CMS-4068-P-102

Submitter : **Mr. Roger Penrod** **Date & Time:** **09/19/2004 04:09:52**

Organization : **Alaska Pharmacists Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

BACKGROUND

I am a pharmacist at an independant pharmacy in Fairbanks, AK

BENEFITS AND BENEFICIARY PROTECTIONS

Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS).
Who will benefit froms MTM can change, so plans should be required to identify new targeted beneficiaries on a monthly basis.
Plans should be required to inform pharmacists who among their patients are eligible for MTM.
Pharmacists and physicians should also be able to identify eligible beneficiaries.
Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
CMA must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.

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

Plans are required to establish a medication therapy management (MTM) program. The purpose of the MTM program is to provide services that will optimize therapeutic outcomes for targeted beneficiaries (individuals with multiple chronic disease, taking multiple drugs, and likely to incur annual costs that exceed a certain level). Plans must establish fees for pharmacusts and others that provide MTM dervices.
Pharmacists, the medication expert on the health care team, are ideal providers of MTMS.
CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). REquiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships.
Plans must be require to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferrd pharmacies for the same service.
CMS must carefully evaluate each plan's application to provide the MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

GENERAL PROVISIONS

Pharmacy access is most important. Local access with a choice of local providers is the most necessary aspect of providing prescription drug benefits. Plan sponsors must meet the Department of Defense TRICARE retail pharmacy access stsndards:
Urban areas: At least 90% of the beneficiaries in the plan service ares, on average live within 2 miles of a participating retail pharmacy.
Suburban areas: At least 90% of the beneficiaries in the plan service ares, on average, live within 5 miles of a participating retail pharmacy.
Rural areas: At least 70% of beneficiaries in the plan's service area, on average, live within 16 miles of a participating retail pharmacy.
I want to be able to serve my patients! To do so, CMS should revise the pharmacy access standard to require plans to meet TRICARE requirements on a local level, not the plan's overall service level. Requiring plans to meet the access standard on a local level is the4 ONLY way to ensure all beneficiaries have convenient access to a local pharmacy.
If the plans are only required to meet pharmacy access standard "on average" across the plan's service area, tghe plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan's pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor.
I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could affect my ability to continue to serve mt patients.
Allowing plans to sidtinguish between pharmacies could allow plans to drive beneficiaries to a particular pharmacy. This goes against Congressional intent. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice.

CMS-4068-P-102

Only preferred pharmacies should count when evaluating whether a plan's pharmacy network meets the pharmacy access standard. That will help patients access a local pharmacy for their full benefit.
Plans must allow beneficiaries to obtain the same benefits at a community pharmacy that they can access at a mail service pharmacy. The benefits could include an extended supply of medication (such as a 90 day supply) which some plans have historically only made available through a mail service pharmacy. However, plans can charge more when beneficiaries obtain an extended supply at a community pharmacy.
If plans are allowed to charge a higher price for an extended supply obtained from a community pharmacy, CMS should clarify that the price difference must be directly related to the difference in service costs, not the cost of the drug product.

CMS-4068-P-103

Submitter : Ms. Sharon Maxwell **Date & Time:** 09/19/2004 04:09:43

Organization : Ms. Sharon Maxwell

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

If this continues on the present track, I will be forced to come up with over $5000 to cover my prescription meds - I am a person living with AIDS and get my meds through medicaid. If I have to use Medicare first then I have to pay for these meds. This is a true undue hardship for a person who has only about $163.00 left over from my SSDI check each month.

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

Sincerely,

Sharon Maxwell
PO BOx 236
Beckemeyer, IL 62219

CMS-4068-P-104

Submitter : Mr. James Hart **Date & Time:** 09/19/2004 06:09:56

Organization : Mr. James Hart

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

People with HIV need to have full access to treatment, regardless of ability to pay.

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

Sincerely,
Jim Hart
2853 McNair Ave.
St. Louis, MO 63118

CMS-4068-P-105

Submitter : **Richard Brittain** **Date & Time:** **09/19/2004 06:09:26**

Organization : **Richard Brittain**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

See Word attachment for comments.

CMS-4068-P-105-Attach-1.doc

CMS-4068-P-106

Submitter : Mr. alfred fagundes III **Date & Time:** 09/19/2004 10:09:26

Organization : Northern Nevada HOPES

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 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.

[INSERT PERSONAL STATEMENT HERE. If you are on Medicare, talk about how these regulations will affect you. Otherwise, write a couple of sentences about the need for people with HIV to have full access to treatment, regardless of ability to pay.]

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

Sincerely,
Alfred FagundesIII
55 franks LN
Sun Valley NV. 89433

CMS-4068-P-107

Submitter : **Mr. David Brockman** **Date & Time:** **09/19/2004 11:09:57**

Organization : **Mr. David Brockman**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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.

CMS-4068-P-108

Submitter : Dr. Heather Allison Greene (Pharm.D.) **Date & Time:** 09/19/2004 11:09:26

Organization : Imperial Plaza Pharmacy

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Currently pharmacists are not allowed to bill under part B for services offered, specifically B-12 injections and allergy shots. We have pharmacy patients who would like to have their injections at our pharmacy which is more convenient to them than going to their physician's office, but they can't afford our fee. We would like to be able to bill medicare for these services as physicians do.

CMS-4068-P-145

Submitter : Eric Hamik

Date & Time: 09/20/2004 09:09:20

Organization : Nebraska Pharmacist Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

I want to comment that the PBM companies are making an incredible amount of money just sitting there and letting there computer process the information. That is a large part of the increase in medications. It you would look in the late 70's and early 80's before they were involved drugs increased at a much lower percentage. What they are doing is just adding another layer of people making money off of prescriptions while we the pharmacists are the ones doing all the work and getting payed less and less. What I am trying to say is that you need to be cautious on who you pick to administer this plan and you need to be protective of the pharmacist. When encounter so many people everyday that cannot get any service or questions answered from their PBM or mail order pharmacy. Then take into account how confused the elderly are already. It could be a disaster if the patient doesn't have there community pharmacy to go to to get there questions answered. I am asking you to make the retail pharmacy the focus of this regulation. Without us this plan could be a disaster.

CMS-4068-P-146

Submitter : Mr. laird miller **Date & Time:** 09/20/2004 10:09:49

Organization : Mr. laird miller

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Medication therapy Management should be performed by the patient's pharmacist. Through the use of computers, the pharmacist will have the most complete picture of the medication profile. Pharmacists have the most education in medications and how they affect patients. Pharmacists have the most ready access to patients. Pharmacists see more patients face to face. While other professions may choose to educate themselves about drugs, Pharmacists do it by training throuhout the educational process, they are trusted by their patients and they WILL do the best job of managing patients

Submitter : Mrs. Alana Podwika **Date & Time:** 09/20/2004 10:09:41

Organization : Mountain Park Health Center

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

September 20, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P Baltimore, MD 21244-8014
Re: CMS-4068-P

Dear Sir or Madam:
? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.
? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice Anticoagulation Disease Management Services. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

? Thank you for considering my view.

Sincerely,
Alana Podwika
VP Pharmacy
Mountain Park Health Center
635 E. Baseline Rd.
Phoenix, Arizona 85042

CMS-4068-P-148

Submitter : **Ms. Jody Klimek** **Date & Time:** **09/20/2004 11:09:58**

Organization : **Ms. Jody Klimek**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

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

Pharmacists are the ideal providers for MTMS. Beneficiaries should not have to obtain MTMS from a specific provider. Also, pharmacists should be allowed to provide MTMS to non-targeted beneficiaries and pharmacists should be able to bill patients directly for the services.

CMS-4068-P-148-Attach-2.doc

CMS-4068-P-148-Attach-1.doc

CMS-4068-P-149

Submitter : **Mr. Charles Barrera** **Date & Time:** **09/21/2004 12:09:59**

Organization : **Mr. Charles Barrera**

Category : **Individual**

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.

As a disabled individual with AIDS, I am not quite sure how the new rules will affect my ability to obtain the medications I depend on. My Social Security benefits fall well below poverty level and it is through the Medicaid program that I am currently able to receive my medications.

Without the Medicaid program, I do not know how I would manage to obtain the medications that I rely on. My yearly Social Security benefits ($6,600.00) fall well below the amount needed ($18,735.72) to obtain just three of the medications I am currently prescribed.

People with HIV should have full access to treatment, regardless of ability to pay.

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

CMS-4068-P-150

Submitter : **Mr. LeRoy Andresen** **Date & Time:** **09/21/2004 12:09:48**

Organization : **Thrifty White Drug**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

1) There are not proper provisions in place to properly implement the TriCare pharmacy access standards that are in place today and this would seriously reduce the ability of patients to obtain their prescriptions from their local pharmacist with whom they have an working relationship and can easily have thier questions & concerns addressed.
#2) The proprosed regulations should prohibit plans from using economic incentives to force patients to use mail order services to obtain their prescription medications.
#3) The regulations should include more specificity as to the medication therapy management (MTM) program. Current regulations don't define the nature and scope of MTM services that the plans whould have to provide, such as who would be eligable to provide these services (Nurse, pharmacist, telephone service?) as well as how these providers would be compensated for their services.

CMS-4068-P-151

Submitter : **Mr. Brad Cherson** **Date & Time:** **09/21/2004 12:09:40**

Organization : **Georgia Pharmacy Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

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

The correct utilization and oversight of drugs and management of disease should be delegated to pharmacists. Our training and motivation has been a long time coming, and I know these services will reduce errors, increase compliance, reduce drug usage due to improper prescribing, and benefit our geriatric community. Pharmacy schools have been training for these services for decades, it is time we get paid to expand our roles in the healthcare system. Use our expertise to better our elderly's quality of life.

CMS-4068-P-152

Submitter : **Mr. Douglas Laing** **Date & Time:** **09/21/2004 01:09:45**

Organization : **Mr. Douglas Laing**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Please do not cut off my AIDS medications in 2006 when the new Medicare drug benefits are scheduled to change. I have gone through this once already when Oregon cut us off until the governor stepped in and found a way to continue drug benefits for People With AIDS. I went without my meds for 2 months while the state was in chaos. My viral load went up and my health started to deteriorate. When drugs became available again I went back on the meds I was taking only to find out they no longer worked. I had now developed a resistance to all the present drugs approved by the FDA. After several months of worsening health, I finally got into a drug trial which is working great. Except that this new drug is hard on the liver and I have Hep C so this is hard, but there is nothing else available.

So cutting my drug benefits would be like writing my death certificate. It falls into the category of cruel and unusual torture. If I could I would take the burden off my government and more to a foreign country but as a foreigner I couldn't get medical coverage there either.

Douglas Laing - My life is in your hands.

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

Please do not cut off my AIDS medications in 2006 when the new Medicare drug benefits are scheduled to change. I have gone through this once already when Oregon cut us off until the governor stepped in and found a way to continue drug benefits for People With AIDS. I went without my meds for 2 months while the state was in chaos. My viral load went up and my health started to deteriorate. When drugs became available again I went back on the meds I was taking only to find out they no longer worked. I had now developed a resistance to all the present drugs approved by the FDA. After several months of worsening health, I finally got into a drug trial which is working great. Except that this new drug is hard on the liver and I have Hep C so this is hard, but there is nothing else available.

So cutting my drug benefits would be like writing my death certificate. It falls into the category of cruel and unusual torture. If I could I would take the burden off my government and more to a foreign country but as a foreigner I couldn't get medical coverage there either.

Douglas Laing - My life is in your hands.

CMS-4068-P-153

Submitter : Dr. Khue Nguyen **Date & Time:** 09/21/2004 02:09:37

Organization : Palo Alto Medical Foundation

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

While I appreciated CMS'recognition that pharmacists will be the primary provider for various aspects of medication management, I'm concerned that leaving the decisions to PDPs may allow PDPs to choose less qualified individuals. Please keep in mind that PDPs will try to minimize costs and one strategy is to spend less on human resources, such as employment of lower-paid individuals. Pharmacists are currently being employed by health plans, pharmacy benefit management companies, medical groups, and hospitals to provide cost and utilization management of medications. All working pharmacists participate in some aspects of medication therapy management, whether through providing drug information for the patient at a community pharmacy or through streamlining a medication regimen at an ambulatory care setting.

I run my own medication therapy management clinic for a medical group, with emphasis on geriatrics with high risk medications or polypharmacy. In order to find funding for this needed service, which supported one full-time pharmacist's salary, I had to prove the value of such services through a demonstration project with outside funding.

The hesitation from medical groups and health-care systems in funding pharmacists to provide such needed services comes from the lack of recognition by Medicare that pharmacists are health care providers. Consequently, their services are not being reimbursed by Medicare nor health plans and the medical institution must generate its own funding to support these services.

CMS-4068-P-154

Submitter : **Mr. Michael Stiller** **Date & Time:** **09/21/2004 02:09:55**

Organization : **Bellin Health**

Category : **Hospital**

Issue Areas/Comments

Issues 1-10

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

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

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the followning MTM services in my practice at Bellin Health in Green Bay, WI including anticoagulation monitoring service, drug interaction review, formulary compliance, medication streamlining, drug selection and optimal dosing for CHF patients, and adverse event monitoring. Plans should be encouraged to use my services to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to having pharmacists provide the MTM service.

Thank you for considering my view.

Michael G. Stiller RPh
Bellin Health Systems
744 S. Webster Avenue
Green Bay, WI 54304
(e-mail: mgstil@bellin.org)
(phone: 920-433-3639)

CMS-4068-P-155

Submitter : Mr. Donald L Pepmeier ,Jr. **Date & Time:** 09/21/2004 02:09:58

Organization : Mr. Donald L Pepmeier ,Jr.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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 am an individual currently recieiving Medicare/Medicaid benefites that will be adversly affected by these changes. The presecription medications that I am required to take are too expensive for me to afford without my Medicare/Mediciad coverage. It is crucial that individuals like myself have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines. HIV affected individuals must continue to have full access to treatment, regardless of their ability to pay.

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

Sincerely,

Donald L. Pepmeier, Jr.
504A NE Brookwood Circle
Blue Springs, MO. 64014-2961

CMS-4068-P-156

Submitter :	Mrs. Isabelle Ley	Date & Time:	09/21/2004 03:09:55

Organization : Mrs. Isabelle Ley

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-4068-P-156-Attach-1.rtf

CMS-4068-P-157

Submitter : **Dr. Christopher Harris** **Date & Time:** **09/21/2004 03:09:44**

Organization : **Dr. Christopher Harris**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

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

As the pharmacy director of a 398 bed hospital I have seen our involvement in cost containment strategies, drug utilization, medications safety, quality improvement, and medication management increase dramatically over the last two years. In that period of time we have decreased costs, improved patient safety, and maintained or improved patient outcomes. The reality is that pharmacists are uniquely equiped to analyze drug therapy regimens and determine what course of action should be taken. There is no other medical professional that has been educated to keep long term costs under control while assuring safety and optimum care. In the hospital setting, lower cost professionals have been utilized for this type of function. The results have been less than stellar. As a result, the hospital industry and regulatory agencies are looking to pharmacy to play a larger role in establishing best practices, establishing formularies, ensuring medication safety, controlling costs and monitoring/adjusting drug regimens. The same logic should apply in the outpatient setting as applies in the inpatient setting. As a tax payer I urge you to utilize pharmacists exclusively in this capacity. Based on my experience they will provide superior results.

