Submitter : Mr. Jake Bruynzeel **Date & Time:** 08/04/2004 05:08:12

Organization : Master Craftsman

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

These are more programs and more programs, what people need are more "programs" that actually HEAL, not cover up illnesses with drugs or cutting into bodies.

Programs that cut into bodies to take parts out because no one looked in the direction of the CAUSE of the affliction, they looked at covering up the SYMPTOM. That's what usually ends up leading to drugging or cutting bodies.

I know there are holistic methods that actually look at and FIND AND HEAL the source of the affliction. I've used them.

Lets spend the "PEOPLES" money on what "people" are led to believe they are spending it on - healing.

Thank you.

Jake

Submitter : Mr. james utrie **Date & Time:** 08/04/2004 06:08:46

Organization : WEA Insurance Corporation

Category : Health Plan or Association

Issue Areas/Comments

Issues 11-20

FALLBACK PLANS

Page 6/16 of the proposed regulations; second bullet referencing "wrap around plans" states: "As in the previous options, Medicare would provide both direct premium subsidies and reinsurance subsidies to these enhanced drug plans. Please clarify! Does this mean that a wrap around plan is eligible for the 28% subsidy? Are wrap around plans eligible for reinsurance?

My understanding is that the only "subsidy" wrap arounds would receive would be the primary coverage of the Medicare Drug Plan and the subsidized premium of the Medicare Plan.

I look forward to your response.

Submitter : Dr. Steve Bartz **Date & Time:** 08/05/2004 10:08:51

Organization : University of Cincinnati

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

1) Not allowing negotiations with the drug companies for better prices is ludicrous. This is clearly not in the public's best interest.

2) Allowing only one initial physical exam perpetuates the "fix it" instead of the "prevention" mentality of our health system.

Submitter : Ms. Raena Honan **Date & Time:** 08/06/2004 04:08:56

Organization : Hop Tribe Office of Elderly Services

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

POLICY ISSUE
Agency: Hopi Tribe
Activity: HHS Office of Elderly Services
Author: Raena Honan, Dir. OES

EXEMPTION FROM FORCED PARTICIPATION IN MEDICARE DRUG CARD FOR NATIVE AMERICANS

Funding request: $0

The provision of health care to Native Americans through Indian Health Services (IHS) is a mandate under treaty and other federal law. Yet many Native American elders are forced to pay Medicare premiums of $66.60 per month in fear that without Medicare IHS will deny them necessary health services. IHS-provided health care services are obligatory and not meant to be dependant upon Medicare qualification or any other measurement of patient means.

In requiring Native American elders to apply and pay for Medicare coverage, IHS is then able to bill Medicare and Medicaid programs for the health care services IHS provides. Since IHS, Medicare and Medicaid are all federally funded and administered, as each program bills another it causes additional taxpayer costs with each administrative transaction in addition to the extra expense to the individual elder receiving the IHS health services.

It is the position of the Hopi Tribe that all Native Americans should be provided quality health care without cost in fulfillment of the federal government?s promises to do so as evidenced in treaties and other federal law. The policy of IHS regarding Native American elders and Medicare requirements contradicts this federal obligation.

Now, Congress has recently passed new Medicare provisions whose intent is to allow seniors to participate in prescription drug discounts. The Native American elder population that uses IHS is not mentioned in this law. Instead of attempting to deal with this oversight in a way that provides quality health care to the elders in accordance with its federal obligations, IHS is considering a policy of encouraging Native elders to purchase discount drug cards from Medicare. Such a policy would be a further acquiescence to the lack of commitment demonstrated by the federal government to fully fund the IHS and thereby provide the health care services guaranteed by law.

In light of this, the Hopi Tribe cannot promote the purchase of the new Medicare drug card by Tribal elders. The participation in and provision of more funding of a system that should be without cost to our population is tantamount to condoning the continued lack of commitment to our people.

Submitter : Mr. Ricky Guidry, RPh **Date & Time:** 08/09/2004 11:08:03

Organization : Independent Pharmacy Owner

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

I am an independent pharmacy owner and I service a rural area. My concern is that the new regulations will once again look for discounts on prescriptions from the pharmacy itself. As you know or may not know, discounts for the Medicare Prescriptions Discounts cards that we are currently providing to seniors came directly out of our pockets! We can not afford to be forced to accept PBM's take it or leave it contracts that they now offer. It sounds like PBM's will be given all contracts with the new plan. As a small business owner, I am being forced not to sign contracts with lower reimbursement rate because I just can not make a fair profit. Is CMS looking at the effect on small rural pharmacies that low reimbursements from PBM's will bring? We have given all the discounts that we can. I think that it is time for the drug manufacturers to pass rebates and discounts down to pharmacies so that we can pass on the savings directly to the consumer. It seems to me that every time the rising cost of prescription drugs are talked about, we never hear about the real problem which is double digit price increases that drug companies enjoy every year. If you want to better understand the whole picture on what is happening in the real world.....visit an independent pharmacy like mine and I'll guarentee you the truth! PLEASE HELP THE SMALL BUSINESS MAN LIKE MYSELF!!!!!!!!!!!!

Submitter : Mr. Ricky Guidry, RPh **Date & Time:** 08/09/2004 11:08:03

Organization : Independent Pharmacy Owner

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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Submitter : Mr. Brett Reish **Date & Time:** 08/16/2004 07:08:47

Organization : General Electric Company

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

How will the Medicare Secondary Payer Regulations change, if any, to accommodate the 4 Medicare Part D employer proposals for effective coordination of benefits with a LGHP with a drug benefit? Will there be additional rountines established by CMS/IRS, as today for Medical Coverage, to identify members covered by a LGHP with a Drug Benefit as it relates to MSP?

Submitter : Dr. Raymond Kordonowy MD **Date & Time:** 08/18/2004 12:08:37

Organization : Internal Medicine of SW Florida

Category : Physician

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Is there any way medicare providing physician's can participate in dispensing medications at the office service level? My understanding of the current lanquage is "no".

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

The currently published facts regarding the medication benefit program seem to limit prescription benefits to essentially insurance companies/prescription benefit programs. Historically, for the past several years insurance benefits have been receding in this area as insurance companies realize that one of the largest areas of expense for an insurance company is prescription coverage. The insurance companies are yearly increasing premium rates to individuals while pushing more and more prescription expenses upon the individual via the mechanism of higher copays and deductables (in order to maintain or increase profitability).

I would like to propose a model/option of delivering medications that eliminates the additional middle man expense of having this benefit managed by an insurance carrier. I suggest that the government create and purchase Medicare formulary medications directly via competitive bidding. The government already has a very robust formulary in existence (albeit it has some deficiencies); it is the VA formulary. This could be a starting point with additional medications added more frequently to keep up with the rapidly changing medication advances.

I propose that the government allow physicians to provide prescription medication at the office level as a service. I would suggest that the "Medicare formulary" be accessible to physician's for dispensing. Participating licensed physician's could be allowed to bill medicare for the services of dispensing and managing the patient's medications. By bypassing insurance models for those who want to participate, additional savings to Medicare would be achieved. Patients' will have point of care service of medication dispensation provided they are eligible for prescription benefits under the new CMS ruling. Payment for services could include some percentage mark-up of medications dispensed with incentives created for proper generic equivalent usage (to promote cost effectivness) or payment could be done based upon simple dispensation fees on a per unit basis. Physician involvement and financial incentives will result in a much more effectively delivered system. The government needs to understand that without physician involvement, any proposed system will fail. The current proposal demonstrates a total lack of physician concerns regarding the use and cooperation of a medicare medication dispensing program. The current proposal promises to increase physician burden with nothing but financial disincentives in place. I am not interested in increasing my workload, paperwork and legal risk trying to conform to another logistical nightmare.

As has been demonstrated this past decade with Medicare HMO models (such as United Healthcare), it has been proven that having insurance companies involved in the management of Medicare patients, actually increase adminstrative overhead while patient access to phycicians went down. No cost savings were realized and in fact most HMO plans had to stop due to insolvency. I think we can expect a similar result if we leave the current model only open to networked insurance vendors and large chain pharmacies. Patient access to medication dispensing can be expected to go down, the physician "hassle factor" can expect to go up logrithmically and in the end the benificaries and providers will be very unhappy.

The model I am suggesting is just a broadstroke idea but I believe you can see how this would be more pro patient and pro provider as well as more cost effective. I would welcome a conversation with the Secretary of Health or any representative if a trial program wanted to be tested or discussed in finer detail.

I would welcome comment/critique or direct comments regarding my suggestions. My group has a patient population of about 85% Medicare benificiaries currently. We would be happy to consider a pilot project if the government is interested in pursuing this.

