if there is no novation by the new owner of the Medicare contract of the prior owner. If there is no novation, then the Medicare contract becomes invalid and the new owner would have to apply separately to be PDP. The regulation should provide a Special Enrollment Period for beneficiaries and a right to continuity of care.

Subpart M - Grievance, Coverage, Reconsiderations, and Appeals

We are deeply concerned that the proposed regulations fail to meet the requirements of the Due Process Clause of the Fifth Amendment to the United States Constitution and to satisfy the requirements of the statute.

As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid recipients whose prescription requests are 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. As will be discussed in more detail below, CMS has failed to comply with the language of those provisions. In addition, CMS, in implementing Section 1852(c) and in

settlement of *Grijalva v. Shalala*, adopted 42 C.F.R. 422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D.

- 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 redeterminations 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.
- There are no requirements that any of the notices/decisions be provided in other languages or formats if the enrollee has LEP or is visually impaired.

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 require plans to provide information about appeals, grievances, etc. to enrollees in alternative formats. The proposed regulations at 423.562 only require drug plans to provide "written information" to all enrollees about appeals, grievances, etc. This requirement should be expanded to include alternate formats, for example, for the visually impaired.

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 redetermination) 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.

The final regulations must allow appeals for determinations about prescription drugs if the enrollee has no further liability to pay for them and about coverage of drugs obtained from a non-network pharmacy. The proposed regulations omit an appeals process for these two important scenarios and this must be added into the final regulations.

Consumers must either be allowed to select whether they want their complaint to be treated as a grievance or appeal, or to dispute the plan's determination. The proposed regulations state that when a drug plan gets a complaint, it is responsible for first deciding whether to send the complaint through the grievance or the appeal process, and then telling the enrollee. There must be a process to allow a beneficiary to select which process they are choosing and/or to dispute the plan's decision on this matter.

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 include 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.

All complaints about "quality of services" received by the plan should be forwarded to the Quality Improvement Organization (QIO). Under the proposed regulations, complaint about quality of services can be made to the drug plan or to the QIO or both. Ideally, while either should be able to receive complaints about quality of services, all such complaints received by the plan should be forwarded to the QIO. As

written, the regulations would allow for two different review processes with no clarity as to how these two systems would work together, whose decision prevails, etc.

Consumers must be able to obtain an expedited coverage determination even where 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 redetermination, or about the drug plan's refusal to give an expedited coverage determination or redetermination, 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 final regulations must include better record-keeping requirements for grievance documentation. The proposed regulations have very minimal record-keeping requirements for plans for grievances. There must be additional requirements imposed including that plans track the entity (or the division within the plan) which is the subject of the complaint, how the enrollee was notified and by whom, what information was included in rendering the decision, etc.

Section 423.562 (c)(2) may preclude an enrollee from challenging a plan's determination that it has no obligation to cover a drug received from a non-network pharmacy and should be deleted. As stated elsewhere in these comments, the actual regulatory language in 423.124 does not establish clear criteria as to when a plan must cover drugs received from non-network pharmacies. Thus, there is no guarantee that plans will interpret the regulation as CMS describes in the preamble. Taken together, proposed 423.124 and 423.562(c)(2) place at risk vulnerable individuals such as those in institutions whose purchases from long-term care pharmacies are all treated as if they are from a non-network pharmacy.

Section 423.566(b) needs to clarify further what constitutes a coverage determination. The proposed definition does not include in the list of coverage determinations from which an appeal can be taken a determination by the PDP that a drug is not a covered drug under Part D. An enrollee should be entitled to appeal to determine whether, in fact a drug the plan claims is not covered under Part D, is covered.

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.

Finally, the regulation should state that the presentation of a prescription to the pharmacy constitutes a coverage determination. If the pharmacy does not dispense the prescription, then the request for coverage should be deemed denied, and the enrollee should be entitled to notice and to request a redetermination. Without such clarification, enrollees will not be informed of their rights, and the appeals process will become meaningless. We refer CMS to the website of the Florida Agency for Health Care Administration, http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/multi_source.shtml, for an example of information Florida pharmacies must provide when they deny a prescription under the Florida Medicaid program.

Plans must not be allowed to delay making timely coverage determinations where the delay might or could affect health. The language in 423.566 of the proposed regulations states that PDP sponsors "must have a procedure for making timely coverage determinations", but offer too narrow a standard for reviewing delays ('that it would affect one's health'). The standard should instead be where it might or could affect health.

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.

Section 423.568(b) should be eliminated. There should be no distinction in time frames when an enrollee requests payment.

The final regulations must account for the reality that pharmacies will more regularly be the ones informing the enrollees that the plans will not cover a prescribed drug. The regulations should require the plan sponsor to develop a notice explaining the right to seek a redetermination, and the right to ask for expedited review. The pharmacy should be required to give the notice to the enrollee. Section 423.568(c) of the proposed regulations places the responsibility for providing notice of a coverage determination on the plan sponsor. This presumes a situation in which the person presents a prescription, the pharmacy contacts the plan, and then the plan takes

14 days to decide whether or not to cover a drug. In reality, the pharmacy in most situations tells the enrollee that the plan will not cover the drug. Without notice provided by the pharmacy, most enrollees will not know to tell the pharmacy to submit the prescription anyway so they can get a notice from which to appeal. They also may not know or understand their right to seek expedited consideration of the initial coverage determination, or an exception if the drug is not on the formulary or on too high a tier. If the enrollee pays out of pocket and then seeks reimbursement from the plan, she will not be eligible for expedited consideration. Any potential burden of requiring pharmacies to give out notices is minimized by the requirement that there be electronic communications between the pharmacies and the plans in order to keep up-to-date with formularies, coinsurance, and calculations of an enrollee's out-of-pocket expenses.

The final regulations must be more specific about content of the notices both for 423.568 and for 423.572. The proposed regulations talk about using "approved notice language in a readable and understandable form." They need to be more specific, and must include information about how to use the exceptions process. A recently settled Florida class action lawsuit filed on behalf of Medicaid recipients determined that the state had not provided written notification to people whose prescription coverage was denied of their right to appeal the decision. The settlement's provisions require the state to provide:

- Written notification that explains why the coverage request was denied
- Information on how to resolve the issues that triggered the rejection
- Instructions that explain how consumers can request an appeal
- Steps consumers can take to receive medication coverage pending the outcome of an appeal. *Hernandez et al. v. Medows*, U.S. District Court for the Southern District of Florida (May 2003).

We suggest the following:

- Notice about exceptions and appeal rights should be presented immediately upon denial (including upon determination that a drug is not covered on formulary, and including by the pharmacist) and should explain why coverage was denied, options for obtaining necessary medications, and appeal procedures
- Notice should include the clinical or scientific basis for denial
- Notice should be in the language or format required by the enrollee

Plans must be required to make all notices available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking.

The notice should not include a description of the rest of the appeals process beyond the next step. Having info about the entire process given will make the notices too cumbersome, confusing and more intimidating to the consumer.

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 with mental illness and other vulnerable individuals 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. These days medications are vital to sustaining behavioral and physical 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.

We support the proposed regulation at 423.570 allowing an enrollee to request an expedited review for any coverage determination, unless it is about payment of a drug already received. However, we recommend several revisions to the regulations as written. This regulation should be expanded to allow an <u>authorized representative</u> as well as the enrollee and the prescribing physician to request an expedited process.