CMS-4068-P-158

Submitter :	Ms. Bonnie Baris	Date & Time:	09/21/2004 04:09:11
Organization :	Ms. Bonnie Baris		
Category :	Social Worker		

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 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 adherence to the HIV medicines is one of the most important treatments we have against the devastation of the disease. As a mental health therapist, I hear almost daily horror stories about the consequences of not having affordable access to medicines. It would be untenable to deny access to those medications for the people living with HIV/AIDS. We alrady compromise the individual's ability to access proper medical care with the cruelly long times they wait for approval for Medicaid. It would be cruel and unusual punishment to sweep this population under the rug and make them more marginalized and underserved.

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

Sincerely,

Bonnie Baris, LISW
143 South Monroe Avenue
Columbus, OH 43205

CMS-4068-P-159

Submitter : **Ms. Jennifer Short** **Date & Time:** **09/21/2004 04:09:41**

Organization : **APhA-Academy of Student Pharmacists**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for allowing me to submit the following points to consider when revising the MPDB. As a student pharmacist, I want to know that my future patients receive the best benefit and choice protections possible.

Pharmacy Access Standards:

Pharmacists need to be able to serve their patients. To do that, the pharmacy access standard must be revised to require plans to meet the TRICARE requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy. If plans are only required to meet the pharmacy access standard ?on average? across the plan?s service area, the plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan?s pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor.

Any Willing Provider:

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

Level Playing Field:

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

Thank you!

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

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation. I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently see pharmacists providing MTM services at my internship site on a regular basis, and I myself am learning the skills needed to provide this valuable service within my PharmD education at the University of New Mexico. Optimizing drug therapy is achieved with the expertise of a pharmacist. I am concerned, however, that letting plans independently choose MTM providers will allow them to choose less qualified providers to provide MTM services. Plans should be encouraged to use pharmacist services allowing patients to make the best use of their medications.

Please consider the following points for MTMS:

Targeted Beneficiaries

? Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS).
? Who will benefit from MTM can change, so plans should be required to identify new targeted beneficiaries on a monthly basis.
? Plans should be required to inform pharmacists who among their patients are eligible for MTM.
? Pharmacists and physicians should also be able to identify eligible beneficiaries.
? Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
? Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
? CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.

Providers

? Pharmacists, the medication expert on the health care team, are the ideal providers of MTMS.
? CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships.

Fees

? Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
? CMS must carefully evaluate each plan?s application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

Services

? MTM services are independent of, but can occur in conjunction with, the provision of a medication product.
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as performing a health assessment, formulating a medication treatment plan, monitoring and evaluating a patient?s response to therapy, etc.
? Face-to-face interaction between the beneficiary and the patient is the preferred method of delivery whenever possible. The initial assessment should always be face-to-face.

I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004. (Definition and Criteria are available at http://www.aphanet.org/lead/MTMS_definition_FINAL.pdf).

CMS-4068-P-160

Submitter : Donald Thibodeau **Date & Time:** 09/21/2004 11:09:21

Organization : PillHelp Company, LLC

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I have been market testing my polypharmacy information services and medication mangement tools for out patient physicians and consumers for five years. I have been charging $90.00 an hour and every patient except one has decreased med use to a degree that recovered their cost within three months. All patients and most physicians have agreed that quality of life has improved. Refer to www.pillhelp.com

CMS-4068-P-161

Submitter : **Mr. John Sahm** **Date & Time:** **09/21/2004 11:09:56**

Organization : **Mr. John Sahm**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

When drafting the policies on the new Medicare prescription coverage please be sure that persons with HIV are not left out. When we hear Medicare we often think of pensioners however there are many disabled people who rely on Medicare for their healthcare. HIV medication cocktails are some of the most complicated and costliest.

Management of HIV infection is a tricky game. Managing sources for prescription coverage has become an art to the many who struggle without insurance. Today there are many diverse ways to get HIV medications to low income individuals with HIV. Most of us use several programs at the same time to obtain our various medications. Some of these programs are:

Medicaid allows (3) Rx per month
State ADAP Program covers up to (4) HIV Rx per month with additional non HIV Rx for prophylaxis (funded by Ryan White Title II)
Harris County Hospital District covers drugs for county residents with very low income
Local ADAP for Houston EMA residents with low income (funded by Ryan White Title I)
Drug Company Patient Assistance Programs (last resort & difficult to apply for)
Phase II & III drug studies & Expanded Access Programs for those of us who are really desperate

Any new Medicare prescription plan must account for these various existing programs, especially Medicaid. The Ryan White funded items are tenuous at best. Last year our local ADAP program shut down when it ran out of funds. The State ADAP program is talking of implementing stricter eligibility guidelines to avoid running out of funds.

Other existing drug programs will see the Medicare Prescription Benefit as an opportunity to eliminate or at least reduce their existing programs. It is imperative that you consider all of these existing programs & the effect the Medicare Prescription Plan will have on them.

Thanks for doing the right thing.

John Sahm
1625 Longacre
Houston, TX 77055
713-647-9535

ELIGIBILITY, ELECTION, AND ENROLLMENT

GENERAL PROVISIONS

CMS-4068-P-161-Attach-1.doc

CMS-4068-P-161-Attach-1.doc

CMS-4068-P-162

Submitter : **Dr. Ann Vassey** **Date & Time:** **09/21/2004 11:09:39**

Organization : **VHA**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

The profession of pharmacy is held to high standards by both society and governing bodies of this country. A patient often has more contact and clinical intervention from a pharmacist than any other health professional. But our profession continues to be ignored when it comes to recognizing the value of our services to society. We continually are left out of reimbursement rules by our own government and insurance companies. Is this because we, as a profession, continue to give great care and service to society even in the face of no recognition?

I suggest it is time for our governing bodies to change their view of what is right.

CMS-4068-P-163

Submitter :		**Date & Time:**	**09/21/2004 12:09:46**
Organization :			
Category :	**Individual**		

Issue Areas/Comments

GENERAL

GENERAL

Re: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. People with HIV/AIDS should have full access to treatment, regardless of ability to pay.

CMS-4068-P-164

Submitter : Mr. Phillip Potter, Jr.
Date & Time: 09/21/2004 12:09:38

Organization : AIDS Coalition of Texas Now!, Triangle AIDS Networ

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 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.

As a consumer and advocate I believe that most of the people affected may already use a state ADAP program. This change would increase the burden on state ADAP programs which are already at capacity. Many ADAP programs across the nation have waiting lists. This change would in effect deny access to medications of many across the nation. I can't call this change to medicare beneficial. Medications for the HIV/AIDS pandemic are crucial in slowing the infection rates of HIV/AIDS across the country. Being from Texas, I recently read a report from our state health department show that in 2003 there were over 4,800 new infections. I can't imaging what 2004 will be like. These medications are a matter of life and death to many. Denying access will on further acerbate the already decaying health of our nation. Do you really want good health to be a luxury afforded only by our nation's wealthy?

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

Sincerely,

Phillip E. Potter,Jr.
6500 Purvis Road
Silsbee, Texas 77656

CMS-4068-P-165

Submitter : **Dr. Philip Mahalik** **Date & Time:** **09/21/2004 02:09:00**

Organization : **Il. Dept of Human Services**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

I support pharmacist payment for cognitive services

CMS-4068-P-166

Submitter : Dr. Ralph Kendall **Date & Time:** 09/21/2004 02:09:26

Organization : Dr. Ralph Kendall

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

We have for some time been charging for a retrospective drug regimen analysis based on a historical review of clinical documentation and prescription claims. These reviews are quite extensive and encompass an assessment of every type of potential problem observed in the patient regimen. We have been billing and have been paid at the rate of $250 per hour for these complex reviews. Our typical billing is in the range of $800-$1,200 per review. These reviews are used by consulting physicians in pursuing possible drug-related problems that contribute to excessive use of or abuse of health care resources. Our concern with legislation is that it will LIMIT our ability to commit the time and resources to this highly valued consultative service. Any fee process and structure identified should NOT LIMIT our ability to apply our knowledge to evaluation of drug therapies nor should it be limited to 'sale of product' transactions. We currently have the ability to identify charges and bill them on federal forms, and receive payment for cognitive services. In our zeal to be recognized we should not under value our services and our knowledge.

CMS-4068-P-167

Submitter : Mr. John Doggett

Date & Time: 09/21/2004 03:09:21

Organization : Mr. John Doggett

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Shifting the current Medicaid prescription drug coverage to the Medicare prescription drug plan with limited drug coverage will increase the overall cost of treating people living with HIV and AIDS. Current Medicaid coverage enables physicians to select from a wide variety of medications to prescribe the most effective regimen for their HIV/AIDS patients.

Medicare Prescription Drug Plans are not required to provide all FDA approved antiretroviral drugs. Anti-retroviral medications have a wide range of side effects including pancreatitis, renal failure and liver toxicity, and patients also develop resistance to some of their medications over time.

If physicians are limited in their choice of regimens, patients will be forced into regimens that are less effective in suppressing HIV or that may produce intolerable side effects. This will result in patients becoming sicker, being hospitalized, and possibly dying. This proposal is neither cost effective nor a responsible policy decision.

CMS-4068-P-168

Submitter : **Dr. Beth Bagwell** **Date & Time:** **09/21/2004 03:09:20**

Organization : **Craig Methodist Pharmacy**

Category : **Long-term Care**

Issue Areas/Comments

Issues 1-10

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

I am a certified geriatric pharmacist working in a continous care retirement community. I would like to strongly recommend the benefit of having medication therapy management performed by a pharmacist and a service fee paid to the pharmacist for their expertise. The advantage to the Medicare program would be reduced
cost and utilization due to use of more non-pharmacologic interventions and a reduction of hospitalizations due to fewer adverse drug events.

CMS-4068-P-169

Submitter : Mrs. Sarah Rivera **Date & Time:** 09/21/2004 03:09:46

Organization : APhA-Academy of Student Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for alllowing me to submit the following points to consider when revising the MPDB. As a student pharmacist, I want insure that my future patients receive the best benefits, the most protection and the best quality of care possible. As pharmacists we need to be able to serve our patients. To do that, pharmacy access plans should be revised to mee the TRICARE requirements on a local level, not on the plan's overall level. Requiring this will insure that patients have convient access to local phamracies. If the plan is only required to meet the average plan across plan access, then there will be less incentive to offer pharmacies acceptable contracts. Requiring plans to provide fair and convient access is a promise made Congress that CMS should keep.

CMS-4068-P-170

Submitter : **Ms. Lindsey Stephens** **Date & Time:** **09/21/2004 03:09:59**

Organization : **Medicap Pharmacy**

Category : **Other Health Care Professional**

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 a plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy 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 appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a heath assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: Medication Reviews, Diabetes Education, Cholesterol Education & Management, Asthma Education, Immunizations, Smoking Cessation, and Osteoporosis Education. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

CMS-4068-P-171

Submitter : Dr. Wendy Mobley-Bukstein **Date & Time:** 09/21/2004 03:09:11

Organization : Dr. Wendy Mobley-Bukstein

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-171-Attach-1.doc

CMS-4068-P-172

Submitter : Ms. Sunshine Stevens **Date & Time:** 09/21/2004 03:09:05

Organization : Ms. Sunshine Stevens

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 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.

In my community of freinds, I have had more than a few experiences watching loved ones choose between basic sustinance and presecription drugs. Eventually, we all pitch in to help our loved ones financially as well as emotionally. Now it seems as if we will be expected to cover even more expeneses in the future if Government subsidies cover even less of these crucial drugs?

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

Sincerely,

Sunshine Stevens
4011 33RD AVE W
Seattle, WA 98199

CMS-4068-P-173

Submitter : **Mr. Norman Wiginton** **Date & Time:** **09/21/2004 04:09:33**

Organization : **ASHP member (Pharmacist)**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Licensure and competencies would demonstrate competencies for application.

BENEFITS AND BENEFICIARY PROTECTIONS

Benefits and beneficiary protections to be successful must be in line with resources to be lasting and meaningful for the long run. Start small and grow with demonstrated results.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Pharmacist want to move from the distributive role to the consultation role. Hospitals are great examples of where pharmacist monitor and offer 'interventions' to and with LIPS (physicians) that improve patient care, avoid waste, conserve resources, and enable physicians to better do their diagnostic and prescriptive functions. Pharmacist help manager therapies for the prescribers and support the patient and nurse with instructional and monitoring needs.

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

Pharmacist, Clinical Pharmacist and Pharmacy Managers deal with these issues daily and are the experts in drug therapy to include, cost, utilization management, quality improvement and therapy management. This is what pharmacist do, giving direction and data to LIPS (licensed independent practioners and patients) to best prescribe and utilize medications. Pharmacist interaction with LIPS and patients is a daily occurance to help patients optimuzing their therapies. Pharmacist are advocates for the patient and the prescriber as an independent expert on the best use on medications based on their pharmacokinetics and pharmacoeconomics. Avoiding duplicate therapies and conserving resources while optimuzing therapy is a pharmacist's forte. Utilizing the knowledge base and expertise of Pharmacist in medication utilization and management has been demonstrated in model after model to make improvements in outcomes. Their interations with patients and other healthcare providers saves resources over current models. The ideal model would be physicians diagnosing and in collaborative consulation with pharmacist prescribing medications to optimize outcomes, while nurses deliver the physicial care to care out ordered therapies and treatments to support patient outcomes.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Criteria for eliigibility, election and enrollment should be established by a collaborative group of physicians, pharmacist and nurses. Pharmacist have the base knowledges of cost, utilization, applications, interactions, kinetics and contact to all everyone in the process of medication therapy.

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

Federal law will guide state law. Once a model is established in Federal Law, states will follow that example.

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

Models can be established through professional organizations in collaboration with those providing the resources and CMS and related services.

Submitter : Dr. Allan C. Anderson **Date & Time:** 09/21/2004 05:09:38

Organization : Memorial Hospital of Sheridan County

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Tuesday, September 21, 2004

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

Dr. Allan C. Anderson
Memorial Hospital of Sheridan County
1401 West Fifth Street
Sheridan, WY 82801

Re: CMS-4068-P
Dear Sir or Madam:
? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.
? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: Critical Care/ICU Management; Hyperlipidemia Management; Diabetes Disease Management; Hypertension Management; Drug Information; Clinical Pharmacokinetics. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

? Thank you for considering my view.

Sincerely,
Dr. Allan C. Anderson
Memorial Hospital of Sheridan County
Dept. of Pharmacy
1401 West Fifth Street
Sheridan, WY 82801
(307) 672-1065

CMS-4068-P-175

Submitter : | **Date & Time:** 09/21/2004 05:09:16

Organization :

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 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 have worked professionally with people living with HIV/AIDS, and know many long time survivors who could be adversely affected by changes in the Medicare Prescription Drug Benefit. At this point in their management of the disease, switching medications or developing new combinations of treatment could be hazardous to their finely tuned programs.