Submitter : Mr. Ed Bettinardi **Date & Time:** 08/19/2004 12:08:00

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Many employers who maintain prescription drug plans for retirees have shifted all or a substantial portion of their plan costs directly to the retirees. Under those circumstances, present regulations would permit those employers to receive a subsidy for maintaining the plan, while incurring little or no expense for the plan as the costs have been shifted to and charged to the retiree. To provide a subsidy to an employer under these conditions is completely unacceptable. If anyone needs a subsidy, it is the retiree who is bearing the cost of the prescriptions, NOT THE EMPLOYER! Please restructure this proposal to reduce or eliminate employer subsidies when costs for the employer program and the prescriptions have been shifted partially or completely to the retiree and are not being paid by the employer. In addition, there should be a requirement to pass through any subsidies to the retirees so that the cost to the retiree is minimized.

Submitter : Dr. Ben Weinberg, MD **Date & Time:** 08/23/2004 03:08:57

Organization : Private Practice

Category : Physician

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I agree completely with the exclusion of coverage of benzodiazepams. I work in Addiction Medicine, and we see more patients than I can count, both young and old, who are inappropriately prescribed these drugs and suffer severely with side effects, and relapse into alcoholism. I support your decision completely.

CMS-4068-P-11

Submitter : Dr. allen nichol **Date & Time:** 08/23/2004 06:08:57

Organization : Grandview Family Practice

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Comments for medication therapy management: Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule.

CMS-4068-P-11-Attach-1.doc

General requirement to have program in place

Law ~ Sec. 1860D-4 (c)

(1) IN GENERAL – The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927 (k)(7)(A)(i)). Whenever the situation presents itself either through the physician or the patient, the pharmacist shall suggest the use of a generic drug or less expensive medication in the same therapeutic category, if the drug appears to be able to deliver a similar clinical effect than a more expensive medication.

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The pharmacist shall review and print a copy of all current medications for the patient and/or authorized caregiver to confirm the correct drug therapy that he/she is on. The pharmacist shall review the name of the medications, strengths, dosage forms, frequency of use, and the indication(s) of the medication with the patient.

(C) A medication therapy management program described in paragraph (2). This review should be performed on a regular basis (every 30-60 days). The pharmacist shall attempt to confirm compliance and discuss with the patient any suggestions to assist in overcoming compliance problems.

(D) A program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

Regulation – Subpart D

§ 423.150 Scope.
§ 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

(a) General rule. Each PDP sponsor or MA organization offering an MA-PD plan must have established, for covered Part D drugs, furnished through a prescription drug plan or MA-PD plan, a cost-effective drug utilization management program, a quality assurance program, a MTMP and a program to control fraud, abuse, and waste as described in § 423.153 (b), § 423.153 (c), § 423.153 (d), and § 423.153 (e), respectively.

(b) Cost-effective drug utilization management. A cost-effective drug utilization management program must –
(1) Include incentives to reduce costs when medically appropriate; and
(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications. The policies and systems shall include:

(i) the pharmacist shall be able to monitor outcomes to have patients strive towards optimal treatment goals

(ii) the pharmacist may review with the patient and/or authorized caregiver on a regular basis (30-60 day interval) current therapy, confirm compliance, and develop a mechanism to overcome compliance problems

(iii) the pharmacist shall maintain individual drug profiles to include medical conditions, allergies, current medications, and dosing parameters.

(c) Quality assurance program. A quality assurance program must include measures and systems to reduce medications errors and adverse drug interactions and improve medication use. The program must establish processes for –
(1) Drug utilization review;

(i) the pharmacist should provide a direct review and printed copy of the patient's medication list to the patient and/or authorized caregiver. This medication list should be held by the pharmacist in either a computerized program or a paper chart.

(ii) this medication list should include, but not be limited to, the following information:

(A) drug name

(B) strength, dose, and dosage form of the drug

(C) directions of use

(D) if possible, medical condition for the use of this drug

(2) Patient counseling; and
(3) Patient information record-keeping

(d) Medication therapy management program. (elements below)

Preamble

2. Cost and Utilization Management, Quality Assurance, Medication Therapy Management, and Programs to Control Fraud, Abuse, and Waste (§ 423.153)

Section 423.153 (a) of our proposed rule would require each PDP sponsor or MA organization a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to establish a cost-effective drug utilization management program, a quality assurance program, a MTMP, and a program to control fraud, abuse, and waste as described in § § 423.153 (b), 423.153 (c), 423.153 (d), and 423.153 (e), respectively.

We have combined these requirements into one section of the proposed regulation because each of these requirements would impact the quality and cost of care provided to beneficiaries. However, note that chronic diseases may require 4 or more medications per disease state to reach an optimal outcome. Furthermore, compliance programs can be compromised by economic

issues faced by patients. Pharmacist may resolve this issue via patient assistance programs offered by manufacturers, as well as distributing necessary samples in the physician's office to their patients. Our intent is to ensure that the prescription drug benefit would be provided using state of the art cost management and quality assurance systems. We also understand the overlapping nature of these requirements and that provisions under one requirement might complement another requirement. For example, drug utilization management early-refill edits used to prevent stockpiling of medications could also identify potential medication misuse by patients. Although these requirements are similar in their underlying goals, they can also be quite different. For example, drug utilization management and quality assurance systems are generally considered to be population based, while medication therapy management involves targeted, direct patient care.

While we understand that some members of industry use various quality assurance measures and systems for controlling utilization and reducing medication errors, less information is available regarding medication therapy management. Medication therapy management has been used to describe a broad range of professional activities and responsibilities. We are familiar with state Medicaid programs (for example, Wisconsin, Mississippi) paying for cognitive services as part of their prescription drug benefit, but we have less information about current similar practices in the private sector. Therefore, our regulatory approach for utilization management, quality assurance, and controlling fraud, abuse, and waste will be different than our approach for medication therapy management. We particularly ask for comments on this section of the proposed regulation.

In general, and within the parameters described later in this preamble and in regulation, PDP sponsors and MA Organizations offering MA-PD plans would have flexibility to design drug utilization management programs, quality assurance measures and systems, MTMPs, and programs designed to control fraud, abuse, and waste.

c. Medication Therapy Management Programs Section 1860D-4(c)(1)(C) of the Act requires PDP sponsors and MA Organizations offering MA-PD plans to establish a MTMP, and § 423.157(d) would codify that requirement. As stated earlier, neither we, nor many private insurers, have extensive experience requiring or reimbursing for MTMPs. As a result, we seek comments on what requirements and/or guidelines for MTMPs should be formulated in our regulation. In this section of the preamble, we are providing a broad overview of the types of activities the PDP sponsor or MA organization offering a MA-PD plan could provide as part of a MTMP. We also discuss various options for determining which beneficiaries might qualify as "targets individuals" and what types of clinicians might provide MTMP services. We plan to conduct further research and seek comments before establishing requirements with respect to MTMPs. We are interested in current MTMP best practices, essential components of MTMPs, and which quality assurance requirements, if any, should be included in MTMPs. We are also interested in measures and information on effective MTMP services that could be publicized and used by beneficiaries who wish to use these services. We are particularly interested in the most effective steps to make valuable, proven MTMP services available to beneficiaries to improve health care quality and reduce costs. We are mindful of the importance of stimulating the evolution of the most appropriate and efficient form of MTMPs, without stifling innovation of prematurely locking-in specific attributes.

Program Description

Law ~ Sec. 1860D-4 (c)

(2) MEDICATION THERAPY MANAGEMENT PROGRAM – (A) DESCRIPTION –

(i) IN GENERAL – A medication therapy management program described in this paragraph is program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

Regulation – Subpart D

§ 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

(d) Medication therapy management program. (1) General rule. A medication therapy management program –

(i) Must assure that drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Must, for the targeted beneficiaries described in paragraph (d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions;

(iii) May be furnished by a pharmacist; and upon a written order, prescription, or certificate of medical necessity (CMN) furnished by the managing or prescribing physician.

(iv) May distinguish between services in ambulatory and institutional setting. Pharmacists working in a collaborative practice activity with a physician are also an acceptable venue for these services to be delivered.

(v) Face to face sessions with the patient and/or authorized caregiver should be considered optimal. Note that these services must be adopted plans in their MTMPs.

Preamble

The description of a MTMP in section 1860D-4(c)(2) of the Act would allow for plans to establish a broad range of additional services. The purpose of a MTMP is to provide services that will optimize therapeutic outcomes for targeted beneficiaries. Specific services to be provided under a MTMP would be distinct from those required for dispensing medication.

Medication therapy management services would be a mandated reimbursable service when provided to targeted beneficiaries who meet the criteria as defined in § 423.153(2) of our proposed rule and discussed later in this preamble.

While we believe that pharmacists will be the primary providers of these services, MTMPs could also include other qualified health care professionals as providers of services. The individual needs of the targeted beneficiary should determine the appropriate provider and setting for MTMP services. For example, consultant pharmacists will likely provide services to beneficiaries in long-term care facilities; retail pharmacists could provide those same services to ambulatory beneficiary choice and ongoing beneficiary-provider relationships should play a role in determining the best provider for MTMP services.