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, 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 only allow extension of the 72 hour timeframe in 423.572 by a showing that the extension is in the best interest of the enrollee. As written, an extension is allowed on a showing that extension is in the interests of enrollee. The regulations should be modified to read **best interest of the** enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. The regulations should also require the plan to inform the enrollee of the extension immediately orally and in writing, not by the expiration of the extension.

There should be no extended time period for requests for payment of drugs already received. This imposes extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to spend money they need for other necessities for their medications because of the uncertainty and length of the appeals process.

The final regulations must articulate a timeframe for sending a decision where an oral notification is not first provided. Section 423.572(c) gives a timeframe for notifying the consumer of an expedited decision when an oral notice is first provided-that is, the decision must be mailed within 3 days of the oral notification. However, if no oral notification is given, there appears to be no timeframe for the decision to be sent. Again, as time is of the essence in these matters, we recommend that if the plan does not provide oral notification of the decision, the decision must be mailed out the same day it is made.

The regulations should require plans to notify the prescribing physician as well the enrollee, in writing, of an expedited determination.

The notice of decision for expedited coverage determinations should contain all of the following: the name of the prescribing physician;the name of the prescribed drug; the date the request was received; <u>all</u> the specific reasons for denial; if the denial was based on insufficient information, identification of the medical or other information needed to render a decision.

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. Again, as before, we maintain a plan should not benefit from its failure to decide and notify an enrollee in a timely manner.

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. The statutory language is not permissive; it does not say that plans may establish additional criteria if they wish. It says that the Secretary is to establish criteria and the plans are to abide by them. Plans should have no discretion whatsoever. The fact that they may establish differing tiered structures is not relevant to the statutory right to request an exception to whatever structure they devise. In fact, the flexibility accorded to plans is why beneficiaries need strong guidelines to protect their interests. **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 must not include as permissible criteria for an exceptions process, any items that are beyond the scope of the statute. Where the proposed regulations include guidance for criteria, the criteria listed exceed the scope of the statute. The regulations propose a "limited number of elements that must be included in any sponsor's exception criteria," but the proposed list includes criteria that contradict the statutory provision for an exception if the physician determines that the preferred drug would not be as effective or would have adverse effects or both, for example:

- Consideration of the cost of the requested drug compared to the cost of the preferred drug has no bearing on whether a drug would not be as effective or would have adverse effects and should not be a consideration.
- Consideration of whether the formulary includes a drug that is the therapeutic equivalent also is not relevant to the statutory standard. The FDA requires that 80 percent to 125 percent of the medication be the same to be considered "therapeutically equivalent." Treatment for certain conditions, including mental illness, is highly individualized given the non-interchangeability of many medications even within the same class, the high degree of variability in how these diseases present themselves in terms of symptoms, and the many other factors that must be taken into account, including overdose lethality in light of heightened risk of suicide. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the deciding factor.
- Consideration of the number of drugs in the plan's formulary that are in the same class as the requested drug, for the reasons stated above, is not relevant to the determination of the treating physician that the requested drug is needed.

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 proposed regulatory standard exceeds the Secretary's authority in contradiction of the statute. A fail first standard could only apply if the statute required the doctor to certify that the drug is not as effective or has caused adverse effects.

The final regulations must state that a plan "may only require the written certification to include the following". The proposed regulations say that the plan sponsor "may require the written certification to include only the following information…" Given that the statute requires a determination by the doctor that the preferred drug would not be as effective, would cause adverse consequences, or both,

plans are going to require some kind of written statement. However, the regulation should limit the statement only to the statutory standard.

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. The only provision for extending coverage now in the regulations is on a one-time basis and occurs only when a drug is being removed from a formulary and the plan fails to provide a timely notice of decision to the enrollee. In that case, the plan must approve the medication for up to a month or until the decision is issued. That allows the plan to give less than a full month's coverage, to the significant inconvenience of enrollees, many of whom may live in rural area, or be elderly or persons with disabilities for whom extra trips to the pharmacy are a burden and an expense

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. However, we are concerned that the "exception" to this protection, which allows the plan to discontinue a drug if safety considerations arise, is too broad. The final regulation should be revised to permit reversal of a previously granted exception only if the FDA determines that the drug is no longer safe for treating the enrollee's disease or medical condition.

The lowest coinsurance amount should apply when an enrollee wins an exception through this process because the drug at issue has been determined medically necessary with no on-formulary drug as a suitable alternative. We agree with the regulation that prohibits a plan from establishing a formulary tier or copay or cost-sharing structure just for drugs approved thru exception process. The exception for the non-formulary drug thus meets the criteria for an exception to the tiered cost-sharing structure as well.

IRE should be able to review the validity of a plan's exceptions criteria and formulary. Under the proposed regulations, if an enrollee seeks an IRE review (assuming a redetermination upholds denying the exception request), the review is <u>only</u> about whether the plan properly applied its own exceptions criteria and <u>not</u> about the validity of the plan's exceptions criteria or formulary. IRE should be able to review the validity. Without some independent review, there is no way to monitor and assure that the formulary and exception criteria are reasonable or are not hurting individual enrollees. Even if the review can occur at the ALJ stage the enrollee can only go to that stage if the amount in controversy exceeds $100. If a lower amount, no review would ever happen.

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 redetermination, standard or expedited, and to request any necessary extensions. Currently, sections 423.580, 423.582 and 423.584 allow only the enrollee to seek redetermination of any coverage determination or an extension in asking for a redetermination, and permit only the enrollee or the prescribing physician to seek an expedited redetermination. Many enrollees need assistance to obtain their benefits and are not able to request redetermination on their own. There is no rational for limiting the prescriber's ability to assist the enrollee in this fashion. As a matter of practice in Pennsylvania, it is very difficult to get the prescribing physician to become involved in appeals, even in the most compelling cases, because of the time and cost involved. However, when the prescriber is willing to become involved, he should not be prevented from doing so by the Secretary.

The phrase "good cause" should be clearly defined in the regulations and should be very broad. Section 423.582 provides that an enrollee generally has 60 days from a determination to request a redetermination, unless the plan extends the timeframe for "good cause." The plans should be required to look at good cause in the light most favorable to the enrollee, given the remedial purpose of the statute, and the population which Part D serves.

All redetermination requests, and particularly those involving exceptions, should be treated as expedited. The proposed regulations indicate that if a prescribing physician says applying the standard timeframe for redetermination may seriously jeopardize the enrollee's life or health or ability to regain maximum function, the plan must expedite the redetermination. This standard is too stringent. **Either all redetermination requests should be expedited or the standard for expediting redeterminations should be changed require expedited redetermination when the physician determines that the standard schedule may jeopardize the enrollee's ability to maintain maximum function. This is the appropriate standard that has worked well for years in Pennsylvania's mandatory Medicaid managed care system.**

The plans should be required to provide a notice in writing in acknowledgement of the request for the redetermination. This notice should inform the enrollee or the party making the request for redetermination on behalf of the enrollee of the right to submit evidence orally, if the request for redetermination is made orally. In Section 423.586, the proposed regulations state that the plan must provide a reasonable opportunity in the redetermination for the enrollee to present evidence and allegations of fact or law, in person as well as in writing, even in the expedited process. However, no further guidance is provided on this issue. It is crucial that the final regulations include clear criteria for informing the enrollee and her/her physician of their right to submit evidence in person or in writing.