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

Sincerely,

Mary Ruffatto
651 King St.
Santa Rosa, CA 95404

CMS-4068-P-176

Submitter : Mrs. Catherine Moskal **Date & Time:** 09/21/2004 06:09:38

Organization : Mrs. Catherine Moskal

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

As a practicing retail pharmacist, I am fully support a drug coverage program includes medication management by a pharmacist. often, the elderly patients are on too many medications, duplications of medications, or expensive new medications prir to even trying less expensive alternatives. In addition, physicians often forget to monitor essential laboratory values, or multiple physicians order duplicate tests. Finally, pharmacists are in a unique environment to interact in a less intimidating location. Patients are more likely to open up to pharmacists in a drugstore than they are to their own physician in his/her office. This benefit for medicare recipients should definitely include a pharmacist directed medication management program. (And this website should add pharmacist as a selection on its registration page as we are definitely a group of health care professionals that have an interest in prescription drug programs.)

CMS-4068-P-109

Submitter : Mr. Terry Boedeker **Date & Time:** 09/20/2004 01:09:30

Organization : Mr. Terry Boedeker

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern: CMS

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 am a person living with HIV and have many friends who would be detrimentally affected by this proposed loss of access to the entire group of antiretrovirals. The decision of drug combo's should be left to the doctor in charge and the patient. This proposed change would limit the life saving choices and cause despair or perhaps untimely deaths. People with HIV and their doctors need to have full access to treatment, regardless of ability to pay.

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

Sincerely, Terry Boedeker

CMS-4068-P-110

Submitter : Mrs. Elizabeth Dawsey **Date & Time:** 09/20/2004 01:09:18

Organization : Mrs. Elizabeth Dawsey

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

Thank you for considering my comments as you finalize the regulations

CMS-4068-P-111

Submitter : **Mrs. Donna Dedon** **Date & Time:** **09/20/2004 01:09:58**

Organization : **Louisiana Medicaid Eligibility Section**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals

423.772 - Definitions

Family Size- individual, spouse, number of individuals related or dependent to/on applicant (more liberal income methodology???)

Resources - means liquid resources and other resources that can be converted to cash within 20 days and real estate that is not the applicant's primary residence. (more liberal resource methodology) (???)

423.773 - Requirements for eligibility

(a)(1) Has income below 150% of FPL applicable to the individual's family size.

Refer to 423.774 and the states responsibility for determining eligibility for subsidies as stated there. What sort of budgeting methodology is to be applied in determining eligibility? For QMB, SLMB, QI we are required to use the methodology of the most closely related program, i.e., SSI. The family size is always an individual or a couple. Please provide further clarification.

In this same section resource eligibility is addressed. It follows the income statement relative to family size. Will there be an allowance for dependents be taken into consideration in determining total resources?

(c) Individuals treated as full subsidy eligible.
(1) Full benefit dual eligible individual - Some individuals who are determined eligible for full benefits under Title XIX have income in excess of 135%/150% FPL. The assumption here is if an individual is eligible for full benefits under Title XIX, regardless of income, that individual is treated as a full subsidy eligible.
(2) SSI recipients
(3) Eligible as a QMB, SLMB, or QI.

Included under # 3 is the statement that... 'The State agency must notify an individual treated as a full benefit dual eligible that the individual is eligible for full subsidy of Part D premiums and deductibles and must either enroll with a PDP or MA-PD or be randomly assigned to a PDP or MA-PD.

Should this say an individual treated as a full subsidy eligible? If not, does this mean we are not required to notify QMBs, SLMBs, and QIs that are not otherwise eligible for Medicaid?

In either case, will CMS provide notice language? How will the State communicate the identity of those individuals receiving the notice to CMS? How will the random assignment be handled?

423.774 ? Eligibility determinations, re-determinations, and applications.

(a) Determinations of eligibility for subsidies under this section are made by the State under its State plan under title XIX if the individual applies with the Medicaid agency, or if the individual applies with SSA...

This legislation does not speak to the creation of a new Medicaid eligibility group for those individuals eligible for Part D subsidies like it did for QMBs, SLMBs, & QIs. However, the proposed regulation indicates the State is to determine eligibility for subsides under its State plan. Please provide further clarification.

(b) Assumption here is that there are no provisions for retroactive eligibility decisions.

(c) (1) Re-determinations and appeals must be made in the same manner and frequency as the re-determinations an appeals are made under the State?s plan.

Please provide further clarification.

Assuming that this legislation does not create a new Medicaid eligibility group, the State would not enter these individuals (those that are not eligible for Medicare cost-sharing) on it's Medicaid data base. Will specific instructions be provided with regard to how/where the State is expected to maintain subsidy eligibility for applications filed and re-determinations of eligibility for those individuals and how the State is expected to communicate that information to CMS?

Submitter : Mrs. Netta Boudreaux **Date & Time:** 09/20/2004 01:09:33

Organization : Mrs. Netta Boudreaux

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I understand that when the new Medicare prescription card becomes available in 2006 that will offer discounted drugs:
1) Medicaid will discontinue the prescription drug coverage for the disabled who have Medicare
2) Pharmaceutical companies who offer free or very low fee prescription drugs to those with low incomes will discontinue this offer for those who have Medicare.

My disabled brother is on SSI and receives a disability check for $691/month. His major expenditure is $ 500/month for personal care home leaving only $ 191 for everything else. Recently Mississippi made the decision to discontinue Medicaid drug coverage for the disabled, but then changed the decision for those with mental illness by receiving a waiver from the federal government. During the time we thought the drug coverage would be discontinued and there would not be a waiver, we checked quite a number of Medicare discount cards to see what the cost of his antipsychotic medications would be with the card. The lowest monthly cost we could find was over $ 600. Therefore, he would have had to choose between lodging/food/care at personal care home or his medications - neither would have been a viable option. However, we did find out that he could apply to the different pharmaceutical companies for assistance and his total monthly drug cost, if approved by all of them, would be about $ 50 - $ 60 monthly, which would have been affordable. We were, however, concerned about what he would do for drug coverage when he became sick with something like pneumonia or bronchitis (he had both at separate times this past winter). But thankfully, the waiver was granted and we didn't have to figure this one out. From this story you can see that we are VERY CONCERNED about what will happen when the 2006 Medicare prescription card becomes available if # 1 and # 2 as I have listed above become a reality. Will the discount available with this card be adequate for persons like my brother to continue to live in personal care home and take their needed medications?

CMS-4068-P-113

Submitter : Mrs. Donna Dedon **Date & Time:** 09/20/2004 01:09:07

Organization : Louisiana Medicaid Eligibility Section

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

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

423.904 - Eligibility determinations for low-income subsidies

This part of the regulations for the most part re-states what has already been stated. The State is required to make eligibility determinations in accordance with 423.774.

(b) Please see questions previously stated with regard to 423.774. How and where is the state to maintain application, re-determination information for subsidy eligible individuals that are not eligible for Medicare cost-sharing and enrollment under the State plan? How is the state expected to communicate full subsidy eligible eligibility?

(d) It is our practice to screen any individual who applies for Medicaid for all Medicaid programs.

These will not be actual Medicaid applications but yet the Medicaid agency must determine eligibility under its State plan. Based on (c)(2) are we required to give them the choice of enrolling for Medicare cost-sharing or can we just approve them for Medicare cost-sharing. What if the individual chooses not to enroll for Medicare-cost sharing?

If we screen these applications and enroll for Medicare cost sharing, we will add these individuals to the Medicaid enrollment data base. What then?

Does this mean that each time we approve an individual who has Medicare for Medicare cost-sharing (QMB, SLMB or QI) as well as for other full dual eligibility but w/o QMB, SLMB, or QI eligibility that we are required to send a separate notice of deemed subsidy eligibility per 423.34(d)? Is this the same notice addressed in 423.773?

Past instructions relative to Medicaid eligibility for Medicare cost-sharing is that States were required to using the methodology of the Supplemental Security Income program to determine income and resources. The instructions given in these regulations seem to indicate a more liberal treatment of income and resources.

Additionally, those individuals currently eligible for full Medicaid benefits under Title XIX who under this legislation are identified as full benefit dual eligibles entitled to full subsidy eligibility are not in all cases eligible for Medicare cost-sharing under QMB or SLMB because income is above the 135% limit.

Also there have been additional comments etc., that 'While the statue permits applications for low-income assistance to be accepted and processed at either Medicaid offices or SSA offices, CMS has been working closely with SSA to implement a consistent and timely system that is coordinated between the states and SSA. SSA is developing a simplified, scan-able, application that can be filed, in person, via the phone or the Internet. State personnel may use the SSA application when assisting beneficiaries with enrollment and forward such application to SSA. SSA will accept applications from states and process such applications and be responsible for associated re-determinations and appeals.'

What and when will the States true role in the process be clearly defined?

CMS-4068-P-114

Submitter : Chris Willoughby **Date & Time:** 09/20/2004 03:09:28

Organization : Concept Medical Technologies, Inc.

Category : Device Industry

Issue Areas/Comments

Issues 1-10

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

One area of tremendous concern is in medication therapy management. Medication noncompliance, not taking prescription medications as prescribed, is a huge burden on the country and the care givers. Here are a few facts to show how big a problem this is: 3rd leading cause of preventable death, 125,000 deaths/year from cardiovascular alone, 10% of hospital admissions, 25% of long term care facility admissions and over $100 billion/year is spent on the complications of noncompliance. Any steps taken to help insure the compliance of medication regimes will cut the financial burden of the Medicare program in other areas as well.

Any effort and or funding for compliance packaging or devices utilizing compliance packaging will be a giant step forward in keeping the aging population independent and healthier. Medications are prescribed in amounts that will optimize the clinical effect of the drug for the benefit of the patient. The desired outcome of the medication can not be achieved and patient improvement not obtained if the regimes are not followed. Advancement of the illnesses and diseases will occur further debilitating and exacerbating the problems.

The intent and main focus of this new law is to help our nation?s quickest growing population segment. One of the main problems with this segment is losing independence and the ability to care for oneself. We as a nation are going to provide them with the much needed medications and we need to also provide aids in insuring that these life giving medications are taken properly to achieve the desired effect.

CMS-4068-P-115

Submitter : Mr. Lee Osborn **Date & Time:** 09/20/2004 03:09:06

Organization : Thrifty White Drug Stores

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

As the regulations are currently written and being proposed, community pharmacy is being dealt several severe blows and as a result, we are at risk of losing a big portion of our Medicare patient prescription base to mail order. Here are key issues that need to be addressed.
Key issues:

1. The proposed regulations do not properly implement the so-called TriCare pharmacy access standards that are in place today, and therefore would seriously reduce the ability of patients to obtain their prescriptions from their trusted local community pharmacist.

2. The new regulations should prohibit plans (PBMs) from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.

3. The regulations must include more specificity in the medication therapy management (MTM) program. Currently, regulations do not define the nature and scope of MTM services that the plans would have to provide, such as who would be eligible to provide these services (pharmacist? Nurse? Telephone service?) and how providers would be compensated for these services.

Sincerely,
Lee Osborn

CMS-4068-P-116

Submitter : Mr. Alberto Zelaya **Date & Time:** 09/20/2004 03:09:56

Organization : Mr. Alberto Zelaya

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

HIV positive patients MUST have access to ALL FDA approved medications to fight the desease, specially now a days when so many of us are becoming drug resistance.

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

Sincerely,

Alberto Zelaya
106 N. Edgemont Street
Los Angeles, CA 90004

CMS-4068-P-117

Submitter : Mr. Gary Boehler **Date & Time:** 09/20/2004 04:09:25

Organization : Thrifty Drug Stores, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

1. It is imperative that the TriCare standard of accessibility be maintained as it is today to insure rural access to patients. PBMs push is to have this broadened, only from the perspective that they can then drive these patients to mail order, and not worry about face to face contact with a pharmacist. They are being greedy and self serving. PBMs have no concerns about the elderly or those impaired risking accessibility to a local pharmacy. Their claim is that mail order can work for everything - we all know that claim is false based on the history of mail order not performing up to the standards of the local community pharmacy.
2. There must be no economic incentives to coerce Medicare recipients to use mail order. Again, a common tactic used by PBMs to NOT offer a level playing field for community pharmacy and again,a self serving agenda. Contracts offered for mail service must match what a mail order facility will accept (in terms of NDCs being used, AWPs being used, MAC lists being used, and spread pricing being disallowed completely).

3. Pharmacists need to be addressed specifically as the professionals to administer medication management services for Medicare recipients and rates determined with an annual escalator clause that matches the national rate of inflation. PBMs again want to address this, and their plan will likely be to push MTM to some kind of telephone service, which to date has proven to be ineffective and misses the majority of patients needing MTM! Nothing can match outcomes that a patient has with a face to face counseling session with his/her pharmacist.

4. A major flaw in the current law is the inability of the government to negotiate costs of drugs with manufacturers. If this is not repealed and changed to require negotations of price, we will be looking at these same issues of double digit increases in prescription drugs one year, five years, and ten years from now. With no controls, manufacturers will continue to raise prices at will with no controls in place. It is interesting to note that with Schering Plough, before Claritin went off patent and Clarinex came on to replace it, Claritin had six price increases in 16 months totaling a whopping 37%!!!!!! Then Clarinex was brought onto the market and Schering Plough touted the fact that is was 5% less than the cost of Claritin. What a numbers manipulation game! I am sure there are other examples. One only needs to research other manufacturers.

5. There must be full and absolute disclosure by PBMs on arrangements they have with pharmaceutical manufacturers on any kickbacks they receive. Note the word kickbacks and not rebates. The way these monies flow from the manufacturers to the PBMs and the demands placed by the PBMs, it is little short of extortion, i.e., 'you play my game or you won't play at all.' PBMs do not lower costs of prescriptions. They are a major factor in rising prescription costs with kickbacks they demand from manufacturers and spread pricing in which plan sponsors are charged more than the provider is being reimbursed.

CMS-4068-P-118

Submitter : Ms. Kirsten Schwiesow **Date & Time:** 09/20/2004 04:09:05

Organization : Ms. Kirsten Schwiesow

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

A number of individuals living with HIV do not have the financial resources to pay for their life saving antiretroviral medications. If individauls are required to rely on Medicare for their prescription medications, a large number of individuals will no longer be able to pay for these medications. In addition, ADAP (AIDS Drug Assistance Program)which does provide coverage, in many states has waitig lists or is cutting down its programs as a result of lack of funds. Taking individuals off Medicaid will only increase the burden and create a society where individuals who need living saving medication may not be able to recieve them.

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

Sincerely,

Kirsten Schwiesow
3954 N Fremont, #2
Chicago, IL 60613

CMS-4068-P-119

Submitter : Dr. Leida Javier-Ferrell **Date & Time:** 09/20/2004 04:09:40

Organization : Mobile AIDS Support Servces

Category : Social Worker

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 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.