Improved therapeutic outcomes through MTMP services will frequently require active beneficiary, or caregiver, participation. While population based quality assurance and cost control measures might adequately be served by impersonal telephone services, we believe that telephone services are only one mode of providing medication therapy management services. Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships. Therefore, to the extent that these services are adopted by plans in their MTMPs, we would expect the range of services offered to reflect this important component and maximize beneficiary participation by considering beneficiary preference and existing beneficiary-provider relationships in determining the appropriate provider and setting for delivery of MTMP services.

Targeted Beneficiaries

Law ~ Sec. 1860D-4 (c)

(ii) TARGETED BENEFICIARIES DESCRIBED – Targeted beneficiaries described in this clause are part D eligible individuals who – (I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive hear failure); (II) are taking multiple covered part D drugs; and (III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

Regulation – Subpart D

(2) Targeted beneficiaries. Targeted beneficiaries for the medication therapy management program described in paragraph (d)(1) of this section are enrolled part D eligible individuals who-

(i) Have multiple chronic diseases;

(ii) Are taking multiple covered part D drugs; and

(iii) Are likely to incur annual costs for covered part D drugs that exceed a predetermined level that CMS determines.

Preamble

Second, section 1860D-4(c)(2)(A)(ii) of the Act requires that MTMP services be provided only for targeted individuals. In other words, not all members of a plan would be entitled to receive these services. As provided under § 423.153(d)(2), "targeted beneficiaries" would be plan enrollees who have multiple chronic diseases, are taking multiple part D covered drugs, and are likely to incur annual costs that exceed a certain level that we determine. We invite comments on how we should provide guidance to drug plans in defining "multiple chronic diseases" and "multiple covered part D drugs" for the purposes of determining which part D enrollees would qualify for MTMP services, or whether such determinations are best left to the plans as part of their benefit design.

While the statute states that CMS sets the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services, our preferred policy is to delegate this function to the private drug plan, as they would be able to evaluate their patients with greater specificity and information. We request comments on this policy as both a policy and legal matter. We believe that, given current evidence, the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services should be determined by the drug plan. We do not think there is sufficient evidence at this point to specify a threshold of annual drug costs to be used for targeting these services to particular part D enrollees. However, we seek comments on what guidance we could provide to plans to ensure these services are targeted in the most efficient manner and to the most appropriate beneficiaries.

In addition, we are concerned about the method that plans should use to determine the costs that enrollees are "likely to incur" to ascertain whether they qualify as targeted beneficiaries. Once plans have historical data on specific patients, determining how to target such services should become easier and more effective. For example, based on their previous experience with providing prescription drug services, plans could qualify enrollees for MTMP services based on whether the enrollees have multiple chronic diseases and whether they are using multiple drugs. As they develop more experience with their Medicare enrollees, past medication history might become another useful guide. We believe that plans would benefit from additional guidance on interpreting the level above which a beneficiary's incurred costs would qualify him or her for MTMP services. By use of current physician ICD-9 procedure codes, billing may be done with either electronic HCFA 1500 or paper format. Physicians generating a written order, prescription, or CMN for the specific diagnosis should be treated as if a general practitioner was referring to a specialist. We invite comments on all the disease, drug, and cost issues that we should consider in further refining the definition of a targeted beneficiary for receipt of MTMP services.

Another issue to be considered relates to which clinicians would be providing MTMP services and the method for providing those services. Section 1860D-4(c)(2)(A)(i) of the Act specifically states that a pharmacist may furnish MTMP services, with a written order from a physician.

Elements

Law ~ Sec. 1860D-4 (c)

(B) ELEMENTS.—Such program may include elements that promote—

(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling , and other appropriate means;

(ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, other compliance programs, other appropriate means; and printed or updated medication list upon completion of the visit.

(iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs Suggestions to the managing or prescribing physician for consideration to enhance quality of care, improve outcomes, and/or avoid potential adverse drug reactions (ADR's).

Preamble

Section 1860D(4)(c)(2)(B) of the Act states that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee and/or authorized caregiver understanding -- through beneficiary education counseling, and other means -- that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, other compliance programs, and other appropriate means).
- Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

In order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management. We would also anticipate that these services could be offered as components of more coordinated disease management programs, but would not expect provision of these services to be limited to such programs. Uniform care standards as much defined by today's ICD-9 coding should be established. Absence of uniformity results in less than optimal care services.

In addition to MTMPs providing for different types of services, we would also anticipate the need for different levels of service based on the individual requirements of targeted beneficiaries. For example, one beneficiary may require only a fifteen-minute phone consultation, while another would be better served by a one-hour in-person visit with the pharmacist. The level of service should be determined by time and resources required to accommodate the specific needs of the individual beneficiary, much so as achieved by today's standards for physicians.

Therefore, we would anticipate that a MTMP would include policies and procedures for ensuring targeted beneficiary access to the appropriate types and levels of service offered by the particular PDP or MA-PD plan. Within this broad framework, we believe that PDP sponsors and MA Organizations offering MA-PD plans can customize their MTMPs. We also believe that a competitive market supported by useful information on MTMP services will provide the best mechanism for establishing optimal MTMPs.

We believe that MTMPs can lead to improved overall health for individuals, while at the same time decreasing overall healthcare costs resulting from the most proper medication use, as well as decreasing adverse drug events. We may provide a mechanism for plans to demonstrate the types of services, levels of service, and quality outcomes associated with their MTMPs to further aid beneficiaries with choosing the plan that will best meet their needs.

DEVELOP WITH PHARMACISTS

Law ~ Sec. 1860D-4 (c)

(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

Regulation – Subpart D

(3) Use of experts. The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

Preamble

In addition, as provided in §423.153(d)(3), a MTMP, as adopted by a plan, would have to be developed in cooperation with licensed practicing pharmacists and physicians.

Beyond these broad parameters for a MTMP, there are several issues to consider as we provide additional guidance to PDP sponsors and MA organizations. First, we consider MTMPs to be administrative activities similar to quality assurance drug utilization review or measures to control fraud, abuse, and waste. Like these other quality improvement services intrinsic to the drug plan, MTMP services would not involve direct beneficiary cost-sharing and Part D

enrollees would not be required to pay separate fees for these services (although the cost could be reflected in the premium rate). The cost of a MTMP is considered an administrative cost incident to appropriate drug therapy and, therefore, not an additional benefit. Nevertheless, unlike the general quality assurance and fraud, abuse, and waste control requirements, MTMP services can be limited to targeted beneficiaries. To the extent that MTMPs reduce drug spending by more than their costs, they have the potential to lower overall Part D costs. To the extent that MTMP services lower overall medical costs for beneficiaries with chronic illnesses, we also seek comment on how to integrate MTMP services and financial incentives into the Medicare Chronic Care Improvement program (Section 721 of the Act).

Coordinate with Chronic Care Programs

Law ~ Sec. 1860D-4 (c)

(D) COORDINATION WITH CARE MANAGEMENT PLANS –

The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807. Coordination with the Chronic Care Program may be:

(A) a stand alone MTMP, or

(B) in coordination with collaborating physicians to enhance patient outcomes via a DSM process in the CCIP patient.

Regulation – Subpart D

(4) Coordination with care management plans. The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program under section 1807 of MMA.

Preamble

Finally, as specified in section 1860D-4(c)(2)(D) of the Act, we are required to establish guidelines that MTMPs operated by PDP sponsors are coordinated with the "chronic care improvement program" (CCIP) under section 1807 of the Act. MTMP can be a component of a Disease Management Program. There should be the use of CPT coding to differentiate between the types of services rendered. Ohio Medicaid currently uses the CPT procedure of 90862 to pay oncologists and psychiatrists for MTMP services. Iowa Medicaid via their state plan amendment, and the Ohio Department of Health/ Bureau for Children with Medical Handicaps asthma management program utilize current E&M, CPT coding and billing exact to physicians. CCIP is a new program established by section 721 of the MMA, which added a new section, section 1807, to the Act. The new section 1807 creates a method for us to assist beneficiaries with multiple chronic conditions in managing their care. The program is targeted only to beneficiaries in original fee-for-service Medicare – not beneficiaries enrolled in MA plans. Therefore, we anticipate that our guidelines will be targeted toward PDP sponsors and not to MA

organizations that offer MA-PD plans. As stated above, the CCIP is a new program. By statute, the first agreements under that program with chronic care improvement organizations should be entered into within 12 months of the MMA's date of enactment. On April 23, 2004, we published the **Federal Register** (69 FR 22065-22079), the solicitation for the CCIP program.