There is also a lack of detail about the notice responsibilities during the redetermination process that must be addressed. The final regulations should be very clear about what notices must contain during the redetermination 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 redetermination and any denial of a request for expediting redetermination. 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 redetermination 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 redetermination, with a representative. The plans should be required to accommodate enrollees in the scheduling and conducting of the redetermination. 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 redetermination.

There are several problems with the required timeframes in section 423.590 of the proposed regulations that need to be addressed. As currently written, the proposed regulations state that if a plan fails to provide a redetermination decision within the required timeframe, it will be considered an upholding of an adverse determination, appealable to the IRE. This is problematic for several reasons. If plans are allowed to issue de facto denials by failing to make a decision, the plans will have no incentive to make redetermination decisions at all but rather have an incentive to sit on a request until the time period for making a redetermination is up. Furthermore, a deemed denial fails to provide any meaningful decision for the enrollee to appeal. The plan is not required to provide a reason for its denial and the enrollee has nothing to refute if

s/he wants to appeal the decision further. **This regulation should be changed so that when a plan fails to make a decision in the required time period, it will be deemed approved.**

Currently, the proposed regulations allow plans to extend the time in which they will make a redetermination decision even in expedited redeterminations. **Plans must only be permitted to extend the timeframe for a redetermination if requested to do so by the enrollee, or if the plan can demonstrate that the extension is in the best interests of the enrollee, for example, when the plan needs to obtain additional information to support the enrollee's request.** This is particularly important in expedited redeterminations, which by definition involve jeopardy to the enrollee's health. **In expedited redeterminations, the plans should not be allowed an extension at all.** Furthermore, while the plan must notify an enrollee if it is extending the timeframe for making a decision, the regulations fail to specify when such notification must be sent. **The plan must be required to send the notice within the original 14-day period.**

There is also an inconsistency in the time period for deciding redeterminations of coverage issues versus redeterminations of payment requests, whereby redeterminations on drug coverage issues must be made within 30 days of the request but redeterminations of payment requests must be made within 60 days. **There is no explanation for this difference, and it should be 30 days in both cases.**

If a plan requests medical information in an expedited redetermination, 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 redetermination 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 redetermination 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.**

Sec. 423.600(a) contains an incorrect reference to 423.582(a). (a) states an enrollee must file a written request for reconsideration at "one of the places listed in sec. 423.582(a)". However, that section contains no list of places

The list of who can file reconsideration requests must be expanded. The proposed regulation allows only enrollees to file requests for reconsideration by an IRE.

Many enrollees will need help with pursuing an appeal or may not be able to act on their own behalf. They cannot be denied their due process rights. **The regulations should be expanded to allow physicians and authorized representatives file requests for IRE reconsideration.**

The enrollee should be allowed to request reconsideration orally, especially in the case of an expedited review.

There should be an automatic referral to the IRE when a coverage redetermation is adverse to an enrollee. The proposed regulations do not cause an automatic reconsideration to occur when a redetermination is adverse to an enrollee (as happens with MA organizations under Part C), and requires enrollees to specifically request redetermination. In the background information for this section the drafters note that the reason for this requirement is that many cases would only involve small amounts in controversy. However, that reason supports the need for an automatic review as cases involving a small amount in controversy cannot go on to the ALJ stage. As a result, an IRE review is the only level of independent review available to these enrollees. The Part C requirement should be copied in Part D, and recondsiderations should trigger automatically when there is an adverse redetermination.

CMS needs to clarify in the final regulations that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. At page 46721 the preamble states that "…The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question…the IRE would not have any discretion with respect to the validity of the plan's exception criteria or formulary". If the IRE does not review all of the evidence and issue a reconsideration decision based on its own analysis, then enrollees will be denied an independent review. In addition, the requirements of due process will not have been met. Because CMS is required by the statute to set standards for the exceptions process, the IRE must have the authority to determine whether the PDP's exceptions criteria comply with the statute. Otherwise, enrollees will have no mechanism for review of arbitrary and improper standards.

The regulations should specify how the views of the prescribing physician will be solicited. The proposed regulations state that the IRE must solicit the views of the prescribing physician, but does not give guidance on how this will happen. More clear direction on this issue should be included in the regulations to provide how the solicitation can occur- by phone? By email? In writing? In person? If the solicitation is in writing, the enrollee should be copied on the letter so they can follow up with their physician and assure that they respond to the solicitation.

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.

The final regulations should set out specific parameters for how the reconsideration will occur. The enrollee should be permitted to submit additional evidence as well as the prescribing physician. The plan should be required to submit to the IRE all the information or evidence it had before it at the redetermination and provide the enrollee with a list of all the information/documents sent. The IRE's decision should also include a description of all additional evidence or information that was solicited from the prescribing physician as well as the enrollee.

The list of who gets a copy of the IRE's decision in 423.602 should be expanded. The proposed regulations require the IRE to mail notice of its reconsideration decision only to the enrollee. The regulations should also provide for sending notice to the prescribing physician in every case, and to the authorized representative if one exists.

The regulations must clarify how the enrollee is told of their right to appeal a reconsideration as well as how, and by whom, an enrollee is told of the amount in controversy in their appeal. The proposed regulations indicate that a notice of an adverse decision must inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement. How the notice conveys this appeal right is important. The final regulation should state that the notice must inform the enrollee of his or her right to an ALJ hearing, and the procedure for requesting such a hearing, including the dollar amount required to request a hearing. In addition, it is not clear how or by whom the enrollee will be informed what the actual amount in controversy is. The regulations must provide that the IRE is to determine the amount in controversy and clearly include it in their decision.

The standard in Section 423.610 must be clarified for when enrollees can join together and combine their appeals to meet the amount in controversy threshold. The proposed regulations state that an enrollee can combine appeals to meet the threshold amount as long as they were all reconsidered by IRE, the request lists all the appeals and is filed within 60 days of when all the reconsideration decisions were received, and the ALJ decides the appeals are all for the same enrollee. The final regulations should clarify that an enrollee should be able to add up the cost of the medicine for a year, if the medicine treats an ongoing, chronic condition, or for the number of refills authorized if the underlying condition is not chronic, when the plan denies coverage, in order to satisfy the jurisdictional amount. The regulations should also clarify whether the 60-day filing requirement means that none of the reconsideration decisions can be more than 60 days old.

The standard must be clarified for when enrollees can join together and combine their appeals to meet the amount in controversy threshold. The proposed regulations state that two or more enrollees can combine their appeals to meet the threshold if they all went through reconsideration, if the ALJ request is within 60 days after all reconsideration decisions were received, and if the appeals are all about the same drug. The regulations should clarify whether the 60-day filing requirement means that none of the reconsideration decisions can be more than 60 days old.

In 423.612(a) there are two references that seem to be incorrect. They refer to "one of the places specified in 423.582(a)" and "the organizations specified in 423.582(a). There is no list of places or organizations in that section.

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 within 24 hours of receipt of the request and the IRE should transmit the file to the ALJ within 24 hours. Without set timeframes, these entities could take long periods of time just to transmit information and thus add to the delay in processing and resolving ALJ appeals.