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

Sincerely,

Leida Javier-Ferrell, PhD
Executive Director
Mobile AIDS Support Services

CMS-4068-P-120

Submitter : Mrs. Shannon Kadlec **Date & Time:** 09/20/2004 04:09:58

Organization : Home Touch Interiors

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Hello,

I feel it is very important to be able to go into the local drug store to get my prescriptions. I don't want to receive them in the mail. I want to be able to discuss the medication with my Pharmacist that I know and trust.

Sincerely,

Shannon Kadlec

CMS-4068-P-121

Submitter : Dr. Susan Cu-Uvin **Date & Time:** 09/20/2004 05:09:38

Organization : The Miriam Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

We have a clinic of over 1,000 patients and a number of them have medicare. There is an urgent need for people with HIV to have full access to treatment, regardless of ability to pay.

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

Sincerely,

Susan Cu-Uvin, M.D.
Director, The Immunology Center
The Miriam Hospital, Brown University

CMS-4068-P-122

Submitter : Gail Souare **Date & Time:** 09/20/2004 05:09:15

Organization : Souare Consulting

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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.

AIDS is a debilitating disease, and it is essential that people living with HIV have full access to treatment, regardless of ability to pay. Unfortunately, HIV/AIDS disproportionately affects women and persons of color, those very persons who are more likely to be low income and have limited access to heatlh care services. It is the government's responsiblity to assist those persons.

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

Sincerely,

Gail Souare
Souare Consutling
5635 Trinidad Way
San Diego, CA 92114

CMS-4068-P-123

Submitter : **Dave Mendenhall** **Date & Time:** **09/20/2004 05:09:15**

Organization : **Dave Mendenhall**

Category : **Social Worker**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Roughly 60,000 PWAs could lose their comprehensive prescription drug coverage in 2006.
According to regulations being drafted, Medicare recipients will no longer be allowed to rely on Medicaid for their prescription drug coverage.
Instead, they will be forced into the new Medicare Rx plans with limited drug coverage. These plans are not required to provide all FDA approved antiretroviral drugs.
This is a huge flaw and other kinds of people with costly diseases/treatments will also be impacted.
The rules need to require that benefits won't be lost under the new rules.

CMS-4068-P-124

Submitter : Mr. Marc Yanow, R.Ph. **Date & Time:** 09/20/2004 06:09:09

Organization : MOON LAKE PHARMACY

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

My name is: Marc Yanow, RPh. I am the pharmacist and owner at Moon Lake Pharmacy in Schaumburg, IL.

My response to [CMS-4068-P] is as follows:

We service AL facilities with customized packaging. Many of the services we provide the residents of these facilities are seperate and distinct from the dispensing process.

1. MTMP are direct proactive interventions designed to enhance patients' ability to take medication correctly and increase patient medication compliance.
2. MTMP is a DIRECT patient care service performed by a pharmacist interacting with a patient and their medications.
3. MTMP include case management and patient counseling, customized packaging and refill management, and specialized patient medication reminders. Customized packaging must conform to United States Pharmacopea (USP) standards.
4. MTMP are generally of an ongoing nature, involving an initial patient intake assessment, followed by routing patient monitoring at regular intervals.
5. MTMP must be reimbursed as a management fee, NOT a dispensing fee. Costs associated with MTMP are seperate and distinct from those costs associated with dispensing.
   * Intake assessment: 30-45min of pharmacists' time per occurrence
   * Monitoring and follow-up: 15-25 minutes of pharmacists yime per occurence.

Please consider these points before you make your final decision.

Thank you...

CMS-4068-P-125

Submitter : **Mr. David Brakebill** **Date & Time:** **09/20/2004 06:09:24**

Organization : **Florida Keys HIV Community Planning Partnership**

Category : **Consumer Group**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

We request that there be special provisions made for Persons Living With HIV/AIDS with regards to formulary and access. By creating a co-pay system, many of our economically disadvantged clients will be in far worse financial and health states than already exist. We urge you to find an appropriate and immediate needs to this special population of individuals, who will soon be faced with many of the same choices facing our seniors and disabled brothers and sisters.

CMS-4068-P-126

Submitter : Pete Ciaramita **Date & Time:** 09/20/2004 06:09:26

Organization : Pete Ciaramita

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

My name is Pete Ciaramita and I am a pharmacist at Lakeview Pharmacy.
My response to "Medicare Prescription Drug Benefit" (CMS-4068-P) is as follows:
1. MTMP are direct proactive interventions designed to enhance patients ability to take medicine correctly and increase patient medication compliance
2. MTMP is a direct patient care service performed by a pharmacist interacting with a patient and their medications
3.MTMP include case management and patient counseling, customized packaging and refill management, and specialized patient medication reminders. Customized packaging must conform to United States Pharmacopoeia (USP) standards.
4.MTMP are generally of an ongoing nature, involving an initial patient in-take assessment, followed by routine patient monitoring at regular intervals.
5. MTMP must be reimbused as a management fee, NOT as a dispensing fee. Costs associated with MTMP are separate and distinct from those costs associated with dispensing.
 * In-take assessment: 30-45 minutes of pharmacists time per occurrence:
 * Monitoring and following up: 15-25 minutes of pharmacists time per occurrence

CMS-4068-P-127

Submitter : David Rueter **Date & Time:** 09/20/2004 06:09:09

Organization : Thrifty White Pharmacy

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

I work for a small chain of pharmacies that primarily serve rural communities. Access to the local pharmacy, often the only pharmacy in town, is critical. Mail order can not serve the needs of a patient needing an anti-biotic or a pain med. The Tri-Care standard of accessibility needs to be the minimum guideline for the plan. We are seeing PBM contracts that use much lower standards of coverage in order to force patients to use the PBM's own mail order pharmacy. Service to the rural patient has to come before the profits of the PBM. A patient should not be required to drive 60 miles to have a script filled or be forced to go to mail order. Allowing the PBMs to coerse patients to use mail order facilities will force the closure of many pharmacies. A business can not survive if it loses 40% of it's business and the remaining 60% is reimbursed at levels that currently just keep the doors open. Hundreds, or thousands, of pharmacies will close for good if Medicare allows the PBMs to force patients to mail order.
2.) Please include strong safeguards to prevent Plan Providers from coersing patients into mail order. Contracts offered to providers for mail service must match what a PBM's own mail facility will accept. To prevent fraud, the best method would be too prevent the Plan Provider from using it's own mail order pharmacy from filling scripts within the region. The government has seen the danger of allowing an entity to refer business to itself and created the Stark Laws to address this. It's time the same standard applies to prescription drugs. The system of rebates, spread pricing and private NDCs has to be cleaned up. At a minimum, all willing mail order providers must be able to use the same NDCs that PBMs create for themselves, use the same MAC lists and outlaw spread pricing. The middleman has added huge costs to the system. The average cash prescription filled in the United States was $41 las year and the average prescription price when a PBM was used was $59. Where is the alledged cost savings? Why are PBMs and drug manufacturers the businesses with the highest earnings of all companies in the country?
3) More detail needs to be added to the Medication Management Services plan. Pharmacists need to be the professioonal administering this care. A minimum compensation level needs to be specified or the PBMs will offer so little that we can't afford to offer the service. We have seen enough "take it or leave it" contracts from the PBMs to know what will happen if a rate is not established.
4.) The law needs to be ammended to allow the government to use it's purchasing power to negotiate prices directly with the manufacturers. Prescription drug prices rose 11% last year. A 15% savings this year off the new retail does not amount to much savings for the government.
5.) The entire business model of the PBM has to be changed. Medicare should not perpetuate such a corrupt system full of rebates (kickbacks), spread pricing where the plan sponsor is charged more for a drug than the provider is paid, secret deals with manufacturers to promote the manufactur's branded drugs and coersive contracts that sacrifice care to the patient. The system is seriously flawed when the middleman makes more profit on a prescription due to rebates and pricing games than the professional dispensing the medication, stocking the expensive inventory and speaking directly with the patient receives. There is no sense in Medicare spending billions of dollars to "incentivise" PBMs to provide coverage. Especially not when TriCare is already able to provide the service for less money. Profit, not patient care, is the driving force for the middleman. Their own SEC filings state that "acquiring" the refill prescriptions from pharmacies is their growth strategy. Medicare should not encourage the demise of the nation's pharmacy network.

CMS-4068-P-128

Submitter : Mr. Gregg Smith **Date & Time:** 09/20/2004 07:09:57

Organization : Registered Pharmacist

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

?Writing in reference to file code CMS-4068-P to express concerns regarding access and quality aspects of the proposed regulations issued August 3, 2004, that would implement the new Medicare Part D prescription drug benefit program beginning in 2006.
?The proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA; and, therefore, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist.
?The regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.
?The regulations must include more specificity in the medication therapy management (MTM) program. Currently, they do not define the nature and scope of MTM services the plans would have to provide, such as who would be eligible for these services, and how providers would be compensated for these services.

CMS-4068-P-129

Submitter : **Mr. Rory Rickert** **Date & Time:** **09/20/2004 07:09:14**

Organization : **Integrated Healthcare Services**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Integrated Healthcare Services, founded in 1992, helps organizations analyze, target and ultimately grow in the public-sector healthcare market. We offer our assistance to the healthcare marketplace employing a proven, disciplined process that has enabled IHS to help its clients win more than $7 billion in contracts over the last 12 years.
Public-sector healthcare faces many challenges. By 2005, roughly one in five people in the United States will be eligible for Medicare. There is a renewed focus on DoD/VA information sharing, benefits, resources as well as improved coordination between the DoD and VA. Public-sector healthcare resources are now challenged at every level. DoD?s resources are currently focused on wartime efforts and maintaining mission readiness. The VA, both as a whole and as a backup resource to DoD, has new access and care issues that are stretching its capacity to deliver on its mission. Other traditional federal healthcare organizations, including NIH, CDC, and the FDA, also face increased occupational health demands amidst new requirements to address emerging diseases and public heath threats. Government officials are confronted with the daunting task of managing increased costs while striving to develop and maintain viable healthcare programs. CMS itself is faced with implementing the rest of the Medicare Modernization Act of 2003 in addition to its traditional role as managing the existing Medicare and Medicaid program.
To this end, CMS faces a daunting task of providing health care payment coverage for not only the nation's Medicare eligibles, but to those who are eligible for Medicaid as well. With the responsibility of assisting tens of millions of individuals meet skyrocketing healthcare costs, CMS must constantly identify new and innovative ways of reducing overall program costs in the face of increasing financial demands. Over the past four years, CMS has initiated pilot disease management programs in an attempt to develop solutions to the nation?s healthcare dilemma and has invested heavily in creative cost cutting measures
IHS welcomes the opportunity to comment on the issues surrounding coordination of benefits in pharmacy that are contemplated in the MMA and on the interim final rules being proposed.
We acknowledge that COB for pharmacy expenditures as it relates to the volunteer Part D enrollees presents significant challenges. Some of these challenges include legislative mandates for CMS to administer, while others arise from the current lack of automated COB in pharmacy claims payment today.
Although voluntary, one may predict a significant adoption of the Part D funded drug benefit. Many beneficiaries have access to other health insurance coverage vehicles. Prudent management of the Medicare Trust Fund dictates that, where possible, other primary, secondary or tertiary payors be billed for covered drugs dispensed to eligible Medicare beneficiaries. In this spirit, we offer comments, and make ourselves available to comment further should CMS so desire.
Our understanding is that COB is required whether the drug benefit is managed by a Medicare Advantage plan (MA) or by a Prescription Drug Plan (PDP). There may be some variability depending on the nature of the 'other' drug plan with which the coordination takes place. SPAP, for example, cannot be assessed fees for COB.
The two points we would like to make in this discussion are that the fragmentation of other health insurance makes adoption of an elegant, simple pharmacy COB impossible employing the current claims processing and adjudication environment. Secondly, even though more than 98% of funded pharmacy prescriptions are handled electronically, making even small changes to these highly structured, standardized systems to support CMS on COB, is a monumental task fraught with risk to all parties involved. (continued-see next page)

CMS-4068-P-130

Submitter : Mr. Paul Bucceri Jr **Date & Time:** 09/20/2004 07:09:42

Organization : Mr. Paul Bucceri Jr

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,

I would like to make the following points:

? Writing in reference to file code CMS-4068-P to express concerns regarding access and quality aspects of the proposed regulations issued August 3, 2004, that would implement the new Medicare Part D prescription drug benefit program beginning in 2006.

? The proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA; and, therefore, they would seriously reduce the ability of patients
to obtain their prescription medications from their trusted local community pharmacist.

? The regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.

? The regulations must include more specificity in the medication therapy management (MTM)program. Currently, they do not define the nature and scope of MTM services the plans would have to provide, such as who would be eligible for these services, and how providers would be compensated for these services.

Thank you for considering these points.

Sincerely,

Paul A Bucceri Jr.

CMS-4068-P-131

Submitter : Nechama Katz **Date & Time:** 09/20/2004 07:09:04

Organization : Nechama Katz

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services 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 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.

People with HIV need to have full access to treatment, regardless of ability to pay.

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

Sincerely,

Nechama Katz
629 South St.
Roslindale, MA
02131

CMS-4068-P-132

Submitter : **Joseph Mortz** **Date & Time:** **09/20/2004 07:09:10**

Organization : **Joseph Mortz**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

People on disability, SSDI and SSI can not afford to pay for prescriptions especially not for chronic medications

CMS-4068-P-133

Submitter : **Mr. Rory Rickert** **Date & Time:** **09/20/2004 07:09:46**

Organization : **Integrated Healthcare Services**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Continued from previous comment:
To establish a reference point for this comment paper, we will describe a prescription fulfillment scenario, and comment on the chain of events as they impact COB and also TrOOP.

A CMS beneficiary who has elected and enrolled in Part D, and also maintains secondary prescription coverage, will typically go to a retail pharmacy to get a prescription filled for a drug covered by both Medicare and their 'own' private insurance company.

The pharmacy filling the beneficiary's prescription will request the patient's drug card whereupon they will typically present their Medicare Part D card as it is provided from their MA, PDP or fallback plan administrator. The information on this card will allow the pharmacy to confirm eligibility and determine both the beneficiary's cost share and the balance due the pharmacy from the plan's PBM. Today, a sophisticated PBM may have the ability to track whether or not a beneficiary has other health insurance, but almost certainly does not have the ability to interface with a secondary payor in real time to accurately determine payment status --considering up-to date deductible status, out-of-pocket status, or any other parameter that must be considered to definitively validate beneficiary payment amounts.

Thus, a PBM gets enrollment and plan information only from those plans with which it conducts business and has previously aligned its electronic system. If this beneficiary?s other insurance company is not a customer of the same PBM, no coordination of real time benefits is possible for this beneficiary. Moreover, even if the secondary insurance company is a customer of the PBM and provides some level of COB support, it is typically only limited to a status flag in the beneficiary's eligibility record (with possible batch exchange of data to periodically update the status of deductibles or out of pocket maximums). Further complications arise when the parameters include other family members or non-pharmacy payments.