Because the program has not yet been established, however, we cannot provide a great deal of guidance at this time regarding how the MTMPs under Part D would coordinate with the CCIP. We are concerned with the possibility of beneficiaries receiving duplicative services. We seek comments on how MTMP services provided through CCIP can be effectively coordinated with MTMP services provided by PDPs. There are several different ways that communication could take place so that a beneficiary enrolled in both the CCIP and a PDP receives efficient assistance with managing their chronic diseases. For example, the CCIP might collect information at intake, obtain a beneficiary information release, and inform the PDP of enrollment. An alternate approach is for us to use the enrollment files from the two programs to communicate to the respective parties. Levels of care given to patients are identified via current physician procedure coding. MTMP services could use the existing code of 90862 for a stand alone service. For a more complex DSM services where MTMP is merely a component of the services and care delivered, pharmacists would bill using standard physician E&M coding. This E&M coding would depend on the level of the care delivered with the appropriate documentation to substantiate such billings. We invite comments on this issue and these proposed options. We may provide further interpretive guidance on coordination with the CCIP once the section 1807 agreements are finalized and the new program is in place. We invite comments from interested parties relating to specific key issues that should be addressed in this guidance.

Fees

Law ~ Sec. 1860D-4 (c)

(E) CONSIDERATIONS IN PHARMACIST FEES –

Since these services are commensurate in nature with physician fees and services; similar fees and service reimbursement should be provided to the pharmacist providing such (Iowa Medicaid and Ohio Department of Health/ Bureau for Children with Medical Handicaps asthma management program) services. Exact CPT coding should prevail. The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to implement the medication therapy management program under paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927 (b)(3)(D) apply to information disclosed under this subparagraph.

Regulation – Subpart D

(5) Considerations in pharmacy fees. An applicant to become a PDP sponsor or an MA organization wishing to offer an MA-PD plan must –

(i) Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing medication therapy management services for covered Part D drugs under a prescription drug plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 927(b)(3)(D) of the Act.

(iii) Dispensing of medication fees should have no bearing on compensation fees for MTMP services delivered under the CCIP. It should be understood that:

(A) Many pharmacists delivering these services will probably not be dispensing any medications to patients but merely performing a clinical role, and

(B) The management fees, whether they are a stand alone MTMP activity or part of a DSM program for a CCIP patient, should be no less than the equivalently coded services already in place and utilized by CMS in the existing Medicare Program.

Preamble

Section 1860D-4 (c)(2)(E) of the Act states that in establishing fees for pharmacists or others providing MTMP services, to the extent that these services are adopted by a plan in its MTMP, a PDP sponsor must take into account the resources and time associated with implementing the MTMP. Section 423.153(d)(5) codifies that requirement.

We propose to implement this requirement as follows: We would expect potential PDP sponsors to describe, as part of their applications, their plan to consider the resources used and the time required to implement their MTMP in establishing fees for pharmacists and other providing services under the MTMPs. These should follow standard Medicare guidelines for services, documentation, and compensation.

While section 1860D-4(c)(2)(E) of the Act specifies that the time and resources necessary to implement the MTMP must be taken into account when establishing fees, it does not specify how these fees should be paid. We believe that fees associated with provision of medication therapy management services are separate and distinct from dispensing fees discussed in section § 423.100 of the preamble for this proposed regulation. Although section 1860D-4(c)(2)(E) of the Act states that PDP sponsors must disclose to the Secretary the amount of "any such management or dispensing fees", it merely governs disclosure. There should be a strict prohibition that MTMP fees are not to be included/commingled in the dispensing fees of the patient's medication. The differentiation of services most probably will be provided by different pharmacists or at a minimum, delivered at a different time and physical setting. Therefore, costs associated with MTMPs, including these management fees, are included as part of the general administrative overhead costs in the plan bid.

For purposes of evaluating the administrative component of a PDP's bid, we will ask a PDP sponsor or MA organization to disclose the fees it pays to pharmacists or others, including an

explanation of those fees attributable to MTMP services, as well as those fees delivered for services at a higher level for DSM services for CCIP patients. The fee information provided to us under this authority would be protected under the confidentiality provisions of section 1927 (b)(3)(D) of the Act. Under those provisions, we would be prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider providing the MTMP services – except to the extent necessary to administer the Part D program, to permit the Comptroller General to review the information, or to permit the Director of the Congressional Budget Office to review the information. If we were to discover situations in which plans systematically did not pay the fees described in their applications – and, if those errors were not corrected upon notification, we might, at our discretion, employ the broad ranges of intermediate sanctions or termination provisions available under Subparts K and O of the regulations.

While we expect to perform the due diligence described above through application review and potentially following up on any complaints we do believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services.

Private FFS and MA Plan Exemptions

Regulation – Subpart D

(f) Exception for private fee-for-service MA plans offering qualified prescription drug coverage. In the case of an MA plan described in §422.4(a)(3) of this chapter, the requirements under paragraphs (b) and (d) of this section do not apply.

Submitter : Ms. Diane Galarneau **Date & Time:** 08/23/2004 08:08:10

Organization : Ms. Diane Galarneau

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please, I would ask you to revise this amendements as it could be quite cruel to many of your older's patients this lack of benzodiazepine. Having cut out this drug after 10 years use, I can assure you the pain was unbearable and still today after 4 years, I am having some left sensitivies to many food chemicals, plus some spasms that keep me up at nights sometimes.

Upon a Medicare recipient?s request for a covered benzodiazepine alternative, benzodiazepine therapy is likely to be suddenly stopped. Since many of my Medicare-recipient clients have been taking benzodiazepines for more than 2 months, abrupt cessation may cause severe withdrawal symptoms such as seizures that require Medicare-funded emergency room treatment and hospitalization.

In the end, you will spend a lot more money on hospitalization costs and emergency costs, plus other drugs to compensate for the pain and all the problems that will come out sooner or later if they are stopped from using their benzodiazepine or if they are switched too fast to another one.

I hope sincerely to be read and to be listened because I want to help our older's in their few remaining life. Benzodiazepine are a drug that hurts much more than what is not the accepted norm from people you write the prescription, not for the one using it though.

CMS-4068-P-13

Submitter : Mrs. Juliet Wills **Date & Time:** 08/24/2004 01:08:33

Organization : Mrs. Juliet Wills

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am sorry that seniors who are already prescribed benzodiazepines will not be able to have their prescriptions covered by the new Medicare prescription Drug Benefit. I agree they should not be covered IF it is a new prescription and quite frankly, no one should be prescribed these drugs long term (longer than 2 weeks), because they are highly addictive and cause terrible discontinuation syndromes that last for months and even years for some people. However, some niave seniors are going to be causing themselves undue suffering, by asking for other drugs to replace the benzodiazepines. Other drugs will not keep many of them from withdrawal. Once it begins it is very difficult to reverse. If you doubt my words, check out benzo.org.uk. The U.K.is lightyears ahead of us in their knowlege of the dangers of benzodiazepines. But let's not let our seniors who are already taking these medications suffer needlessly.

Submitter : Ms. Cynthia Samora **Date & Time:** 08/25/2004 12:08:40

Organization : B.A.N. (benzodiazepine awareness network)

Category : Congressional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Please do more research and rethink this insane idea that you can just take people off these highly addictive drugs without hurting them or that you can switch them from a benzo to an SSRI without real serious complications. Here are a few avenues of information to help you. links of importance:

http://health.groups.yahoo.com/group/benzo/files/ (lots of benzo info)

http://health.groups.yahoo.com/group/benzo/messages (interactive message boards)

www.benzoliberty.com

http://www.benzoliberty.com/stories/cindy%20story.php (my personal recovery story)

http://www.petitiononline.com/benzo/petition.html

www.benzo.org.uk

www.drugawareness.org (focused on SSRI's and the insanity they cause)

http://www.petitiononline.com/effexor/petition.html

http://www.rense.com/general52/exc.htm politicians (Bushes) profit from FDA approval of unsafe meds

http://www.neurogenesis.iact1.com/5312/ (nerve/WD remedy)

http://www.fda.gov/medwatch/report/consumer/consumer.htm

http:// www.mercola.com (the number one health site on the net)
Those of us unfortunate Iatrogenic victims KNOW you can not do this without creating major problems for those seniors currently takin benzo's and one day there will be enough of us joined together by the
web to blow the lid off this ridiculous notion that we Americans are drug experiments in progress, with you, our own congress at the helm, the FDA co-piloting the experiment and all the politicians, doctors and pharmeceutical companies profitting, at the expense of our chance to have any quality of life. STOP THE MADNESS, NOW!!!
Sincerely,
Cindy Samora
a recovered victim of Iatrogenic Benzo related Illness lasting 17 years because of doctor ordered Cold Turkey OFF of Valium and now working to help others like me survive the nightmare these horrible drugs cause when stopped rapidly. What do you plan to do with seniors in shock and having seizures etc.? Are you gonna place them in a rehab for grannies and grampa's or turn your backs on them and let them suffer and die? Probably, you're all so ignorant to the truth about these damn drugs. You'll be hearing more from me and my group, soon. Brace yourselves.