The IRE must send to the ALJ all of the information it has in its file. The regulations need to require the IRE to send all of the information in the file including doctor's statements, enrollee statements and information submitted by the enrollee, and any other information even if it was not relied on in making the IRE's decision. Consumers must be assured that evidence is not omitted when the file is transferred to the ALJ or another appeal entity.

The regulations must specify how the amount in controversy is clarified in an appeal. The proposed regulations indicate that if, on its face, a request for an ALJ hearing shows that the threshold is not met, the request will be dismissed. The regulations should clarify how such a showing would be made. We recommend that the amount in controversy be clarified in the IRE's determination and clearly included in the IRE decision.

The timeline in 423.634 for effectuating all coverage redeterminations should be the same. According to the proposed regulations, if a redetermination completely reverses an initial coverage determination regarding benefits, it must be effectuated within 30 days. However, if a redetermination completely reverses an initial coverage determination of a payment request, it must be effectuated in 60 days. There is no need for the difference in timeframes or any additional delay. All redeterminations should be effectuated within 30 days

All IRE decisions should be effectuated within 72 hours. The proposed regulations state that if the IRE reverses a plan's coverage determination for benefits, the plan must authorize the benefit requested within 72 hours of receiving notice of decision, or provide the benefit within 14 days of the decision. No reason is provided for allowing the alternative 14 day timeframe. It should be eliminated and the plans required to authorize benefits in 72 hours in all cases.

All other coverage decisions should be effectuated within 30 days. The proposed regulations state that plans must effectuate an ALJ, Appeals Council, or higher decision within 60 days of being notified of the decision. This timeframe is unnecessarily long and should be shortened to 30 days.

All other coverage decisions should be effectuated within 30 days. The proposed regulations at 423.638 with respect to expedited redeterminations or reconsidered determinations state that plans must effectuate ALJ, Appeals Council and higher decisions within 60 days of being notified of decision. This timeframe is unnecessarily long and should be shortened to 30 days.

Subpart N - Medicare Contract Determinations and Appeals

No Comments to CMS on this SubPart.

Subpart O - Intermediate Sanctions

Global Concerns

The proposed rules establish four types of sanctions – civil money penalties and enrollment, payment, and marketing sanctions. They also identify six bases for imposing sanctions. However, the rules do not describe any process or methodology for CMS to use in deciding which sanction (or sanctions) to impose in any particular set of circumstances. In addition, the fact that all sanctions are permissive increases the likelihood that none will actually be imposed. CMS needs to develop a process and methodology to use in determining when to impose sanctions.

While sanctions can be imposed only when noncompliance is determined, it is not clear from the rules how CMS will determine that PDPs are not complying with the requirements of the laws. The proposed rules describe Quality Improvement Organization activities, but QIOs are not regulatory bodies and their work is confidential. The proposed rules describe deemed status for accrediting organizations, but deemed status is granted when the standards and survey process are found to be equivalent to CMS' standards and process. What is the CMS process? The proposed rules describe the contracting process, which includes, among other things, a compliance plan, an obligation to self-report quality problems, and maintenance of

records that are subject to audit and review by CMS or its designee. A contract-based system is passive and relies on PDP's disclosure. Finally, the proposed rules say that CMS retains authority to enforce standards against a PDP that does not meet standards as determined by "its own survey" or an accreditation survey. Where is the further description of what this survey would be?

Plans should be sanctioned for the failure to provide medically necessary services, regardless of the actual or possible adverse effect on an enrollee. The proposed regulations at Section 432.752(a)(1) state that a basis for imposing sanction is failure to provide medically necessary services, with adverse effect on the enrollee or substantial likelihood of adverse effect on enrollee. Requiring that there be an "adverse effect" on the enrollee before a sanction can be imposed is untenable. To condition this requirement in any way with an 'effects' test only encourages plans to cut corners.

The final regulations in Section 432.752 must be clearer about how the suspension of enrollment would impact the statutorily mandated requirement that a consumer has a choice of at least 2 plans. While CMS needs to have tools to enforce contractual obligations, consideration must be given to balancing how enforcement tools would impact consumers' rights.

The regulations at 423.752(a) do not implement the preamble's explicit statement that one or more sanctions may be imposed at any one time. Accordingly, we suggest amending this section as follows:

(a) All intermediate sanctions. For the violations listed below, CMS may impose ~~any~~ <u>one or more</u> of the sanctions specified in §423.750 on any PDP sponsor that has a contract in effect.

Sec. 423.756 Procedures for imposing sanctions.

The final regulations must provide for a reconsideration process that allows a plan to partially affirm or rescind decisions. The proposed regulations would only allow for an outright affirmation or rescission. This process should be expanded to include an option to affirm decisions in part. In addition, the regulations must be expanded to include time frames for the issuance of the reconsideration decision

The final regulations must include notification of enrollees, the public, and network pharmacies of the imposition or termination of sanctions. Notice will be a vital factor for the public (enrollees) and pharmacies to make educated decisions about plan choice, for pharmacies seeking to serve/counsel their customers and it will also give plans an additional incentive to conform to the regulations.

The availability of civil money penalties under Section 423.756(e) should be expanded. The proposed rules say that the enrollment, payment, and marketing sanctions may be used in addition to non-renewal or termination. They also suggest that civil money penalties are available in situations where the PDP terminations its contract without following the appropriate process.

We suggest that CMS amend §423.756(e) to provide for the availability of civil money penalties in all instances when it declines to renew or terminates a contract. We suggest the language be changed to read as follows:

> "In addition to or as an alternative to the sanctions described in paragraph (c) or this section and civil money penalties authorized by sections 423.750(a) and 423.758, CMS may decline to authorize, etc" (new language in italics)

The definition of when a civil money penalty for a deficiency may be imposed under Section 423.758 is too narrow and limiting. First, it fails to reflect the various types of noncompliance that are the bases for imposing sanctions, § 423.952(a)(1)-(6). Second, it requires that harm occur, or be very likely to occur, to PDP enrollees before CMS can impose a financial penalty. Third, it fails to recognize that a benefit of civil money penalties as sanctions is their ability to be varied in amount to reflect the extent and seriousness of the noncompliance. Although the rules establish $25,000 as the outer limit of a civil money penalty, such penalties can be lower. CMS should establish a range of civil money penalties, and vary the amount of penalties in each category to reflect the nature and extent of the PDP's noncompliance with requirements.

SupPart P – Low Income Subsidies

Family size should be defined in 423.772 to automatically include children under the age of 21 as part of the applicant group. In addition, pregnant women should be counted twice. The proposed regulations define family size to include (1) applicant, (2) a spouse who lives in residence, and (3) related individuals in the same residence who depend on the applicant or his/her spouse for at least ½ of their financial support. There should be an assumption of eligibility for children under the age of 21, so as not to create a useless administrative burden to prove a child's financial support. There should also be a provision to count pregnant women as two, to more adequately reflect the family size.

The definition of full subsidy eligible individual should refer to the language of Section 423.773(b) *and* (c), in order to avoid ambiguity.