The beginning of a solution to this lack of required, real time information would have this PBM connect online, real time, to literally every public and private sector payor to ensure smooth electronic operations of COB. And even if this scenario were possible, the electronic systems operating today are not designed to support real time, online COB among multiple payors. The system as it exists today employs rigid timeout standards inside the PBM and will not support sending claims to multiple external sites during adjudication. Furthermore, dispensing pharmacists are dependent upon split second responses, and the COB management as proposed would disrupt their ability to handle an ever increasing workloads resulting in a clogged system with drastically slow, complex transactions which would require complex rerouting to multiple sources in order to determine the correct beneficiary cost share and pharmacy receivable for every prescription.

Without all of these connections, the pharmacy and beneficiary will only have access to the coverage due from the primary insurer noted on the card. The time pressures of filling prescriptions in the high volume retail pharmacy environment ensures that pharmacies will not (or can not) trigger two, separate electronic claims systems: one for primary, and another for secondary coverage, even if the information needed to accomplish this requirement was provided on the beneficiary?s drug card. And even if PBMs could, as a customer service incentive, perform a dual eligibility and validation check, the status of the deductible and coverage maximums will rarely be accurate or up to date, necessitating difficult follow up efforts from the beneficiary. (continued-see next page)

CMS-4068-P-134

Submitter : **Mr. Ralph Cline** **Date & Time:** **09/20/2004 07:09:55**

Organization : **Kmart Pharmacy Manager**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

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

I am writing to express concerns regarding access and quality aspects of the proposed regulations issued August 3, 2004, that would implement the new Medicare Part D prescription drug benefit program beginning in 2006. The proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA; and, therefore, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist. The regulations should prohibit plans from using economic incentive that coerce beneficiaries to use mail order services to obtain their medications. The regulations must include more specificity in the medication therapy management (MTM)program. Currectly, they do not define the nature and scope of MTM services the plans would have to provide, such as who would be eligible for these services, and how providers would be compensated for these services.

CMS-4068-P-135

Submitter : **Mr. Joseph Mortz** **Date & Time:** **09/20/2004 07:09:24**

Organization : **Singingheart, Inc**

Category : **Consumer Group**

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 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.

[INSERT PERSONAL STATEMENT HERE. If you are on Medicare, talk about how these regulations will affect you. Otherwise, write a couple of sentences about the need for people with HIV to have full access to treatment, regardless of ability to pay.]

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

Sincerely,

CMS-4068-P-136

Submitter : Mr. Rory Rickert **Date & Time:** 09/20/2004 07:09:19

Organization : Integrated Healthcare Services

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Continued from previous comment:
The realities of the practice of pharmacy today, including prescriptions entered but never picked up, and a myriad of factors that require claim adjustments, --do not align with realities of a real time COB system. Put simply, a real time COB system requires stable, clean claims data which is still a distant reality given current business practices and the existing technical healthcare infrastructure. Even if PBMs were wired real time to the whole world of payors, because claims data is unstable, the COB accumulators cannot perform accurate adjudication

Since the mid 1990s, attempts to automate prescribing have been instituted to improve both system efficiency and patient safety. The proliferation of the Internet offered the illusion that these attempts would quickly succeed, but for many reasons electronic prescribing is still being adopted very slowly. Even if e-scribing were broadly adopted, its value is limited to helping prescribers choose covered/preferred drugs and eliminate some inefficiencies in delivering a prescription to the beneficiary's pharmacy of choice. e-scribing will not have an impact in improving COB, as we have discussed in this paper or as currently contemplated by the MMA.

A better solution than simply connecting every PBM to every public and private sector payor would be to centralize COB information as part of the Medicare Eligibility Database. A range of outcomes can be envisioned, depending on how robust and real time the COB data transfer occurs using a centralized database. One way to maximize the value of this central database is to query the database during pharmacy claims adjudication. Alternatively, a COB data extract, including deductible and TrOOP status, could be periodically delivered to the PBM for claims processing.

If all public and private payors communicated to this centralized database in near real time, one could potentially anticipate improvements in the beneficiary and pharmacy experience and assign prescriptions claims liability to alternative payors and decreasing monies spent from the Medicare Trust Fund on prescriptions.

If a beneficiary has wrap-around coverage, without complete alignment with the primary Part D plan, confusion could reign for that beneficiary. Any misalignments of formulary, or benefit design options, like prior authorization, could leave the beneficiary in a difficult follow-up loop. A drug covered by the Part D plan with no prior authorization, but covered only by the secondary payor with prior authorization, is one such example; a drug covered by the Part D plan that is excluded by the wrap around plan is another example where the electronic claims systems can handle complexity, but the beneficiary may be left struggling to understand why different prescriptions pay differently under COB between the same two payors. (continued-see next page)

CMS-4068-P-137

Submitter : **Mr. Rory Rickert** **Date & Time:** **09/20/2004 07:09:55**

Organization : **Integrated Healthcare Services**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Continued from previous comment:
Keeping the TrOOP up to date is another obstacle that must be overcome, given the definition. Excluding administrative fees, that may be included in claim costs, and trying to capture the value of rebates which are traditionally paid six months after the pharmacy claims occurs, would surely complicate the beneficiary experience with the entire process.

The TrOOP rules themselves introduce complexity in maintaining accurate accumulators in a COB system. For example, in the case of certain beneficiaries, costs paid by anyone other than the beneficiary themselves may still accumulate to their TrOOP; but for other types of beneficiaries this may not be the case. Also changes in coverage decisions after a successful appeal from the beneficiary are yet another example of why an individuals TrOOP may be inaccurate for payment determination on all claims prior to posting an adjustment. The rules themselves may not be difficult to program, but the collection of real time data from all entities that may cover, including premiums, co-pays, claim costs, or other costs on behalf of certain beneficiaries, points out how many connections need to exist to even attempt to keep the TrOOP correctly updated.

In addition to TrOOP complexities, the reassignment of certain drugs covered under Part B to Part D is another area that may cause both COB complexity and beneficiary confusion, due to the complicated nature of coverage criteria. Even it the pharmacy standardized claims format contained fields to report information, to differentiate coverage, pharmacies do not have access to the data necessary to make a claim payable under the varying rules under Medicare Parts B and D.

The likelihood of collecting diagnosis, site of service, or other non standard fields is low.
Beneficiaries with the highest current or anticipated drug use and expenditures are most likely to try and maintain wrap-around or SPAP coverage, and by definition will cause the most COB/TrOOP beneficiary service issues. The only way to reasonably minimize this impending confusion is to employ a centralized database with the capacity to support these complex tracking functions.
For further information, please contact Rory L. Rickert, R.Ph. (408) 451-0148

CMS-4068-P-138

Submitter : Dr. Lawrence Bryer **Date & Time:** 09/20/2004 07:09:28

Organization : Dr. Lawrence Bryer

Category : Physician

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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 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 am a physician, no longer able to work due to complications of diseases which include HIV. My medications are currently covered by my former employer, which happens to be a health plan. (I have part B of Medicare, and assign my benefits to the health plan.) I am not sure how these regulations will affect my particular situation, but I note my situation because it illustrates some of the problems for people with HIV.

I am a long term survivor of HIV, having been infected during a surgery in 1982. Through the years, I have been on several antiretroviral drugs. Some have been discontinued due to the development of viral resistance, and some due to side effects that continue to affect my daily function years after their discontinuation. The discontinued medications no longer have any value in my treatment. Because of this limitation, it is imperative that my own physician be able to prescribe from the full gamut of antiretroviral medications available. Any attempt to limit the drugs he may prescribe is an effective death sentence for me and for many, many others in similar situations.

The need to have access to the full pharmacopeia is not limited to medications for HIV. I am affected by illnesses other than HIV. Some treatments used for my other problems are contraindicated in the presence of some antiretroviral medications. There are problems such as an incompatibility in metabolic pathways, which leads to drug toxicity or viral resistance. Some medications for my other major disorder, which is autoimmune in nature, have uncertain, but probably permanent effects on the immune system. In the presence of HIV, these effects may well be fatal. My physicians must, therefore have access to the entire range of approved drugs to treat all of my conditions. They have that access now, when it's needed. I am concerned that new regulations not remove that access.

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

Sincerely,

Lawrence W. Bryer, MD
5131 Parkridge Dr.
Oakland, CA 94619

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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:

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I am a long term survivor of HIV, having been infected during a surgery in 1982. Through the years, I have been on several antiretroviral drugs. Some have been discontinued due to the development of viral resistance, and some due to side effects that continue to affect my daily function years after their discontinuation. The discontinued medications no longer have any value in my treatment. Because of this limitation, it is imperative that my own physician be able to prescribe from the full gamut of antiretroviral medications available. Any attempt to limit the drugs he may prescribe is an effective death sentence for me and for many, many others in similar situations.

The need to have access to the full pharmacopeia is not limited to medications for HIV. I am affected by illnesses other than HIV. Some treatments used for my other problems are contraindicated in the presence of some antiretroviral medications. There are problems such as an incompatibility in metabolic pathways, which leads to drug toxicity or viral resistance. Some medications for my other major disorder, which is autoimmune in nature, have uncertain, but probably permanent effects on the immune system. In the presence of HIV, these effects may well be fatal. My physicians must, therefore have access to the entire range of approved drugs to treat all of my conditions. They have that access now, when it's needed. I am concerned that new regulations not remove that access.

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

Sincerely,

Lawrence W. Bryer, MD
5131 Parkridge Dr.
Oakland, CA 94619

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

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 with HIV/AIDS who will receive their treatment through this benefit.

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I am a physician, no longer able to work due to complications of diseases which include HIV. My medications are currently covered by my former employer, which happens to be a health plan. (I have part B of Medicare, and assign my benefits to the health plan.) I am not sure how these regulations will affect my particular situation, but I note my situation because it illustrates some of the problems for people with HIV.

I am a long term survivor of HIV, having been infected during a surgery in 1982. Through the years, I have been on several antiretroviral drugs. Some have been discontinued due to the development of viral resistance, and some due to side effects that continue to affect my daily function years after their discontinuation. The discontinued medications no longer have any value in my treatment. Because of this limitation, it is imperative that my own physician be able to prescribe from the full gamut of antiretroviral medications available. Any attempt to limit the drugs he may prescribe is an effective death sentence for me and for many, many others in similar situations.

The need to have access to the full pharmacopeia is not limited to medications for HIV. I am affected by illnesses other than HIV. Some treatments used for my other problems are contraindicated in the presence of some antiretroviral medications. There are problems such as an incompatibility in metabolic pathways, which leads to drug toxicity or viral resistance. Some medications for my other major disorder, which is autoimmune in nature, have uncertain, but probably permanent effects on the immune system. In the presence of HIV, these effects may well be fatal. My physicians must, therefore have access to the entire range of approved drugs to treat all of my conditions. They have that access now, when it's needed. I am concerned that new regulations not remove that access.

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

Sincerely,

Lawrence W. Bryer, MD
5131 Parkridge Dr.
Oakland, CA 94619

CMS-4068-P-139

Submitter : Kate Crockford

Date & Time: 09/20/2004 08:09:54

Organization : Kate Crockford

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Refusing anti-retrovirals to AIDS or HIV patients is unjust and will serve to further the deepening public health crisis in our society. Those who are suffering the worst need the most help, and such an attempt to strip people of their lives for the benefit of bloated pharmaceutical companies is unacceptable.

CMS-4068-P-140

Submitter : | **Date & Time:** 09/20/2004 08:09:06

Organization :

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

1. The proposed regulations do not properly implement the so-called TriCare pharmacy access standards that are in place today, and therefore would seriously reduce the ability of patients to obtain their prescriptions from their trusted local community pharmacist.

2. The new regulations should prohibit plans (PBMs) from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.

3. The regulations must include more specificity in the medication therapy management (MTM) program. Currently, regulations do not define the nature and scope of MTM services that the plans would have to provide, such as who would be eligible to provide these services (pharmacist? Nurse? Telephone service?) and how providers would be compensated for these services.

CMS-4068-P-141

Submitter : Mr. Paul Pelanek **Date & Time:** 09/20/2004 08:09:57

Organization : Representing no organization

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

? Out-of-Network Pharmacies ? The proposed regulations are impractical and inconsistent with the way current industry practices operate. The maxim of ?any willing provider? should prevail if the pharmacy is able to meet the set standards. Under the proposed regulations if the pharmacy the patient chooses is not on the preferred or non-preferred lists, it is out of network which brings in a whole host of logistical issues in getting or accessing the necessary information to process the patient?s prescription including benefit information that the plan needs to give to determine the patient?s out of pocket cost for the prescription. This would be a real problem in rural areas where the choices are limited and the distance to drive can be substantial to get to a preferred or non-preferred plan pharmacy.

? Access Standards ? The regulations proposed would use the Department of Defense?s TriCare pharmacy access standards which frankly are ill-suited for the general population of seniors. The DOD knows from a historical basis that the military retiree population tends to cluster more than the senior population as a whole. Applying the TriCare standards for access in the general population, again for rural areas, provides a restrictive service network. Also, the access standards should be adjusted to use actual driving distance not simply ?within 5 miles? since in parts of the country the road design around natural impediments (rivers, lakes, mountains) just is the way it is.

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

? Standard Benefit Card ? The concept of standardization of the benefit card information is very important to improving the efficiency of how pharmacies process claims and resultant decrease in cost in resources to resolve eligibility issues and other sources of claim processing problems. Since many in the commercial payor market uses and support the NCPDP format, please make this format the standard for the Part D benefit.

? Medication Therapy Management ? The proposed regulations do not define several areas of implementation and that needs to be addressed. First, there is a not a standard package of Medication Therapy Management services defined that a Part D Plan has to provide and this can lead to wide differences of coverage within plans in the same region. Second, while the regulations state that pharmacies need to be paid for these services there is no definition of a minimum payment to the pharmacy. The temptation for the Plan is to set the reimbursement so low that the pharmacy affordability to provide these services may not be there. This needs to be addressed since the community Pharmacist is the prime point of contact and the ?face to face? interaction needs to be there to provide the quality of care that everyone would like to see happen.

PAYMENTS TO PDP AND MA-PD PLANS

? Definition of Negotiated Price/Differential Cost Sharing - The proposed regulations do not clearly define the ?negotiated price? of the prescription, but should reflect the net direct cost to the Part D Prescription Drug Plan and Medicare Advantage-Prescription Drug plan. This price should take into account all the rebates, volume discounts, and other financial tricks that the PBMs (Pharmacy Benefit Managers) use to advance their mail service prescription programs at the expense of the community retail pharmacies to try to drive prescriptions to the PBMs? mail service providers. I do not see the seniors needs being met fairly by being driven to mail service since many of them are easily confused in just managing their medications without the added burden and worry of running out with the consequences that follow. Also, Congressional intent does not allow for differential cost sharing requirements to shift beneficiaries to mail order.

CMS-4068-P-142

Submitter : | **Date & Time:** 09/20/2004 08:09:39

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
I am concerned with the area under Subpart C: Benefits and Beneficiary Protections dealing with the establishment of preferred and non-preferred pharmacies. As it is now, Plan Sponsors would determine which pharmacies make up the preferred group and not all pharmacies would be able to join that group. This means that plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. I believe that all pharmacies should be able to become a member of the preferred pharmacies to ensure fair competition between businesses.
Thank you for considering my opinion.