CMS-4068-P-15

Submitter : Blair Barton-Percival **Date & Time:** 08/25/2004 01:08:23

Organization : Blair Barton-Percival

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Not allowing CMS to negotiate prescription drug prices for Medicare beneficiaries is a crime. The purchasing power of 41 million united people is huge and the legislation has removed that power by legislating that individuals research and purchase drugs on their own. Legislating that it is illegal to purchase prescription medicines from across national borders is also removing more power from Medicare beneficiaries by removing viable options.

The Medicare Prescription Drug Discount Card is a farce. Prescription Drug Discount Cards have been around for years and have been successfully assisting many people purchase prescription medicines at a reduced cost. The Medicare Discount Cards will help very few people that are not already receiving assistance through an existing program.

The Medicare Modernizations Act has many flaws. The outlook for health care for our senior population does not look good. Please reconsider amending this Act with real and true assistance for the masses.

Submitter : Ms. Jo Murphy **Date & Time:** 08/26/2004 06:08:38

Organization : Area Agency on Aging of Western Michigan

Category : Social Worker

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Beneficiaries worry they will make a selection and the companies will change drug lists or their doctor will change medicines. They would like protection from formulary changes.

ELIGIBILITY, ELECTION, AND ENROLLMENT

It has been diffcult to enroll older adults into the discount card program because there are too many choices (41 in Michigan). For the Part D benefit, two or three choices per region (state) would be the maximum number of choices in order to have beneficiaries sign up. A large number of choices overwhelm people and they give up without enrolling.

GENERAL PROVISIONS

It would be better to have Part D pay 50% of all drug costs rather than 75%, 0%, and 95%. The older adults I work with, balk at paying a premium and also paying 100% of their drug sosts.

Submitter : Mark Burke **Date & Time:** 08/26/2004 11:08:34

Organization : Satellite Healthcare

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

Issues 1-10

BACKGROUND

It has been nearly 20 years since geographic wage differences have been taken into account in setting dialysis facility reimbursement. The last time that CMS adjusted dialysis reimbursement using the composite rate methodology?and therefore incorporated the geographic wage index?was in 1986 (at which time it reduced the base rate by $2.00 per treatment and diverted $.50 per treatment to fund the ESRD Networks).

Since that time US demographics have experienced profound changes through economic expansion, housing, wage and labor costs and geographical population redistribution. CMS has provided for ongoing wage and labor index adjustment throughout various sectors of healthcare. Most recently the OMB has defined and redrawn boundaries of the country?s Metropolitan Statistical Areas (MSAs). These updated MSAs are currently being used by CMS as proxies for hospital labor markets.

Geographic labor issues have been further exaggerated in markets such as California, New York and other expanding MSAs. We are providing examples of wage increases covering the period of 2001 to 2004 and current examples of the type of labor contracts that have been negotiated by the California Nurses Association with such key providers as Kaiser, Sutter Health and HCA.

CMS Rationale for no action

CMS has publicly acknowledged that they have an ?outdated? wage index (pg 56) based on 1980-1986 data, admit they have a current wage index that could be applied but have chosen to take no action to replace them with revised measures pending completion of an assessments.

The ruling states, ?we recognize that the new OMB definitions will have implications for the various payment systems we administer that reflect payment distinctions based on geographical location. Any changes adopted will not only result in payment redistributions among ESRD facilities, but will also affect hospitals, ?.?

?Therefore it is essential that we evaluate any proposals to revise the area definitions and assess the impact of changes in geographical areas on those payments systems that incorporate adjusters for area wage levels among urban and rural locations.?

Provider Comments

1. CMS has both an opportunity and obligation to clean up long standing inequities in geographical labor and wages difference.
2. CMS may have misinterpreted the language in MMA regarding the wage index. In three places (pgs 1,10 & 56)) they state that MMA (1) ?allows? the Secretary or `gives him discretion? to adjust the rate by a geographic index if the Secretary determines it appropriate? and (2) that it would/could be phased in over a multi-year period.?
a. SEC 623 Payment for Renal Dialysis Services (D) states ?The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period?.
3. Numerous wage and labor indexes currently exist and are updated annually for multiple segments of healthcare so no new indexes are required.
4. New OMB definitions of MSAs, CSAs and ?micropolitan? have been developed and implemented for the hospital industry. CMS has gone further and developed specific multi year transition plans for the hospital industry including the 50/50 blend of the 2004 wage index.
5. We believe the Secretary?s actions or lack of action is discriminatory in light of efforts made in other areas of healthcare.
6. CMS is putting Medicare beneficiaries at risk of reduced level of care, or worse, no care at all. Providers in high labor cost markets will neither be able nor willing to deliver care at a financial loss, nor can it be expected that commercial payors are available to underwrite losses incurred from inappropriate CMS payments.
7. CMS provides no guidance or time

GENERAL PROVISIONS

Recommendations:

We believe in the case of geographical wage index a course of no action is far more damaging than a course that leverages the work already provided by OBM and CMS. We are recommending CMS take affirmative action towards implementing the needed update to the geographical wage index.

We are recommending the following actions;

1. Within 180 day CMS deliver a report evaluating the impact of implementing new geographic wage index
2. CMS would use the OMB definitions of MSAs, CSAs and ?micropolitan? and apply it to the dialysis community, including the same redrawn labor market boundaries of the country?s MSA defined and applied to hospitals.
3. We agree with the Secretary such adjustments should be phased in over a multi year period, we recommend such transition period not to exceed three years.
4. CMS would utilize those methodologies provided to the hospital industry to provide for ongoing updates to the labor index.

We believe this would be the least disruptive courseto providers and least resource intense way for CMS to act on the intent of the MMA. Furthermore this resolves long overdue inequities within the dialysis composite rate derived from geographical labor differences and avoids the looming realities for reduced or no coverage for Medicare beneficiaries.

Submitter : Mrs. Lynn Casey **Date & Time:** 08/27/2004 01:08:18

Organization : Renal Care Group

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

Dialysis patients lose water soluble vitamins every treatment and require a prescription vitamin (retail cost $7-$10 for 100 pills) to prevent malnutriton. These should be a covered benefit and you could limit the type allowed to be prescribed to the cheapest ones available.

Submitter : Mrs. Patricia Reddicks **Date & Time:** 08/27/2004 09:08:44

Organization : Renal Care Group-Havasu

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

As a renal dietitian,I see the need for prescription coverage for water-soluble vitamins for hemodialysis and peritoneal dialysis patients. The types of vitamins needed by this group are unique to the diagnosis of end-stage renal disease. Please reconsider the types of vitmins covered under the prescription plan to include these as well.

CMS-4068-P-20

Submitter : Mr. James Utrie **Date & Time:** 08/31/2004 03:08:54

Organization : WEA INSURANCE CORPORATION

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

I write in reference to the "Discussion Paper: CMS Employer Open Door Forum.

We are an insurer of public school employees in Wisconsin. About 20% of our enrollemtn is age 65 and above.

Two questions from the above document:

1. Page 4 under Enhanced Benefits Through Medicare Part D Plans states; Under c) Employers and unions can use these savings to "Become a Medicare Par D plan offering enhanced benefits only to that employer or union's retirees." What does this mean for an insurer sponsored by a teacher union? Can we become a Part D provider for our limited subscriber base?

2.On page 9 is the statement: "Finally, some eployers that currently offer retiree group health insurance make little or no contribution to the cost of that coverage. Such employers will not qualify for the retiree drug subsidy,".... What does this mean for an insurer sponsored by a union, if anything? If we choose to continue rpoviding primary drug coverage to our Medicare population, would we be eligible for the 28% subsidy if employers make no contribution to retiree drug plans?

Submitter : Dr. Michael Rupp **Date & Time:** 08/31/2004 07:08:22

Organization : Midwestern University - Glendale Campus

Category : Academic

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

I am in strong support of defining dispensing fees in the Medicare Prescription Drug Benefit to include only those activities necessary to appropriately transfer possession of the drug product from the pharmacy to the beneficiary (Option 1).

Ideally, dispensing fees in PDPs should recognize the costs incurred by pharmacy providers to effect the safe and effective exchange of the pharmaceutical product between the pharmacy provider and the patient. These include all activities that are routinely included in calculating a pharmacy's average cost to dispense a prescription such as product ordering and stocking, processing the prescription order, repackaging, labeling, and dispensing the product in combination with all legally mandated drug utilization review and patient counseling services. The dispensing fee also appropriately includes a reasonable margin beyond the actual operational costs of dispensing (i.e., profit).