The definition of institutionalized individual in Section 423.772 should include those individuals eligible for home and community based services under a Medicaid waiver (see, e.g., definition of "institutionalized spouse" at 42 U.S.C. §

1396r-5(h)(1)(A)), since those individuals must meet the acuity standards for Medicaid coverage in a nursing facility, and should include individuals in ICFs-MR and individuals in any institution in which they are entitled to a personal needs allowance. The definition should not include the language "for whom payment is made by Medicaid throughout the month" since an individual could conceivably be a full benefit dual eligible recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month. Even though in that month all their drugs are likely to be paid for by Medicare Part A, as a practical matter, for continuity and minimum disruption, they should not lose their status as an "institutionalized individual." The same reasoning should apply to a full benefit dual eligible individual who might be hospitalized during an entire month, during which their entire stay would also be paid for by Medicare Part A.

In addition to their definition of resources, the regulations should include specific examples of items that will and will not be counted as resources based on the "20 day" rule. The proposed regulations define resources as 'anything that can be converted into cash within 20 days' (excluding §1613 items, and real estate that is not a primary residence or related land). While this is an excellent proposed standard, the regulation is likely to cause significant confusion without clear guiding criteria or illustrative examples. For instance, is the cash value of an insurance policy a resource, and does the answer depend on how responsive the insurer is?

Increases in the resource limit after 2006 in 423.773 should never be rounded down. The proposed regulations provide for an annual adjustment of the resource limits for eligibility for subsidies. The increase is based on the 2006 resource limit adjusted for Consumer Price Index percentage change, as of September of the previous year, *rounded to the nearest $10*. This should be changed to adjust the resource limit *up to the nearest $10*, as it is illogical to round a resource limit *below* what has been determined to be a minimum level of need.

The final regulation for Section 423.773(a), Subsidy eligible individual, needs to be modified. Although the statute defines a subsidy eligible individual as one enrolled in a Part D plan, the requirement in Subpart S that states take applications for the low-income subsidy beginning July 1, 2005, before Part D plans are available to be enrolled in makes it clear that CMS believes people should be able to apply for the low-income subsidy without being enrolled in a Part D plan. This is actually imperative, as otherwise, an individual would be forced to pay a plan premium that the subsidy, in fact, pays for them. The subsidy eligibility determination would be done "conditionally" – conditioned upon the individual enrolling in a Part D plan. The regulations should reflect this reality and clearly direct both SSA and state Medicaid programs determining eligibility that the individual can both apply *and be determined* subsidy eligible before she or he has enrolled in a plan

Section 423.773(c) should be edited to replace the term "full benefit dual eligibles" with "full subsidy eligbles", where appropriate. The proposed regulations appear to have an error in part (c). In (c)(1) the regulations indicate that *Full benefit dual eligibles* will be treated as full subsidy eligibles. In (c)(3) the regulations say the same will apply for *Medicare buy-in populations*, but then go on to state that state agencies must notify *full benefit dual eligibles* that they are eligible for full subsidy on Part D premiums and deductibles, and that they must enroll in a PDP/MA-PD plan or they will be randomly auto-enrolled. The term "full benefit dual eligibles" in (c)(3) should be changed to "full subsidy eligibles".

The final regulations for Section 423.773(c), Individuals treated as full subsidy eligible, should conform to Subpart S Section 423.904(c)(3) that requires states to notify all deemed subsidy eligible individuals of their subsidy eligibility. It should specify that the notice must be given by July 1, 2005 for those individuals eligible at that time. For those who subsequently become eligible, notice should be given at the same time the individual is notified of their eligibility for the benefit that qualifies them to be treated as a full subsidy individual. The notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. For those who will lose Medicaid coverage January 1, 2006, the notice should explain their appeal rights as well. Individuals should also be told of their right to appeal the level of subsidy to which they are entitled.

States should be required to notify "other subsidy eligibles" of their eligibility for subsidies. The proposed regulations require states to notify full subsidy eligibles of their eligibility for subsidies, but have no similar requirement that state agencies notify other low-income subsidy eligibles of their eligibility for subsidy, and language to this effect should be added.

The final regulations for Section 423.773(c) need to include a clear meaning of automatic eligibility. Section 423.773 states that both full benefit dual eligibles and MSP beneficiaries are <u>eligible</u> for the low income subsidy, but it does not explicitly state that these beneficiaries are automatically <u>enrolled</u> in the subsidy program. The regulations should be absolutely clear that an individual treated as full subsidy does not have to take any further action with respect to the subsidy (i.e., make application or in any other way verify their status), but only to the extent they need to enroll in a Part D plan. This will help smooth the transition from Medicaid drug coverage for dual eligibles, and should improve participation for others.

Section 423.773(c)(3) must be expanded to include requirements for notification for automatically eligible beneficiaries. Proposed Section 423.773(c)(3) states that a state Medicaid agency must notify full benefit duals that they are eligible for the low-income subsidy and should enroll in a Part D plan. The regulations do not

state, however, when this notice should be issued, or what the notice should say. Consistent with our comments above and those accompanying 423.904(c)(3), the notification should be sent to beneficiaries on or near July 1, 2005, when states will have made the automatic eligibility determinations.

We also suggest that CMS should develop model notices based on input from beneficiaries, which would explain the purpose of new subsidy simply and clearly. As mentioned above, the notice should make clear to individuals what they need to do to use their subsidy, and should direct them to a source for information, counseling and assistance in choosing a Part D plan. It should also explain as simply as possible what level of subsidy the beneficiary will receive, and the beneficiary's appeal rights if she believes the subsidy level is in error.

The final regulations for Section 423.773(c) must be expanded and include eligibility for spenddown beneficiaries. The proposed rule does not address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period. These beneficiaries should be informed of their likely eligibility for a low-income Medicare subsidy and given an opportunity to enroll. When they have met their spenddown, they should be informed of their entitlement to a lower co-payment, if applicable, as a deemed subsidy eligible.

The final regulations must require that eligibility for low-income subsidies be presumed for a fully year after initial eligibility is determined. The comments to the proposed regulations state that individuals who become eligible by "spending-down" excess medical expenses will not be "eligible as medically needy until he or she satisfies their spenddown obligation." Neither the comments nor proposed regulations address the rules for the "spend-down" individuals with respect to low-income subsidies. Due to the monthly yet continuous nature of their eligibility, the regulations should require that once an individual is determined eligible for a low-income subsidy, their eligibility is presumed for a full year, so as to avoid the burden to the enrollee and the administrative cost of re-applying for subsidies every month.

The final regulations for Section 423.774(a), notification of new applicants, must be expanded to require a determination notice to be sent to applicant no later than 30 days after application is filed. Section 423.774(a) provides that determinations of eligibility for the subsidy are to be made by state Medicaid agencies or by SSA, depending on where an individual applies. We believe that in order to ensure prompt enrollment in both the subsidy and ultimately in a plan, the regulations should specify that a determination notice must be sent to the applicant no later than 30 days after the application is filed. Because determinations for the low-income subsidy should be a simple process, very little time should be required to render a decision. Both SSA and states should be required to notify CMS with 24 hours of a individual being determined eligible for the subsidy.

In order to avoid delays in beneficiaries' being able to use their subsidy benefits while their application is pending, the final rule for Section 423.774(b), should offer beneficiaries the option of applying through a presumptive eligibility system. Such a system would be especially helpful to beneficiaries who have enrolled in a Part D plan but are not yet receiving the low-income subsidy. Applicants can complete a short form in which they declare their family size, income and assets. If their income and assets are below the relevant eligibility levels, they are found presumptively eligible. Applicants may still be required to complete a full application within a prescribed period of time (typically 30 to 60 days) if additional information is required. In the meantime, however, beneficiaries are given temporary cards that they can present to health care providers and receive services immediately.