Sincerely,
A Concerned Pharmacy Student

Issues 1-10

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

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.
Under the section entitled Medication Therapy Management Program, it states that MTM services would be reimbursable when adopted by a plan and only when provided to targeted beneficiaries. As a pharmacy student who is about to be come a pharmacist, I feel it is the responsibility to provide MTM services to any patient in order that they fully understand their therapy and any associated problems that might arise with that therapy. It does not make sense that we should only be reimbursed for a select few patients when we provide these services to all patients.
Also further in the section, it states that CMS will not set a certain amount plans must pay pharmacists or other providers to provide MTMP services because CMS does not believe it has the authority to do so. If CMS is going to be paying pharmacists and other healthcare professionals for MTMP, they will be setting a setting a standard. If there is no standard, there could be much confusion on the issue with different plans reimbursing at different rates. This would not be fair either to the healthcare provider or to the insurance company. I believe that CMS should set a standard rate of reimbursement to avoid this confusion.

Thank you for considering my opinions.
Sincerely,
A Concerned Pharmacy Student

CMS-4068-P-143

Submitter : | **Date & Time:** 09/20/2004 08:09:43

Organization :

Category : **Health Care Provider/Association**

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 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.

With the number of individuals becoming infected it's imperative that coverage is provided for all, not just a select few of low end treatment options.

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

Sincerely,

Kel
Brooklyn, NY

CMS-4068-P-144

Submitter : Mr. Richard McCormick **Date & Time:** 09/20/2004 08:09:22

Organization : Mr. Richard McCormick

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

? Writing in reference to file code CMS-4068-P to express concerns regarding access and quality aspects of the proposed regulations issued August 3, 2004, that would implement the new Medicare Part D prescription drug benefit program beginning in 2006.

? The proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA; and, therefore, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist.

? The regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.

? The regulations must include more specificity in the medication therapy management (MTM)program. Currently, they do not define the nature and scope of MTM services the plans would have to provide, such as who would be eligible for these services, and how providers would be compensated for these services.

CMS-4068-P-145

Submitter : Eric Hamik **Date & Time:** 09/20/2004 09:09:20

Organization : Nebraska Pharmacist Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

I want to comment that the PBM companies are making an incredible amount of money just sitting there and letting there computer process the information. That is a large part of the increase in medications. It you would look in the late 70's and early 80's before they were involved drugs increased at a much lower percentage. What they are doing is just adding another layer of people making money off of prescriptions while we the pharmacists are the ones doing all the work and getting payed less and less. What I am trying to say is that you need to be cautious on who you pick to administer this plan and you need to be protective of the pharmacist. When encounter so many people everyday that cannot get any service or questions answered from their PBM or mail order pharmacy. Then take into account how confused the elderly are already. It could be a disaster if the patient doesn't have there community pharmacy to go to to get there questions answered. I am asking you to make the retail pharmacy the focus of this regulation. Without us this plan could be a disaster.

CMS-4068-P-146

Submitter : **Mr. laird miller** **Date & Time:** **09/20/2004 10:09:49**

Organization : **Mr. laird miller**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

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

Medication therapy Management should be performed by the patient's pharmacist. Through the use of computers, the pharmacist will have the most complete picture of the medication profile. Pharmacists have the most education in medications and how they affect patients. Pharmacists have the most ready access to patients. Pharmacists see more patients face to face. While other professions may choose to educate themselves about drugs, Pharmacists do it by training throuhout the educational process, they are trusted by their patients and they WILL do the best job of managing patients

Submitter : Mrs. Alana Podwika **Date & Time:** 09/20/2004 10:09:41

Organization : Mountain Park Health Center

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

September 20, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P Baltimore, MD 21244-8014
Re: CMS-4068-P

Dear Sir or Madam:
? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.
? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice Anticoagulation Disease Management Services. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

? Thank you for considering my view.

Sincerely,
Alana Podwika
VP Pharmacy
Mountain Park Health Center
635 E. Baseline Rd.
Phoenix, Arizona 85042

CMS-4068-P-148

Submitter : **Ms. Jody Klimek** **Date & Time:** **09/20/2004 11:09:58**

Organization : **Ms. Jody Klimek**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

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

Pharmacists are the ideal providers for MTMS. Beneficiaries should not have to obtain MTMS from a specific provider. Also, pharmacists should be allowed to provide MTMS to non-targeted beneficiaries and pharmacists should be able to bill patients directly for the services.

CMS-4068-P-148-Attach-2.doc

CMS-4068-P-148-Attach-1.doc

CMS-4068-P-149

Submitter : **Mr. Charles Barrera** **Date & Time:** **09/21/2004 12:09:59**

Organization : **Mr. Charles Barrera**

Category : **Individual**

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.

As a disabled individual with AIDS, I am not quite sure how the new rules will affect my ability to obtain the medications I depend on. My Social Security benefits fall well below poverty level and it is through the Medicaid program that I am currently able to receive my medications.

Without the Medicaid program, I do not know how I would manage to obtain the medications that I rely on. My yearly Social Security benefits ($6,600.00) fall well below the amount needed ($18,735.72) to obtain just three of the medications I am currently prescribed.

People with HIV should have full access to treatment, regardless of ability to pay.

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

CMS-4068-P-150

Submitter : **Mr. LeRoy Andresen** **Date & Time:** **09/21/2004 12:09:48**

Organization : **Thrifty White Drug**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

1) There are not proper provisions in place to properly implement the TriCare pharmacy access standards that are in place today and this would seriously reduce the ability of patients to obtain their prescriptions from their local pharmacist with whom they have an working relationship and can easily have thier questions & concerns addressed.
#2) The proprosed regulations should prohibit plans from using economic incentives to force patients to use mail order services to obtain their prescription medications.
#3) The regulations should include more specificity as to the medication therapy management (MTM) program. Current regulations don't define the nature and scope of MTM services that the plans whould have to provide, such as who would be eligable to provide these services (Nurse, pharmacist, telephone service?) as well as how these providers would be compensated for their services.

CMS-4068-P-151

Submitter : Mr. Brad Cherson **Date & Time:** 09/21/2004 12:09:40

Organization : Georgia Pharmacy Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

The correct utilization and oversight of drugs and management of disease should be delegated to pharmacists. Our training and motivation has been a long time coming, and I know these services will reduce errors, increase compliance, reduce drug usage due to improper prescribing, and benefit our geriatric community. Pharmacy schools have been training for these services for decades, it is time we get paid to expand our roles in the healthcare system. Use our expertise to better our elderly's quality of life.

CMS-4068-P-152

Submitter : Mr. Douglas Laing **Date & Time:** 09/21/2004 01:09:45

Organization : Mr. Douglas Laing

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Please do not cut off my AIDS medications in 2006 when the new Medicare drug benefits are scheduled to change. I have gone through this once already when Oregon cut us off until the governor stepped in and found a way to continue drug benefits for People With AIDS. I went without my meds for 2 months while the state was in chaos. My viral load went up and my health started to deteriorate. When drugs became available again I went back on the meds I was taking only to find out they no longer worked. I had now developed a resistance to all the present drugs approved by the FDA. After several months of worsening health, I finally got into a drug trial which is working great. Except that this new drug is hard on the liver and I have Hep C so this is hard, but there is nothing else available.

So cutting my drug benefits would be like writing my death certificate. It falls into the category of cruel and unusual torture. If I could I would take the burden off my government and more to a foreign country but as a foreigner I couldn't get medical coverage there either.

Douglas Laing - My life is in your hands.

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

Please do not cut off my AIDS medications in 2006 when the new Medicare drug benefits are scheduled to change. I have gone through this once already when Oregon cut us off until the governor stepped in and found a way to continue drug benefits for People With AIDS. I went without my meds for 2 months while the state was in chaos. My viral load went up and my health started to deteriorate. When drugs became available again I went back on the meds I was taking only to find out they no longer worked. I had now developed a resistance to all the present drugs approved by the FDA. After several months of worsening health, I finally got into a drug trial which is working great. Except that this new drug is hard on the liver and I have Hep C so this is hard, but there is nothing else available.

So cutting my drug benefits would be like writing my death certificate. It falls into the category of cruel and unusual torture. If I could I would take the burden off my government and more to a foreign country but as a foreigner I couldn't get medical coverage there either.

Douglas Laing - My life is in your hands.

CMS-4068-P-153

Submitter : Dr. Khue Nguyen **Date & Time:** 09/21/2004 02:09:37

Organization : Palo Alto Medical Foundation

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

While I appreciated CMS'recognition that pharmacists will be the primary provider for various aspects of medication management, I'm concerned that leaving the decisions to PDPs may allow PDPs to choose less qualified individuals. Please keep in mind that PDPs will try to minimize costs and one strategy is to spend less on human resources, such as employment of lower-paid individuals. Pharmacists are currently being employed by health plans, pharmacy benefit management companies, medical groups, and hospitals to provide cost and utilization management of medications. All working pharmacists participate in some aspects of medication therapy management, whether through providing drug information for the patient at a community pharmacy or through streamlining a medication regimen at an ambulatory care setting.

I run my own medication therapy management clinic for a medical group, with emphasis on geriatrics with high risk medications or polypharmacy. In order to find funding for this needed service, which supported one full-time pharmacist's salary, I had to prove the value of such services through a demonstration project with outside funding.

The hesitation from medical groups and health-care systems in funding pharmacists to provide such needed services comes from the lack of recognition by Medicare that pharmacists are health care providers. Consequently, their services are not being reimbursed by Medicare nor health plans and the medical institution must generate its own funding to support these services.

CMS-4068-P-154

Submitter : Mr. Michael Stiller **Date & Time:** 09/21/2004 02:09:55

Organization : Bellin Health

Category : Hospital

Issue Areas/Comments

Issues 1-10

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

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

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the followning MTM services in my practice at Bellin Health in Green Bay, WI including anticoagulation monitoring service, drug interaction review, formulary compliance, medication streamlining, drug selection and optimal dosing for CHF patients, and adverse event monitoring. Plans should be encouraged to use my services to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to having pharmacists provide the MTM service.

Thank you for considering my view.

Michael G. Stiller RPh
Bellin Health Systems
744 S. Webster Avenue
Green Bay, WI 54304
(e-mail: mgstil@bellin.org)
(phone: 920-433-3639)

CMS-4068-P-155

Submitter : Mr. Donald L Pepmeier ,Jr. **Date & Time:** 09/21/2004 02:09:58

Organization : Mr. Donald L Pepmeier ,Jr.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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 am an individual currently recieiving Medicare/Medicaid benefites that will be adversly affected by these changes. The presecription medications that I am required to take are too expensive for me to afford without my Medicare/Mediciad coverage. It is crucial that individuals like myself have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines. HIV affected individuals must continue to have full access to treatment, regardless of their ability to pay.

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

Sincerely,

Donald L. Pepmeier, Jr.
504A NE Brookwood Circle
Blue Springs, MO. 64014-2961

CMS-4068-P-156

Submitter : **Mrs. Isabelle Ley** **Date & Time:** **09/21/2004 03:09:55**

Organization : **Mrs. Isabelle Ley**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-4068-P-156-Attach-1.rtf

CMS-4068-P-157

Submitter : Dr. Christopher Harris **Date & Time:** 09/21/2004 03:09:44

Organization : Dr. Christopher Harris

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

As the pharmacy director of a 398 bed hospital I have seen our involvement in cost containment strategies, drug utilization, medications safety, quality improvement, and medication management increase dramatically over the last two years. In that period of time we have decreased costs, improved patient safety, and maintained or improved patient outcomes. The reality is that pharmacists are uniquely equiped to analyze drug therapy regimens and determine what course of action should be taken. There is no other medical professional that has been educated to keep long term costs under control while assuring safety and optimum care. In the hospital setting, lower cost professionals have been utilized for this type of function. The results have been less than stellar. As a result, the hospital industry and regulatory agencies are looking to pharmacy to play a larger role in establishing best practices, establishing formularies, ensuring medication safety, controlling costs and monitoring/adjusting drug regimens. The same logic should apply in the outpatient setting as applies in the inpatient setting. As a tax payer I urge you to utilize pharmacists exclusively in this capacity. Based on my experience they will provide superior results.

CMS-4068-P-158

Submitter : Ms. Bonnie Baris **Date & Time:** 09/21/2004 04:09:11

Organization : Ms. Bonnie Baris

Category : Social Worker

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 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 adherence to the HIV medicines is one of the most important treatments we have against the devastation of the disease. As a mental health therapist, I hear almost daily horror stories about the consequences of not having affordable access to medicines. It would be untenable to deny access to those medications for the people living with HIV/AIDS. We alrady compromise the individual's ability to access proper medical care with the cruelly long times they wait for approval for Medicaid. It would be cruel and unusual punishment to sweep this population under the rug and make them more marginalized and underserved.

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

Sincerely,

Bonnie Baris, LISW
143 South Monroe Avenue
Columbus, OH 43205

CMS-4068-P-159

Submitter : Ms. Jennifer Short

Date & Time: 09/21/2004 04:09:41

Organization : APhA-Academy of Student Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for allowing me to submit the following points to consider when revising the MPDB. As a student pharmacist, I want to know that my future patients receive the best benefit and choice protections possible.

Pharmacy Access Standards:

Pharmacists need to be able to serve their patients. To do that, the pharmacy access standard must be revised to require plans to meet the TRICARE requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy. If plans are only required to meet the pharmacy access standard ?on average? across the plan?s service area, the plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan?s pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor.

Any Willing Provider:

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

Level Playing Field:

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

Thank you!

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

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation. I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently see pharmacists providing MTM services at my internship site on a regular basis, and I myself am learning the skills needed to provide this valuable service within my PharmD education at the University of New Mexico. Optimizing drug therapy is achieved with the expertise of a pharmacist. I am concerned, however, that letting plans independently choose MTM providers will allow them to choose less qualified providers to provide MTM services. Plans should be encouraged to use pharmacist services allowing patients to make the best use of their medications.

Please consider the following points for MTMS:

Targeted Beneficiaries

? Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS).
? Who will benefit from MTM can change, so plans should be required to identify new targeted beneficiaries on a monthly basis.
? Plans should be required to inform pharmacists who among their patients are eligible for MTM.
? Pharmacists and physicians should also be able to identify eligible beneficiaries.
? Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
? Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
? CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.

Providers

? Pharmacists, the medication expert on the health care team, are the ideal providers of MTMS.
? CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships.

Fees

? Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
? CMS must carefully evaluate each plan?s application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

Services

? MTM services are independent of, but can occur in conjunction with, the provision of a medication product.
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as performing a health assessment, formulating a medication treatment plan, monitoring and evaluating a patient?s response to therapy, etc.
? Face-to-face interaction between the beneficiary and the patient is the preferred method of delivery whenever possible. The initial assessment should always be face-to-face.

I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004. (Definition and Criteria are available at http://www.aphanet.org/lead/MTMS_definition_FINAL.pdf).