It is important the dispensing fee is not confused with the cost of the pharmaceutical product, the reimbursement for which is appropriately based on a reasonable estimate of - if not the actual - acquisition cost. Further, the dispensing fee should not be confused with additional professional services that may be performed by pharmacy providers for selected patients with special needs. Such activities (e.g., medication therapy management services) represent extra-distributive professional services that are appropriately considered separately from the prescription drug transaction, and perhaps separately from the PDP entirely.

In 1975, the then Department of Health, Education and Welfare (DHEW) mandated that when establishing the dispensing fee for Medicaid patients, 'States should take into account the results of surveys of costs of pharmacy operation.' This was to be achieved by requiring states to periodically conduct surveys of pharmacy operational data including such components as overhead, professional services and profits. In 1987, the Department of Health and Human Services (DHHS) eliminated the requirement that states conduct periodic cost-of-dispensing surveys, but stipulated that states would still be required to determine 'reasonable dispensing fees.'

Despite this stipulation, the extent to which accurate and timely dispensing-relevant cost data are being systematically integrated into state Medicaid programs continues to be minimal. It is my hope this does not occur in the Medicare Prescription Drug Benefit. Dispensing-relevant cost data are not being routinely considered in Medicaid progams partly because traditional methods of conducting pharmacy cost-of-dispensing analysis were time-consuming, expensive, and had significant methodological variance across vendors. Recent advances in the use of standard online real-time cost-of-dispensing analysis has eliminated these historical barriers. In so doing, this technology affords the opportunity to operationally define dispensing fees, and to appropriately consider this important component separately from others with which it is routinely combined and/or confused in PDPs.

CMS-4068-P-22

Submitter : Mr. Martin Kim **Date & Time:** 09/03/2004 02:09:10

Organization : Mission Pharmacy

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

My name is Martin Kim and I am a pharmacist at Mission Pharmacy.
1. MTMP are direct proactive interventions designed to enhance patient's 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 menagement and patient counseling, customized packaging and refill management, and specialized patient medication reminders. Customized packaging must conform to 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 reimbursed as a management fee, NOT as a dispensing fee. Cost associated with MTMP are separated and distinct from those costs associated with dispensing.
In-take assessment: 30-45 minutes of pharmacist's time per occurrence;
Monitoring and following up: 15-25 minutes of pharmacist's time per occurrence.
Thank You for listening....

Submitter : Mr. Michael Guglielmino **Date & Time:** 09/03/2004 06:09:03

Organization : Trinitas Hospital

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I am concerned about dually eligible Medicare/Medicaid beneficiaries being able to afford co-pay expenses under new regulations. For our patients, especially those on multiple medical and psychotropic medications this would be an undue burden and would likely impact adversely on patient care outcomes, i.e., increased ER visits and hospitalizations/rehospitalizations.

Submitter : Larry Korelc **Date & Time:** 09/07/2004 02:09:27

Organization : Minooka Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

My name is Larry E. Korelc, RPh. and I am a pharmacist at Minooka Pharmacy. My response to "Medicare Prescription Drug Benefit" [CMS-4068-P] is as follows:

MTMP are direct proactive interventions designed to enhance patients' ability to take medicine correctly and increase patient medication compliance.

MTMP is a direct patient care service performed by a pharmacist interacting with a patient and their medications.

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.

MTMP are generally of an ongoing nature, involving an initial patient in-take assessment, followed by routine patient monitoring at regular intervals.

MTMP must be reimbursed as a management fee, NO 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 occurance;
Monitoring and follow-up: 15 - 25 minutes of pharmacists' time per occurance.

CMS-4068-P-25

Submitter : Mr. Angelo Greco **Date & Time:** 09/07/2004 03:09:57

Organization : Medicap Pharmacy #309

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

My Name is Angelo A Greco and I am a phamacist at Medicap Pharmacy in Pittston, Pennsylvania.

My response to 'Medicap Prescription Drug Benefit [cms-4068-P] is as follows:

1. MTMP are direct proactive interventios 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 family) and their medications.
3. MTMP include case management and patient conseling, 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 reimbursed as a MANAGEMENT FEE, not as a dispensing fee. Cost associated with MTMP are separate and distinct from those costs associated with dispensing.
   a. In-take assessment: 30-45 minutes of pharmacists' time per occurrence;
   b. Monitoring and following up: 15-20 minutes of pharmacists' time per occurrence.

Submitter : Dr. Richard Blum **Date & Time:** 09/07/2004 07:09:05

Organization : Dr. Richard Blum

Category : Physician

Issue Areas/Comments

Issues 1-10

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

I wish to comment on the following sections 423.578, 423.123(c),423.123(d),423.564, and any other section that governs quality of care and the exception process.

I consider the exception process paramount safety net for the protection of patient safety.

As a practicing physician in the field of special populations I feel that you have severely underestimated the time that would be necessary to comply with PDP special need requests, as is estimated in 423.578. 500 hours/year in my practice woiuld be more like it. Will reimbursement for these administrative services be available?

There is a method which can be employed to streamline the exception process, and that is standardization of the exception process. These standardized exception criteria are to be based on the special needs of the patients. They shall be: EXEMPTION CRITERIA:

1. Individual patient clearance issues [e.g increased or decreased CYP 450, renal disease, hepatic disease, age, etc.]

2.Medical need for different dosage forms

3.Medical need for different route of administration.

4. Demonstrated medication failure on the preferred drug of the same class[family].

5.Known allergic or adverse events to the preferred agent.

6. Demonstrated antibiotic resistance to the preferred agent.

7. Medical needs of special populations

In the mechanics of the system #'s 1-7 will be ther reasons for the exception and they can be listed right on the prescription. This will make the process cleaner, more uniform and easier to navigate for the PDP and the patient/physician. Of course all exception will be open to the scientific DUR process by the PDP. This can easily be fit into the NCPDP format, and ICD-9 codeds can be included if necessary.

Should the PDP still refuse to dispense the drug,then the physician must be able to adjudicate the clinical case with another 3rd party physician. This shall be done by the QIO mechanism. The QIO's are equipted to do this immediately, and if the QIO is not open the patient gets an automatic 72 hr. amount of medication so as to prevent suffering. This evaluation by a 3rd party would go a long way to add credibility and validate the process.

The procedure of going to the QIO's would also help to fulfill the quality improvement portion of the program including medication therapy management as is stated in 423.153(c)(d).

The funds to complete this task can come from disbanding the states DUR programs, which will not be able to fulfill their tasks as was spelled out in 1988, as patients under parts C & D of medicare are withdrawn from the medicaid database.

Respectfully submitted

Ricahrd S. Blum, MD,FCP,FACP
Medical Director United Cerebral Palsy Suffolk Co., NY

Chairman P&T Committee & Consultant in pharmacology, St. Francis Hospital

Asst. Prof Clinical Medicine SUNY Stonybrook
Adjunct Asst. Prof. of Clinical Pharmacy St. John's University School of pharmacy

Adjunct Professor of Pharmacology Long Island University

Vice Chairman NY State DUR Board

United Stated Pharmacopoeia Expert Committees of therapeutic decision making, Nominating, and Medicare Model Guidelines.

CMS-4068-P-26-Attach-1.txt

CMS-4068-P-26-Attach-2.txt

September 4, 2004

Dear administrator,

As per your request for public comment on the proposed Part D Medicare benefit I wish to comment on the following sections, specifically § 423.578, § 423.153(c), § 423.153(d), § 423.564. These and other sections concern the exception process. I consider the exception process as the paramount safety net for the patient. As a practicing physician, I believe that you have underestimated the length of time necessary for a physician to comply with a PDP's request. If past history is any indication of future activity the time per physician will be much greater than estimated in § 423.578. In a special needs population a physician can spend upwards of 500 hours a year getting what their patients need. Will the physician be reimbursed for their administrative time. There is a method that can be used to streamline the system, and make is user friendly to the PDP, Physician and patient alike, and that is by using standardized exception criteria. These criteria are based on the medical need of the patient population. THE Standardized EXCEPTIONS to be considered are 1. Individual patient clearance issues [e.g renal disease, hepatic disease, increased or decreased CYP levels, age, etc] 2. Medical need for different dosage forms 3. Medical need for different routes of administration 4. Medical needs of special populations 5. Demonstrated medication failure on the preferred drug of the same class [family] 6. Known allergic, or adverse events to the preferred drug 7. Demonstrated antIbiotic resistance to the preferred agent. In the mechanics of the system, 1-7 will be the reasons for exception. These can be the listed by the physician, on the prescription, for the exception process. This will make the process cleaner, more uniform, and easier to navigate for both the PBM and the patient/prescriber. Of course all exceptions will be open to the scrutiny of the insurance company via a scientific DUR process. This is also a nice easy way to fit into the NCPDP format for the pharmacist if they need it. If necessary, and permissible under HIPPA, the ICD-9 code for that visit can too be included on the prescription. Should the PDP still refuse to dispense the drug, under the exception, then the physician must be able to adjudicate the difference of opinion with another physician on a clinical basis, and that shall be done via the QIO mechanism. The QIO's, on a daily basis know the standards in the community, and can handle it immediately, so that the patient will not suffer. If the exception comes up at a time that the QIO is not open then the patient will automatically be dispensed 72 hours of the prescribed medication. This evaluation by an impartial 3rd party would go a long way to add credibility to the process. This procedure, of going to the QIO's, would also help fulfill the quality assurance portion of the program as stated in § 423.153(c), including the medication therapy management program required under § 423.153 (d) The money to fund this project can come from disbanding the entire DUR projects in the states. Medicare Part C & D have taken away a large number of patients available for scrutiny under DUR, and the programs no longer can do the job they were designed to do in 1988.