Applicants for the low-income subsidy could be found presumptively eligible at state Medicaid offices, SSA offices, pharmacies, or other providers. If the low-income subsidy application form is simple enough, applicants could complete the form itself and self-attest to their income and assets. If they appear to be eligible, they would be enrolled in the appropriate subsidy while their application is processed. They would receive some form of temporary certification stating that they have been presumptively enrolled, which their pharmacy would accept while their application is processed. Such a system would encourage beneficiaries to apply, as they would be able to see the benefits of the system immediately.

We believe there should be a provision at Section 423.774(c) for prompt reconsideration of a subsidy eligibility determination, for beneficiaries who believe they have either been erroneously denied eligibility or approved for the wrong subsidy category. The provisions in Section 423.774(c) applying the appeal rules of state Medicaid plans or SSA do not provide for a prompt reconsideration process. Because obtaining prescription drugs can be of vital interest for Medicare beneficiaries, and especially because low-income beneficiaries are unable to pay the costs of their prescription drugs out of their own pockets, a quick reconsideration process is essential.

The final regulations for Section 423.774(c) should establish that all determinations are for one year. The regulation refers to redeterminations and appeals under the state Medicaid plan. To maximize enrollment, the rule should establish that all determinations are for one year, per the Secretary's authority under the statute. We also urge CMS to adopt an annual, passive, and simple redetermination for all beneficiaries, whether they have enrolled through SSA or states. Should it be necessary, the Secretary should direct the Commissioner of SSA to create such a system. Under a passive redetermination system, beneficiaries would be sent a statement of the relevant information on file and asked to respond only if any of that information had changed over the year. If they do not respond, their coverage would continue unchanged for another year.

The final regulations for Section 423.774(d) should make clear to both states and SSA that no documents should be required of the individual as long as applicant authorizes the agency to verify information from financial and other institutions. Documentation production should be only the absolute last resort.

If CMS plans to design a universal application for subsidies, the regulations at 423.774 should set out standards for the application and establish a process for public comment on the application. The comments to the proposed regulations state that CMS will be designing one model application form that will be able to assess for all subsidies. This form is not mentioned in the regulations, and there is no provision for the public to view and/or comment on that form.

The regulations should clearly set limits as to how telephonic proxy designations can be made and acted upon, to protect vulnerable enrollees. In addition proxy certifications should only apply to the accuracy of the proxy's transcription, and <u>not</u> to the accuracy of the underlying information. The proposed regulations create a proxy signature process. This process raises two concerns. First, inconsistencies between the regulations and the comments to the regulations, leave us unclear as to when proxies will be allowed to take telephonic applications on behalf of clients. The regulations should be clear, in order to protect applicants from improper/inaccurate solicitations via telephone by private companies which attempt to gain their consent to apply for benefits, particularly in light of the fact that some choices (for example plan choice) for some consumers will be choices they are 'locked' into for the year. Second, the regulations require proxies to *certify the accuracy of the information* they are communicating to CMS or the state administrator. This standard must be changed to *certification of the accuracy of the proxy's <u>transcription</u>* of the information as provided by the applicant. Otherwise, there will be a great chilling effect on the number of legitimate proxies willing to assist enrollees.

Verification should be done on a random basis, or by clear and defined criteria which do not disparately impact against any class of individuals based on demographic factors such as race, income, disability, age, etc. The comments to the proposed regulations indicate that verification processes will be designed using 'profiling criteria' to do 'specific targeting' of individuals who are likely to be committing misrepresentation in their applications. This 'profiling' and 'targeting' should not be allowed, and the verification analysis should be random, or at the very least, the criteria upon which it is based should be made public for commentary about potential abuses.

The regulations at Section 423.780 must require plans and/or CMS to provide clear notice to consumers about set premium standards, such as "benchmark" premium levels, so consumers can evaluate plans with full understanding of their

premium options and liability. The regulations also must place clear responsibility upon plans – subject to punishment for noncompliance – to ensure that enrollees always receive the most favorable base-premium calculation, as per the proposed regulations. The proposed regulations allow full reimbursement for subsidy premiums for full subsidy eligibles, up to the greater of certain complex premium level calculations (for example, "benchmark premiums", which are based on a weighted average of basic premiums). This presents two problems for enrollees. First, they have no way of understanding what the set premium limit will be at any time. Notice about premium levels, such as the benchmark premium, should be provided to clients so that they can choose plans with a full understanding of how much of their premium will be subsidized. Second, even if clients do understand what the premium calculations are, it is not clear in the regulations how the requirement to apply the *greater* of the calculation options will be applied and enforced. The regulations need to place a clear responsibility on plans to ensure enrollees are informed and provided with the greater premium calculation option.

The regulations regarding full subsidy eligibles at Section 423.782 must place clear responsibility upon plans – subject to punishment for noncompliance – to ensure that non-institutionalized dual eligibles always receive the less costly cost-sharing option, as per the proposed regulations. The proposed regulations indicate that non-institutionalized dual eligibles who have exceeded the initial coverage limit will have cost-sharing that is the lesser of two specified amounts. However, the regulations provided no guidance as to how enrollees will be informed of their right to the lesser option, or how that right will be enforced. The regulations need to place a clear responsibility on plans to ensure enrollees are informed and provided with the less costly option.

Adjustments in required cost-sharing amounts after 2006 should never be rounded upward. The proposed regulations also indicate that some cost-sharing contributions by consumers will be adjusted annually based on the consumer price index, *rounded to the nearest* $.05 or $.10. This provision should be changed to round the adjustment *down to the nearest* $.05 or $.10, as it is illogical to round *upward* and charge consumers more than their estimated spending limit.

Adjustments in the deductible amounts after 2006 should never be rounded upward. The proposed regulation will adjust the deductible annually based on average per capita aggregate expenditures for Part D drugs, *rounded to nearest* $1. This provision should be changed to round the adjustment *down to the nearest $1*.

The regulations should authorize the use of state Medicare buy-in rules where a state's plan does not deviate substantially from the default regulatory standard. In the comments to the proposed regulations, it states that CMS was authorized to allow state Medicare buy-in rules to become the subsidy standard where the state's plan does

not deviate much from the default plan of the regulations. The comments state that CMS has decided not to make use of this authority for reasons of (1) uniformity, and (2) administrative burden. It is unreasonable to argue that state rules should not be used for reasons of 'uniformity' when the statute specifically authorizes use of state rules. If uniformity were the highest priority, congress would not have prohibited the use of state rules, as it did in countless areas where they wanted to proscribe reference to state rules. Furthermore, because state agencies will be doing a significant portion of the subsidy administration, it is unreasonable to posit that administrative burden will be lessened by adding an additional standard to the states' calculations. CMS should use the authority of the statute, and authorize states to use their own Medicare buy-in rules to set standards for subsidies.

We are concerned that there is no provision in Section 423.800(a) specifying a time period by which CMS must notify a plan that an enrollee is eligible for a subsidy. This is an essential step in the process, because without the subsidy, prohibitive costs will prevent low-income beneficiaries from using their Part D benefits. We propose that CMS be required to inform Part D plans of beneficiaries' enrollment in the subsidy no later than 24 hours after the application for the subsidy is approved. As this will likely be an electronic notification, it should not be burdensome. It is vital that plans know which beneficiaries are enrolled in the subsidy, so that these low-income beneficiaries do not have to pay the full cost of their prescriptions while their subsidy application is process.