CMS-4068-P-160

Submitter : **Donald Thibodeau** **Date & Time:** **09/21/2004 11:09:21**

Organization : **PillHelp Company, LLC**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

I have been market testing my polypharmacy information services and medication mangement tools for out patient physicians and consumers for five years. I have been charging $90.00 an hour and every patient except one has decreased med use to a degree that recovered their cost within three months. All patients and most physicians have agreed that quality of life has improved. Refer to www.pillhelp.com

CMS-4068-P-161

Submitter : **Mr. John Sahm** **Date & Time:** **09/21/2004 11:09:56**

Organization : **Mr. John Sahm**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

When drafting the policies on the new Medicare prescription coverage please be sure that persons with HIV are not left out. When we hear Medicare we often think of pensioners however there are many disabled people who rely on Medicare for their healthcare. HIV medication cocktails are some of the most complicated and costliest.

Management of HIV infection is a tricky game. Managing sources for prescription coverage has become an art to the many who struggle without insurance. Today there are many diverse ways to get HIV medications to low income individuals with HIV. Most of us use several programs at the same time to obtain our various medications. Some of these programs are:

Medicaid allows (3) Rx per month
State ADAP Program covers up to (4) HIV Rx per month with additional non HIV Rx for prophylaxis (funded by Ryan White Title II)
Harris County Hospital District covers drugs for county residents with very low income
Local ADAP for Houston EMA residents with low income (funded by Ryan White Title I)
Drug Company Patient Assistance Programs (last resort & difficult to apply for)
Phase II & III drug studies & Expanded Access Programs for those of us who are really desperate

Any new Medicare prescription plan must account for these various existing programs, especially Medicaid. The Ryan White funded items are tenuous at best. Last year our local ADAP program shut down when it ran out of funds. The State ADAP program is talking of implementing stricter eligibility guidelines to avoid running out of funds.

Other existing drug programs will see the Medicare Prescription Benefit as an opportunity to eliminate or at least reduce their existing programs. It is imperative that you consider all of these existing programs & the effect the Medicare Prescription Plan will have on them.

Thanks for doing the right thing.

John Sahm
1625 Longacre
Houston, TX 77055
713-647-9535

ELIGIBILITY, ELECTION, AND ENROLLMENT

GENERAL PROVISIONS

CMS-4068-P-161-Attach-1.doc

CMS-4068-P-161-Attach-1.doc

CMS-4068-P-162

Submitter : **Dr. Ann Vassey** **Date & Time:** **09/21/2004 11:09:39**

Organization : **VHA**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

The profession of pharmacy is held to high standards by both society and governing bodies of this country. A patient often has more contact and clinical intervention from a pharmacist than any other health professional. But our profession continues to be ignored when it comes to recognizing the value of our services to society. We continually are left out of reimbursement rules by our own government and insurance companies. Is this because we, as a profession, continue to give great care and service to society even in the face of no recognition?

I suggest it is time for our governing bodies to change their view of what is right.

CMS-4068-P-163

Submitter : | **Date & Time:** 09/21/2004 12:09:46

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Re: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. People with HIV/AIDS should have full access to treatment, regardless of ability to pay.

CMS-4068-P-164

Submitter : Mr. Phillip Potter, Jr. **Date & Time:** 09/21/2004 12:09:38

Organization : AIDS Coalition of Texas Now!, Triangle AIDS Networ

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 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.

As a consumer and advocate I believe that most of the people affected may already use a state ADAP program. This change would increase the burden on state ADAP programs which are already at capacity. Many ADAP programs across the nation have waiting lists. This change would in effect deny access to medications of many across the nation. I can't call this change to medicare beneficial. Medications for the HIV/AIDS pandemic are crucial in slowing the infection rates of HIV/AIDS across the country. Being from Texas, I recently read a report from our state health department show that in 2003 there were over 4,800 new infections. I can't imaging what 2004 will be like. These medications are a matter of life and death to many. Denying access will on further acerbate the already decaying health of our nation. Do you really want good health to be a luxury afforded only by our nation's wealthy?

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

Sincerely,

Phillip E. Potter,Jr.
6500 Purvis Road
Silsbee, Texas 77656

CMS-4068-P-165

Submitter : Dr. Philip Mahalik **Date & Time:** 09/21/2004 02:09:00

Organization : Il. Dept of Human Services

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

I support pharmacist payment for cognitive services

CMS-4068-P-166

Submitter : **Dr. Ralph Kendall** **Date & Time:** **09/21/2004 02:09:26**

Organization : **Dr. Ralph Kendall**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

We have for some time been charging for a retrospective drug regimen analysis based on a historical review of clinical documentation and prescription claims. These reviews are quite extensive and encompass an assessment of every type of potential problem observed in the patient regimen. We have been billing and have been paid at the rate of $250 per hour for these complex reviews. Our typical billing is in the range of $800-$1,200 per review. These reviews are used by consulting physicians in pursuing possible drug-related problems that contribute to excessive use of or abuse of health care resources. Our concern with legislation is that it will LIMIT our ability to commit the time and resources to this highly valued consultative service. Any fee process and structure identified should NOT LIMIT our ability to apply our knowledge to evaluation of drug therapies nor should it be limited to 'sale of product' transactions. We currently have the ability to identify charges and bill them on federal forms, and receive payment for cognitive services. In our zeal to be recognized we should not under value our services and our knowledge.

CMS-4068-P-167

Submitter : Mr. John Doggett **Date & Time:** 09/21/2004 03:09:21

Organization : Mr. John Doggett

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Shifting the current Medicaid prescription drug coverage to the Medicare prescription drug plan with limited drug coverage will increase the overall cost of treating people living with HIV and AIDS. Current Medicaid coverage enables physicians to select from a wide variety of medications to prescribe the most effective regimen for their HIV/AIDS patients.

Medicare Prescription Drug Plans are not required to provide all FDA approved antiretroviral drugs. Anti-retroviral medications have a wide range of side effects including pancreatitis, renal failure and liver toxicity, and patients also develop resistance to some of their medications over time.

If physicians are limited in their choice of regimens, patients will be forced into regimens that are less effective in suppressing HIV or that may produce intolerable side effects. This will result in patients becoming sicker, being hospitalized, and possibly dying. This proposal is neither cost effective nor a responsible policy decision.

CMS-4068-P-168

Submitter : **Dr. Beth Bagwell** **Date & Time:** **09/21/2004 03:09:20**

Organization : **Craig Methodist Pharmacy**

Category : **Long-term Care**

Issue Areas/Comments

Issues 1-10

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

I am a certified geriatric pharmacist working in a continous care retirement community. I would like to strongly recommend the benefit of having medication therapy management performed by a pharmacist and a service fee paid to the pharmacist for their expertise. The advantage to the Medicare program would be reduced
cost and utilization due to use of more non-pharmacologic interventions and a reduction of hospitalizations due to fewer adverse drug events.

CMS-4068-P-169

Submitter : Mrs. Sarah Rivera **Date & Time:** 09/21/2004 03:09:46

Organization : APhA-Academy of Student Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for alllowing me to submit the following points to consider when revising the MPDB. As a student pharmacist, I want insure that my future patients receive the best benefits, the most protection and the best quality of care possible. As pharmacists we need to be able to serve our patients. To do that, pharmacy access plans should be revised to mee the TRICARE requirements on a local level, not on the plan's overall level. Requiring this will insure that patients have convient access to local phamracies. If the plan is only required to meet the average plan across plan access, then there will be less incentive to offer pharmacies acceptable contracts. Requiring plans to provide fair and convient access is a promise made Congress that CMS should keep.

CMS-4068-P-170

Submitter : **Ms. Lindsey Stephens** **Date & Time:** **09/21/2004 03:09:59**

Organization : **Medicap Pharmacy**

Category : **Other Health Care Professional**

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 a plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy 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 appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a heath assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: Medication Reviews, Diabetes Education, Cholesterol Education & Management, Asthma Education, Immunizations, Smoking Cessation, and Osteoporosis Education. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

CMS-4068-P-171

Submitter : Dr. Wendy Mobley-Bukstein **Date & Time:** 09/21/2004 03:09:11

Organization : Dr. Wendy Mobley-Bukstein

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-171-Attach-1.doc

CMS-4068-P-172

Submitter : Ms. Sunshine Stevens **Date & Time:** 09/21/2004 03:09:05

Organization : Ms. Sunshine Stevens

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 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.

In my community of freinds, I have had more than a few experiences watching loved ones choose between basic sustinance and presecription drugs. Eventually, we all pitch in to help our loved ones financially as well as emotionally. Now it seems as if we will be expected to cover even more expeneses in the future if Government subsidies cover even less of these crucial drugs?

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

Sincerely,

Sunshine Stevens
4011 33RD AVE W
Seattle, WA 98199

CMS-4068-P-173

Submitter : **Mr. Norman Wiginton** **Date & Time:** **09/21/2004 04:09:33**

Organization : **ASHP member (Pharmacist)**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Licensure and competencies would demonstrate competencies for application.

BENEFITS AND BENEFICIARY PROTECTIONS

Benefits and beneficiary protections to be successful must be in line with resources to be lasting and meaningful for the long run. Start small and grow with demonstrated results.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Pharmacist want to move from the distributive role to the consultation role. Hospitals are great examples of where pharmacist monitor and offer 'interventions' to and with LIPS (physicians) that improve patient care, avoid waste, conserve resources, and enable physicians to better do their diagnostic and prescriptive functions. Pharmacist help manager therapies for the prescribers and support the patient and nurse with instructional and monitoring needs.

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

Pharmacist, Clinical Pharmacist and Pharmacy Managers deal with these issues daily and are the experts in drug therapy to include, cost, utilization management, quality improvement and therapy management. This is what pharmacist do, giving direction and data to LIPS (licensed independent practioners and patients) to best prescribe and utilize medications. Pharmacist interaction with LIPS and patients is a daily occurance to help patients optimuzing their therapies. Pharmacist are advocates for the patient and the prescriber as an independent expert on the best use on medications based on their pharmacokinetics and pharmacoeconomics. Avoiding duplicate therapies and conserving resources while optimuzing therapy is a pharmacist's forte. Utilizing the knowledge base and expertise of Pharmacist in medication utilization and management has been demonstrated in model after model to make improvements in outcomes. Their interations with patients and other healthcare providers saves resources over current models. The ideal model would be physicians diagnosing and in collaborative consulation with pharmacist prescribing medications to optimize outcomes, while nurses deliver the physicial care to care out ordered therapies and treatments to support patient outcomes.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Criteria for eliigibility, election and enrollment should be established by a collaborative group of physicians, pharmacist and nurses. Pharmacist have the base knowledges of cost, utilization, applications, interactions, kinetics and contact to all everyone in the process of medication therapy.

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

Federal law will guide state law. Once a model is established in Federal Law, states will follow that example.

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

Models can be established through professional organizations in collaboration with those providing the resources and CMS and related services.

CMS-4068-P-174

Submitter : Dr. Allan C. Anderson **Date & Time:** 09/21/2004 05:09:38

Organization : Memorial Hospital of Sheridan County

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Tuesday, September 21, 2004

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

Dr. Allan C. Anderson
Memorial Hospital of Sheridan County
1401 West Fifth Street
Sheridan, WY 82801

Re: CMS-4068-P
Dear Sir or Madam:
? Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.
? Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: Critical Care/ICU Management; Hyperlipidemia Management; Diabetes Disease Management; Hypertension Management; Drug Information; Clinical Pharmacokinetics. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

? Thank you for considering my view.

Sincerely,
Dr. Allan C. Anderson
Memorial Hospital of Sheridan County
Dept. of Pharmacy
1401 West Fifth Street
Sheridan, WY 82801
(307) 672-1065

CMS-4068-P-175

Submitter : | **Date & Time:** 09/21/2004 05:09:16

Organization :

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 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 have worked professionally with people living with HIV/AIDS, and know many long time survivors who could be adversely affected by changes in the Medicare Prescription Drug Benefit. At this point in their management of the disease, switching medications or developing new combinations of treatment could be hazardous to their finely tuned programs.

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

Sincerely,

Mary Ruffatto
651 King St.
Santa Rosa, CA 95404

CMS-4068-P-176

Submitter : **Mrs. Catherine Moskal** **Date & Time:** **09/21/2004 06:09:38**

Organization : **Mrs. Catherine Moskal**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

As a practicing retail pharmacist, I am fully support a drug coverage program includes medication management by a pharmacist. often, the elderly patients are on too many medications, duplications of medications, or expensive new medications prir to even trying less expensive alternatives. In addition, physicians often forget to monitor essential laboratory values, or multiple physicians order duplicate tests. Finally, pharmacists are in a unique environment to interact in a less intimidating location. Patients are more likely to open up to pharmacists in a drugstore than they are to their own physician in his/her office. This benefit for medicare recipients should definitely include a pharmacist directed medication management program. (And this website should add pharmacist as a selection on its registration page as we are definitely a group of health care professionals that have an interest in prescription drug programs.)

CMS-4068-P-177

Submitter :	**Dr. M Patel**	**Date & Time:**	**09/21/2004 08:09:06**
Organization :	**Dr. M Patel**		
Category :	**Other Health Care Professional**		

Issue Areas/Comments

Issues 1-10

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

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

Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards.
Allowing plans to count their non-preferred pharmacies conflicts with Congress?intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

Subpart D: Cost Control & Quality Improvement Requirements for
Prescription Drug Plans
? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS? recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: drug-drug interaction monitoring, drug-food interaction monitoring, adverse effect monitoring, identification of non-compliance and non-adherence. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

Thank you for considering my view.

CMS-4068-P-178

Submitter : **Ms. cassandra carter** **Date & Time:** **09/21/2004 08:09:51**

Organization : **Ms. cassandra carter**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

drug prescriptions are very necessary for elderly and are costly any help from medicare is quite necessary

CMS-4068-P-179

Submitter : Dr. Aviram Cohen

Date & Time: 09/21/2004 09:09:51

Organization : K-Mart Pharmacy

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Hi, my name is Aviram Cohen, I hold a Dr. of Pharmacy degree from Nova SouthEastern University in Davie Florida, and I am a registered pharmacist in the state of Florida. I am Writing in reference to file code CMS-4068-P to express concerns regarding access and quality aspects of the proposed regulations issued August 3, 2004 that would implement the new Medicare Part D prescription drug benefit program beginning in 2006.

? The proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA; and, therefore, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist.

? The regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.

? The regulations must include more specificity in the medication therapy management (MTM)program. Currently, they do not define the nature and scope of MTM services the plans would have to provide, such as who would be eligible for these services, and how providers would be compensated for these services.

Thank you,

Aviram Cohen, Pharm.D.

CMS-4068-P-180

Submitter : Mr. Gordon Nary **Date & Time:** 09/21/2004 09:09:15

Organization : AIDS Drug Assitance Protocol Fund

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.

People with HIV/AIDS are dependent upon the miraculous drugs that extend their life and often allow them to be productive members of society. Limitation of access to these drugs would seriously compromise the survival and quality of life of many people with HIV/AIDS and could be a death sentence for some.

Access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing is central to the term, quality and dignity of life of people with HIV/AIDS. This is why I ask CMS to 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.