Respectfully submitted,
Richard S. Blum, M.S., M.D., F.C.P., F.A.C.P.
Medical Director United Cerebral Palsy,
Suffolk County, NY
Chairman, Pharmacy & Therapeutics, & Consultant in Pharmacology, St. Francis Hosp. Assistant

Professor of Clinical Medicine SUNY Stony Brook Adjunct, Assistant Professor of Clinical Pharmacy, St. John's University, School of Pharmacy Adjunct, Professor [level 4] of Health Science, Long Island University - C.W. Post Campus Special Government Employee Expert & Former Consultant, Food and Drug Administration Member, United States Pharmacopoeia Expert Committees, Therapeutic Decision Making, Nominating & Medicare Modeling Guidelines Vice Chairman, New York State Department of Health DUR Board Richard S. Blum, M.S., M.D., F.C.P., F.A.C.P. 25 Spruce Drive East Hills, New York 11576-2331

Tel: [516] 484-0491 email:Pharmboy@optonline.net

September 4, 2004

Dear administrator,

As per your request for public comment on the proposed Part D Medicare benefit I wish to comment on the following sections, specifically § 423.578, § 423.153(c), § 423.153(d), § 423.564. These and other sections concern the exception process.

I consider the exception process as the paramount safety net for the patient.

As a practicing physician, I believe that you have underestimated the length of time necessary for a physician to comply with a PDP's request. If past history is any indication of future activity the time per physician will be much greater than estimated in § 423.578. In a special needs population a physician can spend upwards of 500 hours a year getting what their patients need. Will the physician be reimbursed for their administrative time?

There is a method that can be used to streamline the system, and make is user friendly to the PDP, Physician and patient alike, and that is by using standardized exception criteria. These criteria are based on the medical need of the patient population.

THE Standardized EXCEPTIONS to be considered are

1. Individual patient clearance issues [e.g renal disease, hepatic disease, increased or decreased CYP levels, age, etc] 2. Medical need for different dosage forms 3. Medical need for different routes of administration 4. Medical needs of special populations 5. Demonstrated medication failure on the preferred drug of the same class [family] 6. Known allergic, or adverse events to the preferred drug 7. Demonstrated antIbiotic resistance to the preferred agent

In the mechanics of the system, 1-7 will be the reasons for exception. These can be the listed by the physician, on the prescription, for the exception process. This will make the process cleaner, more uniform, and easier to navigate for both the PBM and the patient/prescriber. Of course all exceptions will be open to the scrutiny of the insurance company via a scientific DUR process. This is also a nice easy way to fit into the NCPDP format for the pharmacist if they need it. If necessary, and permissible under HIPPA, the ICD-9 code for that visit can too be included on the prescription.

Should the PDP still refuse to dispense the drug, under the exception, then the physician must be able to adjudicate the difference of opinion with another physician on a clinical basis, and that shall be done via the QIO mechanism. The QIO's, on a daily basis know the standards in the community, and can handle it immediately, so that the patient will not suffer. If the exception comes up at a time that the QIO is not open then the patient will automatically be dispensed 72 hours of the prescribed medication. This evaluation by an impartial 3rd party would go a long way to add credibility to the process.

This procedure, of going to the QIO's, would also help fulfill the quality assurance portion of the

program as stated in § 423.153(c), including the medication therapy management program required under § 423.153(d)

The money to fund this project can come from disbanding the entire DUR projects in the states. Medicare Part C & D have taken away a large number of patients available for scrutiny under DUR, and the programs no longer can do the job they were designed to do in 1988.

Respectfully submitted

Richard S. Blum
Richard S. Blum, M.S., M.D., F.C.P., F.A.C.P.
Medical Director United Cerebral Palsy, Suffolk County, NY
Chairman, Pharmacy & Therapeutics, & Consultant in Pharmacology, St. Francis Hosp.
Assistant Professor of Clinical Medicine SUNY Stony Brook
Adjunct, Assistant Professor of Clinical Pharmacy, St. John's University, School of Pharmacy
Adjunct, Professor [level 4] of Health Science, Long Island University - C.W. Post Campus
Special Government Employee Expert & Former Consultant, Food and Drug Administration
Member, United States Pharmacopoeia Expert Committees, Therapeutic Decision Making, Nominating & Medicare Modeling Guidelines
Vice Chairman, New York State Department of Health DUR Board
Richard S. Blum, M.S., M.D., F.C.P., F.A.C.P.
25 Spruce Drive
East Hills, New York 11576-2331

Tel: [516] 484-0491 email:Pharmboy@optonline.net

CMS-4068-P-27

Submitter : Mr. Ian Salditch **Date & Time:** 09/07/2004 10:09:47

Organization : Pharmacists for the Protection of Patient Care

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

My comments refer to Section 1860D-4 of the Medicare Drug Benefit (CMS-4068-P), specifically that which refers to Medication Therapy Management Programs.

In general, upon review of pages 209 to 222, I feel quite strongly that CMS has failed to fulfill it?s duty to provide clarity, and to set minimum standards for what is intended (by law) to be an essential Medicare Benefit.

Even those CMS responsibilities required by statute appear to be delegated, perhaps illegally, to private contractors. Quoting from page 215, ?While the statute states that CMS sets the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services, our preferred policy is to delegate this function to the private drug plans,?? This position is in direct opposition to the language of the law.

The law requires Plan Sponsors to provide MTMP. CMS must provide a minimum acceptable definition of MTMP. I suggest the following simple definition for consideration:

1) Medication Therapy Management Services are direct pro-active interventions designed to enhance patients? ability to take their medicine correctly, and increase the likelihood that patients adhere to their prescribed medication therapies, over time.

2) Medication Therapy Management is a direct patient care service performed by a pharmacist interacting with a patient and their medications. (Medication Therapy Management is unlike Quality Assurance (QA), or Drug Utilization Review (DUR), that can be performed remotely, and/or retrospectively, at the Plan Sponsor level).

3) Medication Therapy Management Services include case management and patient counseling, customized packaging and refill management, and specialized patient medication reminders. (Customized packaging must comport with the United States Pharmacopoeia (USP) standards for customized packaging.)

4) Medication Therapy Management Services are generally of an ongoing nature, involving an initial patient in-take assessment, (to consolidate the knowledge of all of a patient?s drug therapy, by all prescribers, as well as OTCs and supplements), followed by routine patient monitoring, and follow-up at regular intervals.

Further, CMS must provide a definition for Targeted Beneficiaries. I suggest the following simple definition for consideration, (much of this language is taken directly from the law):

Targeted beneficiaries must meet one or more of the following requirements:

-Medicare Beneficiaries that have multiple chronic diseases, (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

-Medicare Beneficiaries that are taking multiple covered Part D drugs; and

-Medicare Beneficiaries that are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary (Suggested $1200).

Perhaps, the most egregious portion of the current CMS document can be found on page 220, ??we do not believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services.? I believe this statement alone will ensure that MTMP services (guaranteed by law) will be of the poorest quality, will have the most limited availability, and will produce none of their intended cost-saving and life-saving benefit. I urge you, most emphatically, to reconsider this position.

Respectfully,
Ian Eric Salditch, Advocate

Pharmacists for the Protection of Patient Care

CMS-4068-P-27-Attach-1.doc

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

September 7, 2004

Dear Sir or Madam,

My comments refer to Section 1860D-4 of the Medicare Drug Benefit (CMS-4068-P), specifically that which refers to Medication Therapy Management Programs.

In general, upon review of pages 209 to 222, I feel quite strongly that CMS has failed to fulfill it's duty to provide clarity, and to set minimum standards for what is intended (by law) to be an essential Medicare Benefit.

Even those CMS responsibilities *required by statute* appear to be delegated, perhaps illegally, to private contractors. Quoting from page 215, "While the statute states that CMS sets the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services, our preferred policy is to delegate this function to the private drug plans,…" This position is in direct opposition to the language of the law.

The law requires Plan Sponsors to provide MTMP. CMS must provide a minimum acceptable definition of MTMP. I suggest the following simple definition for consideration:

- Medication Therapy Management Services are direct pro-active interventions designed to enhance patients' ability to take their medicine correctly, and increase the likelihood that patients adhere to their prescribed medication therapies, over time.