The regulations must set forth a clear required administrative process for plans to reduce cost-sharing and premiums for subsidy eligibles. The proposed regulations state that plans must reduce subsidy eligibles' premiums and cost-sharing, and inform CMS of this, in "a manner determined by CMS". This provision must be clarified, and the 'manner' must be defined, so as to ensure that the reductions and notice occur. A suggested methodology should be provided so that beneficiary groups can comment and understand how CMS will be informed.

The regulations must place clear responsibility upon plans – subject to punishment for noncompliance – for failure to reimburse subsidy eligibles when appropriate. The regulations must explain how CMS will monitor reimbursement, and set a 10-day minimum time period for reimbursement to occur after the date of subsidy effectiveness. The proposed regulations state that plans must reimburse individuals for cost-sharing paid by individuals before an individual is notified of subsidy eligibility and after the date the subsidy is effective. The likelihood of violation of this regulation requires that CMS adopt stronger policies to monitor this function and ensure compliance.

Adoption of a presumptive eligibility system would alleviate this problem. As an additional alternative, the regulations should provide that beneficiaries may present

their notice of approval for the subsidy to their pharmacy when they seek prescription drugs. Pharmacies should accept this notice as adequate to relieve the beneficiary from making a co-payment, and instead seek reimbursement for the beneficiary's plan.

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

Section 423.871 Contract terms and conditions.

The final regulations for fallback plans should be clear about what structures, such as premiums or cost sharing, can be different, and about what protections must be in place to ensure that consumers are clearly informed of the differences and are protected from unfair practices. The proposed regulations create an entirely different structure for fallback plans, and beneficiaries in areas with these plans will struggle to understand these fallback plans. Failure to create strict guidelines for fallback plans and help inform beneficiaries will be exacerbated by the rural areas where most of these plans are likely to operate.

The final regulations must give fallback plans incentives to reduce costs. The proposed regulations create a cost-reimbursement structure which reimburses fallback plans for actual and administrative costs, giving fallback plans no apparent incentive to reduce costs. The final regulations must address this, and provisions should be designed to ensure beneficiaries will not ultimately be charged more for their drugs because there is a poor incentive structure to control costs for fallback plans. This is particularly true because a structure that allows fallback plans to overcharge will act as an incentive for companies to pursue fallback plans rather than become full PDP and MA-PD plans.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

What is considered "allowable retiree costs" under Section 423.882 must be tightened and information on employer costs and disbursements made public.
In considering allowable costs for a qualified retiree prescription drug plan, CMS must apply a test that considers only an employer's financial contribution to retiree prescription drug coverage, not of any payments by the retiree.

In addition, to be consistent with the requirements of the law under Section 1860 D—22 and CMS's own stated goal (69 Fed Reg 46741, August 3, 2004), CMS must require the employer's contribution to be at least as generous as the net value of the standard Medicare Part D benefit (i.e., the expected amount of paid claims under Medicare Part D minus beneficiary premiums).

Furthermore, as the Preamble discussion makes clear (p. 46736ff), accounting for retiree costs eligible for the subsidy will be a difficult accounting problem that may be subject to confusion or abuse. We believe one of the best ways to ensure a fair and equitable use of the subsidy amounts is to make the information on employer costs and reimbursements from Medicare public data which employee organizations and advocates can monitor.

The requirements for qualified retiree prescription drug plans under Section 423.884 should be expanded and clarified.

Actuarial Attestation.

> CMS has proposed the use of random audits to ensure qualifying employment-based retiree prescription drug plans meet the actuarial equivalence test. However, given the significant and unprecedented employer subsidy established under the MMA, it would be wise to provide additional protections against improper payment of the federal subsidy. In order to help accomplish that, the attestation submitted by employers must include information on the assumptions that are the basis for the valuation of the plan for purposes of determining actuarial equivalence. This information must be available for public inspection.

Late enrollment penalties.

> In addition, the appropriate regulation should make it clear that employees should be held harmless from late enrollment penalties in the event that a retiree plan is discovered to have been in violation of creditable coverage due to an error or misrepresentation of the value of a retiree plan. (See also our comments on sections 423.46 and 423.56.)

The information required by Section 423.888 to be submitted to ensure accurate subsidy payments should include information on how actual spending compares to projected spending (submitted as basis for actuarial equivalence attestation). Such information should be available for public inspection.

Other parties in addition to an employer should be able to take advantage of an appeal under Section 423.890. To provide further protection against improper payment of the employer subsidy, third parties (such as employee organizations or other advocates) should be granted the right to appeal a CMS determination regarding the actuarial equivalence of an employer's retiree prescription drug plan.

Subpart S – Special Rules for States-Eligibility Determinations for Subsidies and General Payment

Sec 423.904 Eligibility determinations for low-income subsidies.

We are very concerned about the eligibility and enrollment for the lower-income subsidies.

The directions to the states in making eligibility determinations under Section 423.904 should be clarified. 904 (a) directs states to make eligibility determinations in accordance with the provisions of 423.774. It should cross reference the entire Subpart P, or, at a minimum the definitions included in 423.772. Under .904(b) the states should be directed to notify CMS of eligibility determinations within 24 hours of making them. A similar provision should be included in 423.774 with respect to SSA determinations.

The proposed regulation at Section 423.904 (c) regarding states' obligations to screen subsidy applicants and offer them enrollment in Medicare Savings Programs ("MSPs") are inadequate. In particular, proposed § 423.904(c)(2) should specify what "offer enrollment" means. We believe an applicant must be offered the opportunity to enroll during the same visit or contact (in office, by phone, or by mail), without providing any further documentation or completing any additional forms. Only if enrollment is easy and convenient will Congress's intent of increasing participation in MSPs be accomplished. Furthermore, because under the current rules, enrollment in an MSP may be the only entry into the subsidy for some beneficiaries, a quick and easy application for MSP programs is essential.

As written, the regulation would permit states to say they have "offered enrollment" simply if they tell applicants that they might be eligible for an MSP and may return another time to complete another application form if they wish to apply. Such an outcome would defeat the purpose of the screen and enroll provision included in the new Section 1935(a)(3) established in Section 103(a) of the statute. Instead, the low-income subsidy application should include an "opt-out" provision, under which qualified applicants would be enrolled in an MSP unless they affirmatively decline to do so. This provision would explain that enrollment in an MSP may be another way to qualify for the low-income subsidy.

Because enrollment in an MSP may affect receipt of other public benefits, there is a tremendous need for good quality counseling of beneficiaries. In addition, in order to ensure that enrollment requirements between MSPs and the low-income subsidy are aligned, states should not be permitted to pursue estate recoveries against MSP beneficiaries. Such recoveries are not cost-effective and can deter beneficiaries from enrolling. Any information provided to beneficiaries about MSP enrollment should tell applicants whether they will be subject to estate recovery if they enroll in an MSP.

In the interest of further aligning eligibility rules for MSPs and the low-income subsidy and easing administrative burdens, we suggest that CMS should direct states to apply the definitions of resources used in Subpart P, section 423.772, in making their resource determinations for MSP applicants.