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

Sincerely,

Gordon Nary
Executive Director
AIDS Drug Assistance Protocol Fund
320 West Illinois, Ste 211
Chicago, IL 60610

CMS-4068-P-181

Submitter : Ms. lynn robinson **Date & Time:** 09/21/2004 10:09:31

Organization : catholic Charities

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern:

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

CMS must designate people living with HIVAIDS 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 have affordable access to all FDA-approved antiretrovirals, ina all approved formulas as is recommended by the Public Health Service HIV treatment guidelines.

Let's not turn into a developing nation and lag behind the countries we keep espousing our help to. Let's be humane and take care of our own first. Let's give folks complete access to medical care regardless of ability to pay or this become a classist issue.

I have been working in this field both here in the U.S. as well as in Sub Saharan Africa since 1985 and have lost many of my own friends due to the disease. Now more than ever we need to be vigilant and humane.

Thank you for your consideration on this intensely important topic.

Lynn Robinson, MFT

CMS-4068-P-182

Submitter : Ms. Robyn Jones **Date & Time:** 09/22/2004 12:09:38

Organization : University of Maryland Medical System

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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. People living with HIV must have full access to medical treatment and medication regardless of their ability to pay. The changes that are being suggested will force my clients and friends to go without life sustaining treatment. I urge you to listen to my letter and those living and working with people infected by HIV/AIDS.

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

Sincerely,

Robyn Jones, LCSW-C
University of Maryland Adult HIV program
Evelyn Jordan Center
16 S. Eutaw St #300
Baltimore, MD 21202

The HIV Medicare and Medicaid Workgroup is a coalition of national,
state and local AIDS advocacy
organizations, community groups, healthcare providers, and universities
committed to ensuring that people
living with HIV/AIDS have access to appropriate, cost-effective health
care and drug treatment. The
HIVMMWG is an affiliated working group of the Federal AIDS Policy
Partnership. The working group is
committed to protecting and expanding coverage for people living with
HIV/AIDS under Medicare and
Medicaid.

CMS-4068-P-183

Submitter : Ms. JANE WARD **Date & Time:** 09/22/2004 12:09:35

Organization : Ms. JANE WARD

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I feel the patients ability to obtain their medications from their community pharmacist will be reduced. The regulations must be more specific in the mtm program

CMS-4068-P-184

Submitter : Mr. Harry Godlewski Jr. RPh   **Date & Time:** 09/22/2004 12:09:14

Organization : Mr. Harry Godlewski Jr. RPh

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposed regulations do not implement the Ticare pharmacy access standards included in the MMA. This will restrict the ability of patients to obtain their prescriptions from a community pharmacy. I have seen first hand the confusion elderly patients have when they are forced (encouraged) to sent prescriptions through the mail. There are countless episodes of patients not taking their medications because they did not know how to use the system, or because they did not receive their medication. The elderly trust community pharmacists they feel comfortable talking to someone they know. Please keep this in mind when making your decisions on whether to allow plans to use economic incentives to force (encourage) the elderly to use mail order. The U.S. healthcare system does not save any money if seniors do not take their medication and suffer additional (avoidable) health problems.

Thank You

CMS-4068-P-185

Submitter : Mr. Stephen Weeks **Date & Time:** 09/22/2004 12:09:04

Organization : IHS Pharmacy and Wellness Center

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

The only effective why to educate patients about their medicines is to legislate reimbursement for cognitive skills by pharmacists. This will effectively create a system where counseling is actually done. It will create a checks and balances system. Pharmacists are now graduating with 6 and 7 years of college and have a knowledge base that can prevent many of the problems that occur today. The current system where counseling only needs offered doesn't work. My experience is that nearly 1/3 of patients don't even know what their medicine is and that is very dangerous and ultimately expensive

CMS-4068-P-186

Submitter : Mr. Ronald Macon **Date & Time:** 09/22/2004 12:09:36

Organization : Mr. Ronald Macon

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am responding to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. As a current Medicare enrollee and a person living with HIV-AIDS 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.

It is crucial that CMS 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 have affordable access to all FDA-approved anti-retroviral medications, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

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

Sincerely,
Ronald E Macon
141 Mill Street
Worcester, MA 01603
508-754-4876

CMS-4068-P-187

Submitter : **Crystal Kezar** **Date & Time:** **09/22/2004 01:09:36**

Organization : **Crystal Kezar**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

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

Sept 21, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
Re: CMS-4068-P
Dear Sir or Madam:
Thank you for the opportunity to comment on the proposed regulation to
implement the Medicare prescription drug benefit. As a current pharmacy student at South Dakota State University, this bill will certainly affect my future profession, so I ask that you seriously consider this letter and letters of similar nature. I offer the following comments for consideration as CMS develops the final regulation.
Subpart C: Benefits & Beneficiary Protections:
Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plans overall service level. I plan on working in a community pharmacy when I graduate in 2006 and this is the only way to ensure that my patients will be able to use my local services.
I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating
the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congres's intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

Subpart D: Cost Control & Quality Improvement:
I appreciate that CMS recognizes that different beneficiaries will require different MTM services. I also appreciate CMS recognition that pharmacists will likely be the primary providers, but I am
concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.
Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I would like the opportunity to provide the following MTM services in my future career: diabetes education and blood glucose screenings, blood pressure screenings, cholesterol screenings, and individual reviews of patients medication therapy.
In conclusion, I urge CMS to revise the regulation to include that beneficiaries will be able to get their prescriptions filled at a local pharmacy and not be forced into getting mail order prescriptions. Further, that CMS define specifically what services are covered as MTM services, that pharmacists are listed as providers, and that specific reimbursement guidelines will be listed.

Thank you for considering my view.
Sincerely,
Crystal Kezar
517 4th St S, Brookings, SD 57006
605-690-5561

CMS-4068-P-188

Submitter : Ms. Heidi Stine **Date & Time:** 09/22/2004 01:09:09

Organization : Ms. Heidi Stine

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 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 saw personal friends die in the 80's because they did not have access to drugs or proper healthcare. I became a volunteer caregiver for PWA's as I was so incensed by what what was happening with this disease. It is imperative that People with Aids continue to have access to drugs and healthcare no matter what their ability to pay. When Grady Hospital in Atlanta opened an AIDS clinic in the 80's a number of patients survived longer due to otherwise unavailable healthcare and access to expensive anti-viral drugs. We have made great progress with this disease and we must never look back.

Heidi Stine
34872 N 92nd Place
Scottsdale Az 85262

CMS-4068-P-189

Submitter : Miss. Jennifer Nguyen **Date & Time:** 09/22/2004 03:09:15

Organization : UNC-Chapel Hill School of Pharmacy

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-4068-P

Dear Sir or Madam:

As a student pharmacist, I appreciate the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I would like to offer the following comments for consideration as CMS develops the final regulation.

Subpart C: Benefits & Beneficiary Protections
Please consider changing the pharmacy access standards requirements to a local level rather than the plan?s overall service level. Making this change will ensure that the beneficiaries will still have access to their current pharmacy and/or pharmacy of choice. Also, this will allow me to continue serving current patients.

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
Personally I believe that pharmacists are the most qualified to provide MTM services. It should be made clear that pharmacists are to continue to be the MTM providers and not leaving that decision to the plans. I?m concerned that given the option, the plans may not always choose the most qualified providers and the results will be the beneficiaries not getting the best therapeutic care.

In conclusion, I urge CMS to consider implementing these changes to the regulations. As a future pharmacist, I want to be able provide the MTM services and determine which services the beneficiaries need. Pharmacists have the most drug knowledge on the health care team so ideally we?d be the best resource to provide MTM services to the beneficiaries.

Thank you for considering my views.

CMS-4068-P-190

Submitter : **Mr. mark nowak** **Date & Time:** **09/22/2004 04:09:17**

Organization : **Mr. mark nowak**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

I have been infected with the HIV virus since 1988 and am alive only because I have had medication available. I am to sick to work and lost my job and health beneifts. By loosing the much needed medication I will die. There are only a few medical combinations availabe. Since I have been on medication since 1988 , the virus has mutated and is resistant to many medications approved. Your limitations will kill me and many others. Please do not take this away from my family and I.

CMS-4068-P-191

Submitter : Ms. Connie Cole **Date & Time:** 09/22/2004 10:09:21

Organization : Ms. Connie Cole

Category : Other Health Care Professional

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 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.

[INSERT PERSONAL STATEMENT HERE. If you are on Medicare, talk about how these regulations will affect you. Otherwise, write a couple of sentences about the need for people with HIV to have full access to treatment, regardless of ability to pay.]

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

Sincerely,

Connie Cole
6222 Kincaid Road
Cincinnati, OH 45213

CMS-4068-P-192

Submitter : **Dr. Joyce Broyles** **Date & Time:** **09/22/2004 12:09:49**

Organization : **Dr. Joyce Broyles**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

This comment is in support of Medicare fees for medication management. Pharmacists have a long history, well supported in the scientific literature, at assisting patients with the management of chronic disease states. This includes asthma, diabetes, anticoagulation, thyroid disease and lipid management. These services have been shown to be cost effective, and safe for patients. A major block to wider implementation of such programs is the lack of reimbursement available for pharmacists outside of the academic setting. The proposed change in regulations would increase the opportunities available, and give many Americans access to these programs.

CMS-4068-P-193

Submitter : Sara Schmitt **Date & Time:** 09/22/2004 02:09:31

Organization : Sara Schmitt

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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.

People living with HIV/AIDS need access to the wide range of HIV medications to best manage their HIV disease. The complexities of treating HIV, and the medically dangerous consequences of inadequate treatment, require that people living with HIV/AIDS have full access to these life-prolonging medications.

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

Sincerely,
Sara Schmitt

Issues 1-10

GENERAL PROVISIONS

Medicare recipients who are also dually eligible to receive Medicaid should not be restricted to using only the new Medicare drug benefit. States should be allowed to draw a federal match for providing Medicaid wrap-around services for their dually-eligible population--often the most medically vulnerable of Medicare recipients.

CMS-4068-P-194

Submitter : Mr. Michael Weiss **Date & Time:** 09/22/2004 02:09:33

Organization : Full Circle Medical Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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.

Many people living with HIV/AIDS are long term survivors and have resistance to some drugs. Due to the virus'ability to mutate so easily, treatment must be specialized for each person. It is not possible for all people living with HIV/AIDS to be on the same treatment. It is extremely important that people living with HIV/AIDS have access to all of the medications that are available. Their survival depends on it.

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

Sincerely,

Michael Weiss, BS, DTR
3631 Fieldbrook Rd.
Fieldbrook, CA 95519

CMS-4068-P-195

Submitter : Dr. Leonard Edloe **Date & Time:** 09/22/2004 02:09:55

Organization : Edloe's Prof. Pharmacies

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

My name is Leonard L. Edloe and I own three inner city pharmacies in Richmond, Virginia. Medication therapy management programs for the medicare program are a must. Seniors take more medications and require extra interactions to make sure they take their medications properly. With the complexities of drugs, their therapy needs to be monitored by drug specialist.

Since most seniors obtain their medications from community pharmacies just like mine, so it is my opinion that pharmacist like myself who have been trained to do pharmaceutical care plans should provide medication therapy management.

I also feel that pharmacists should be reimbursed separately for this service. I have been a practicing pharmacist for over 30 years and watched remibursed to unacceptable levels. With each decrease in fees pay to the pharmacists, I have seen an increase in utilization. Utilization is what is driving pharmaceutical costs. Without pharmacists managing therapy, it will increase even more.

We can improve outcomes, decrease cost, and provide a higher quality of life if pharmacists are reimbursed for providing medication therapy.

CMS-4068-P-196

Submitter : Dr. Blake Edwards **Date & Time:** 09/22/2004 02:09:16

Organization : Hamilton Memorial Hospital

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I am a LIcensed practicing clinical Pharmacist and wanted to take this opportunity to voice my support for the new legislation which will provide for Medication therapy management services and the recognition of Pharmacists as providers. This is a positive step in the right direction for healthcare in the United States and I applaud all who have sponsored and supported this bill and made it become a reality. Time will tell just how great this new aspect of healthcare services will impact the provision of quality healthcare in the USA. Thanks for the support and keep up the good work Blake Edwards R.Ph PharmDc Hamilton Memorial Hospital 611 S. Marshall Ave McLeansboro, Illinois 62859 blake10@ufl.edu

CMS-4068-P-197

Submitter : Mr. John Sowinski R.Ph. **Date & Time:** 09/22/2004 03:09:41

Organization : Medicine Shoppe Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Medication Therapy Mangement services are essential for Patient care. Pharmacists are the perfect profession to deliver this care. Every day I improve outcomes just by the services I provide. The day has come when our professional activity should be recognized. With face to face contact with our patients, we can improve the tharapy they are provided. We can decrease medicine mistakes and mishaps. We can truly improve patients lives as I have seen 1st hand with the Lakeshore Diabetes Project. Payment for our services are needed as a relfection of the services we can offer. This can't be done with AWP-18% plus a $2 dispensing fee. Thank You

CMS-4068-P-198

Submitter : **Dr. Elizabeth Musil** **Date & Time:** **09/22/2004 04:09:59**

Organization : **Dr. Elizabeth Musil**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 1-10

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

Please leave in the provision for medication therapy management AND payment for these services!! This is a benefit to everyone involved - keeping patients healthly/avoiding adverse events, preserving the integrity of the relationship with the pharmacists, and promoting pharmacy services beyond "dispensing". Most pharmacy programs have moved to a professional Doctor of Pharmacy degree due to the complexity of pharmacy and the expanding role needed to keep up with all of the changes in health care. It is vital that medicare support this role, since they are leaders in setting standards for other insurance companies to form policy on. This is of major importance to the future of the pharmacy profession as well as to the future of patients that will need help with medication management services in order to prevent adverse events. I support the APHA position on these services and hope you do to!
Thank you!

CMS-4068-P-199

Submitter : Mr. Mark Click, Pharmacist **Date & Time:** 09/22/2004 04:09:56

Organization : Emory Crawford Long Hospital, Dept of Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Would recommend having pharmacists involved in Medication Therapy Management. And that there would be fees provided for such interventions in medication therapy.

CMS-4068-P-200

Submitter : Thomas Butler **Date & Time:** 09/22/2004 04:09:40

Organization : Thomas Butler

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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.

As the recent 400% increases in the prescription drug Norvir emphisize, the need for government intervention in the negotiations for drug cost containment is necessary, but lacking. It would be ironic if people in the third world had better access and cost containment to generics than people in the US who subsidize development costs.

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

Sincerely,

Thomas J. Butler
3718 Taraval St
SF, CA 94116

CMS-4068-P-201

Submitter : Ms. Steve Critz **Date & Time:** 09/22/2004 05:09:32

Organization : Ms. Steve Critz

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I feel Pharmacists are the ideal health care professionals to offer medication management for Medicare. We are the most thouroughly trained health care providers in this area and are the appropriate professionals to manage medication therapy. The Pharmaceutical industry has too much influence over prescribers for them to offer the medication management. I feel this very important aspect of healthcare needs to be done by someone other than the prescriber.