In addition, should CMS adopt a policy, as has been discussed publicly, under which most subsidy applications to state Medicaid agencies would be forwarded to SSA for the actual eligibility determination, the regulations should be clear that the screening for MSP eligibility must take place prior to the processing of the applications to SSA. Potential beneficiaries should not have to wait to be screened and offered enrollment in MSPs. Furthermore, an individual cannot be told, by either SSA or the state that she or he is ineligible for the low-income subsidy until MSP eligibility has been determined (if the individual wishes). It would be confusing beyond repair for an individual to receive a notice from SSA that she is ineligible for a subsidy, have her MSP eligibility determined by the state, and then receive a notice from the state that she is eligible for both MSP and the subsidy. Whatever the mechanics, the individual must be told that MSPs are a route to subsidy eligibility.

Screening and enrollment for full Medicaid

We believe that the regulations should also ensure that beneficiaries are screened for eligibility for full Medicaid and offered enrollment if they qualify, consistent with 42 C.F.R. § 435.404. Ideally, all subsidy applicants would be screened for Medicaid, and offered enrollment if they qualify (similar to current screen-and-enroll procedures under the State Children's Health Insurance Program (SCHIP) described in 42 C.F.R. § 457.350, and in particular for states that use separate SCHIP applications as described in 42 C.F.R. § 457.350(f)(3)). Because the importance of maintaining simple application process for the subsidy is paramount, CMS may wish to consider using a simple screening process based on information obtained through the subsidy application. This screening would trigger a follow-up with applicants who appear to be eligible for full Medicaid.

Screening for other public benefits

Many Medicare beneficiaries who are eligible for a low-income subsidy under the Part D Program will also be eligible for other important benefits. Some of these benefits, such as food stamps, are also administered by states and have eligibility rules that very closely correspond with the new eligibility rules for the Part D subsidies. Historically participation by seniors and people with disabilities in these programs has been low, despite the fact that the benefits that low-income Medicare beneficiaries would be able to receive could help them struggle less to make ends meet every month.

The Part D enrollment process offers an historic opportunity to connect Medicare beneficiaries in these other programs.

Beyond saying that applications may be filed either with a State's Medicaid program or with SSA, the proposed rule has very little detail about how the application process is likely to work. We urge CMS to specify that the new eligibility process should dovetail with other programs so that low-income Medicare beneficiaries can be enrolled as seamlessly as possible in all the state- or SSA-administered benefits for which they qualify. In particular:

- Outreach materials that SSA and CMS/State Medicaid programs design should contain information about other major benefits for which applicants may be eligible;

- Applications that are filed and other information that applicants provide should be easily shared between SSA, state agencies, and CMS so that it is available to all agencies and duplication of effort can be avoided;

- The federal agencies involved (USDA, CMS, and SSA) should make it a priority to enroll all eligible applicants in all benefit programs. In addition, these agencies should seek to simplify federal program rules so that Medicare beneficiaries can easily access all programs for which they qualify. A model may be the SSA Combined Application Projects that now operate in a handful of states where SSI applicants are asked only a couple additional questions and are certified automatically for food stamps based on their SSI applications

The requirement for notifying those determined eligible for the subsidy set out in Section 423.904(c)(3) must be clarified. The section refers to 423.34(d) with reference to notifying individuals deemed subsidy eligible, but 423.34(d) discusses automatic enrollment of full benefit dual eligibles in Part D plans. Notification of deemed subsidy eligible individuals of their entitlement to a subsidy is a different matter from enrollment in a Part D plan. This reference appears inapt. As discussed in our comments to section 423.773, those who are deemed subsidy eligible need immediate notification of that status and of the fact that they need do nothing more with respect to their subsidy, but that they need to enroll in a Part D plan in order to use the subsidy.

States should not be permitted to impose more burdensome documentation requirements on beneficiaries than could SSA as allowed under Section 423.904(d)(3). This is counter to the principle of simple enrollment underlying the statue. In addition, states should not be permitted under the cost-effectiveness provisions of section (d)(3)(ii) to transfer the costs of verification to beneficiaries by requiring visits to state

Medicaid offices and production of additional documentation. Section (d)(3)(i) should be changed to read: "States may require submission of statements from financial institutions for an application for low-income subsidies to be complete *only if the applicant or personal representative is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information*" (suggested additional language in italics).

The Social Security Administration must be required to screen for eligibility in Medicare Savings Programs and other Medicaid programs that cover cost-sharing. Although the statute requires states that process applications to screen for eligibility in these programs, many consumers will apply directly through the SSA. In the alternative, the roles should be reversed and SSA should act as intake workers and the states should process the applications.

In order to screen for MSP and other Medicaid eligibility, SSA would have to have access to and understanding of all the Medicaid programs and rules that apply in each state. It does not seem possible that SSA could master the rules of Medicaid eligibility and thus, we believe SSA must be required to employ all computerized eligibility screening tools available by the states and contract with state staff to assist in screening for MSP eligibility.

That States must require a personal representative applying for a low-income subsidy to certify under penalty of perjury as to the accuracy of the information provided within will single-handedly halt outreach and enrollment activities by social workers and community service organizations. The definition of personal representative does not refer only to persons with power of attorney or guardians with legal authority and obligation to sign in an applicant's stead. As written, the proposed regulations at Section 423.904 (d)(2)(ii) would expose any agency, volunteer, SHIP program staff, friend or neighbor to legal liability.

The process for how deemed eligibles are actually enrolled into the subsidies needs to be clarified. While the statute and proposed regulations both articulate that certain individuals on Medicaid are deemed eligible for the lower-income subsidies, the proposed regulations do not articulate how the enrollment into the lower-income subsidies will be effectuated. This must be made clear. For example, just because a person is presumptively eligible for Medicaid does not release them of a need to apply and affirmatively articulate a desire to obtain the benefits for which they are deemed eligible. The final regulations must make clear that states are required to send a monthly batch of deemed eligibles to SSA for SSA to effectuate the enrollment with an effective date of the first day of the following calendar month.

Submitter : Miss. Lana Borno **Date & Time:** 10/03/2004 05:10:24

Organization : N/A

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 1, 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 chance to remark on the proposed regulation to implement the Medicare prescription drug benefit. The following are the comments that I offer for deliberation during the process of CMS developing the final regulation.

With regards to Subpart C: Benefits & Beneficiary Protections, I would like to suggest that the pharmacy access standard require plans to meet the TRICARE pharmacy access requirements on a local level, versus being on a service level. After investing six years in being a drug therapy expert, I would like to know that I will be able to be trusted in providing all my patients with the health care they deserve, and I assure you that I will live up to your expectations. I would like for you to ensure me that all patients will have fair access to their local pharmacy.

In relation to Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Benefit Plans, I would like to point out that pharmacists are the medication experts on health care teams, and are clearly the ideal providers for MTMS. Plans should require that fees should be paid for all MTMS providers. Both non-preferred and preferred pharmacy pharmacists should get paid the same for the same services. In addition, Pharmacists are the ideal health care professionals to offer MTM services and have the knowledge and skill to decide which services each beneficiary requires.

In closing, I advocate that CMS to revise the regulation to allow all pharmacists get paid for the same services and for the plans to meet the TRICARE pharmacy access requirements on a local level.

Thank you for considering my views.

Sincerely,

Lana Borno
ltborno@email.unc.edu