- Medication Therapy Management is a direct patient care service performed by a pharmacist interacting with a patient and their medications. (Medication Therapy Management is unlike Quality Assurance (QA), or Drug Utilization Review (DUR), that can be performed remotely, and/or retrospectively, at the Plan Sponsor level).

- Medication Therapy Management Services include case management and patient counseling, customized packaging and refill management, and specialized patient medication reminders. (Customized packaging must comport with the United States Pharmacopoeia (USP) standards for customized packaging.)

- Medication Therapy Management Services are generally of an ongoing nature, involving an initial patient in-take assessment, (to consolidate the knowledge of all of a patient's drug therapy, by all prescribers, as well as OTCs and supplements), followed by routine patient monitoring, and follow-up at regular intervals.

In addition, CMS must also provide a definition for Targeted Beneficiaries. I suggest the following simple definition for consideration, (much of this language is taken directly from the law):

Targeted beneficiaries must meet one or more of the following requirements.

- Medicare Beneficiaries that have multiple chronic diseases, (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

- Medicare Beneficiaries that are taking multiple covered Part D drugs; and

- Medicare Beneficiaries that are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary ($1200).

Perhaps, the most egregious portion of the current CMS document can be found on page 220, "…we do not believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services." I believe this statement alone will ensure that MTMP services (guaranteed by law) will be of the poorest quality, will have the most limited availability, and will produce none of their intended cost-saving and life-saving benefit. I urge you, most emphatically, to reconsider this position.

Respectfully,

Ian Eric Salditch, Advocate

CMS-4068-P-28

Submitter : Dr. Thomas C. Washburn **Date & Time:** 09/08/2004 07:09:07

Organization : none

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This Medicare Program, as presently written, will not adequately meet the needs of senior citizens for affordable prescription drugs. The pharmaceutical companies are taking advantage of the payouts to them from the Act that authoized the prescription drug plan. And they are continuing to increase the cost of prescription drugs that senior citizens use.
My recommendations for the Prescription Drug Benefit Program are as follows:
1. Return to Congress and the President to get authorization to negotiate prices of prescription drugs with the pharmaceutical companies. This is to control the runaway costs of drugs.
2. Return to Congress and the President to get authorization for any and all US citizens and governmental entities to purchase prescription drugs legally from Canada. This is to make more prescription drugs available at lower prices.
3. Return to Congress and the President to get authorization to reduce the so-called donut hole in the present plan. Too many senior citizens take quantities of drugs that do not allow them to afford prescription drugs beyond a certain annual amount.
4. Produce regulations that prevent pharmaceutical companies from raising the cost of prescription drugs beyond the COA each year.
5. Produce regulations that prevent drug card companies and insurance plans from changing the allowable drugs and the allowable amounts to pay for those drugs any more often than once a year and only with prior notification to their clients.
6. Produce regulations that ensure that employers do not cut prescription drug benefits from their insurance plans for retirees.
Thank you for your attention.

CMS-4068-P-29

Submitter : Mr. Tim Lucas **Date & Time:** 09/09/2004 04:09:57

Organization : Down Home Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

My name is Tim Lucas and I am a pharmacist at Down Home Pharmacy in Roanoke, VA.

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 reimbursed as a management fee, NOT a dispensing fee. Costs associated with MTMP are seperate 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

Submitter : Ms. Allison Lucas **Date & Time:** 09/09/2004 04:09:38

Organization : Down Home Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

My name is Allison Lucas and I am a pharmacist at Down Home Pharmacy in Roanoke, VA.

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 reimbursed as a management fee, NOT a dispensing fee. Costs associated with MTMP are seperate 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.

Submitter : Ms. Susan Wooten **Date & Time:** 09/09/2004 04:09:47

Organization : Virginia Commonwealth University-MCV Campus

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

My name is Susan Wooten and I am a pharmacy student at Virginia Commonwealth University-MCV Campus.

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 reimbursed as a management fee, NOT a dispensing fee. Costs associated with MTMP are seperate 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

Submitter : Mr. Doug Alfred **Date & Time:** 09/09/2004 05:09:40

Organization : Mount Carmel Health Plan

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Regulations that require single-product MA plans (with an existing "market-attractive" outpatient drug benefit) to switch to a standard prescription drug coverage in 2006 may actually hurt the plans and their covered beneficiaries. Some such plans already offer drug benefits that currently satisfy the needs of their enrollees. Enrolled beneficiaries in such plans may perceive such changes in 2006 as take-aways when annual Rx deductibles and increased cost-sharing features are introduced under a standard prescription drug coverage design.

CMS-4068-P-33

Submitter : walter toole **Date & Time:** 09/10/2004 12:09:28

Organization : Liberty family Pharmacy

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

My name is Walter A. Toole and I am pharmacist at Liberty Family Pharmacy.
My response to "Medicare Prescription Drug Benefit"(CMS-4068-P) is the
following:
MTMP are direct interventions which are proactive designed to enhance
patients' ability to take medicine correctly and increase patient medication compliance.
MTMP is a directed patient care service performed by a pharmacist interacting with a patient, their medications and physician.
MTMP include patient care management, patient counseling, specific patient medication reminders and customized packaging when required.
MTMP are of an ongoing nature involving an initial patient in-take
assessment followed by routine patient monitoring at regular intervals
MTMP must be reimbursed as a management fee and not as a dispensing fee.
The time involved would be from in-take assessment 30-45 min. of
pharmacists time per occurence and Monitoring and follow up at regular intervals 15-20 min. per occurrence.

Submitter : Dr. Christian S. Tadrus **Date & Time:** 09/10/2004 06:09:24

Organization : Sam's Drugstores, Inc.

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Christian Tadrus, Pharm.D., a pharmacist from the State of Missouri employed by Sam's Prescription Shops, Inc. I also own a LLC under the name of Disease Management Services d/b/a Better Outcomes.

My comments on the Medicare Prescription Drug Benefit [CMS-4068-P] are as follows:

1) MTMP should be viewed as direct, proactive interventions that enhance patients' ability to take medication correctly and increase their compliance with prescribed therapy.

2) MTMP is a patient care service performed by a licensed, trained pharmacist that interacts DIRECTLY IN PERSON with a patient and their medication.

3) MTMP include case management, patient counseling, customized packaging and appropriate screening for managing adherance to refills including specialized patient medication reminders. Customized packaging for such interventions comply with United States Pharmacopoeia (USP) standards as does all pharmacy packaging utilized in the United States.

4) MTMP involve an initial, in person, patient assessment, followed by routine patient monitoring at regular intervals and using medical industry standard assessments and documentation. Initial problem assessments, education and documenation consume between 30 and 60 minutes per distinct problem. Follow-up monitoring for each distinct problem requires 15 to 30 minutes of a pharmacist's time per contact.

5) MTMP must be reimbursed as a management fee and NOT as a dispensing fee as costs associated with MTMP are separate and distinct from those costs associated with dispensing a prescription. Beyond the pharmacist time are costs associated with documentation systems both electronic and paperbased, fixed costs including telephone, insurance and office space as well as employee staffing costs typical of any business venture.

Pharmacists are the most qualified and accessible providers to monitor patient medication therapy in order to ensure desired outcomes, reduce errors, limit waste and assess appropriate use of recipient's medications.

Submitter : Ms. Lawrence Mayhew **Date & Time:** 09/10/2004 08:09:17

Organization : Ms. Lawrence Mayhew

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

I am very concerned that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit (69 FR 46632). 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 person living with AIDS, I have personal experience with coordinating Medicare and Medicaid benefits. My drug regimens are complex and change frequently. Access to all available antiretroviral drugs through public funding allowed me not only to live, but to go back to work after 6 years on Social Security Disability Insurance. Failure to ensure full access to all FDA approved drug regimens for the treatment of HIV disease is terribly short-sighted. The only reason that HIV can be treated as a chronic disease in the United States is current level of access provided by Medicaid programs across the country. Restricting access to all approved regimens for the treatment of HIV disease will result in loss of life and productivity in all 50 states. Thank you for considering my comments as you develop these regulations.

Submitter : Dr. Barbara Gripshover **Date & Time:** 09/10/2004 09:09:32

Organization : University Hospitals of Clevleand/CWRU

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a physician caring for poor HIV-infected persons, I am very concerned about the detrimental effect the new Medicare bill may have on my patients' health. Many of my patients are on Medicare/Medicaid, and this new bill will actually restrict their access to life-saving medications. It is imperative that HIV-infected persons have access to every available medication for HIV infection, as even in the same class they are not equivalent medications and physicians must be able to individualize therapy. Furthermore, HIV patients cannot interrupt their treatment for fear of their virus developing resistance to the drugs. Therefore, patients must have a guaranteed continuous supply of medications that can not be limited by the ability to cost-share. The ADAP program has been immensely helpful in bridging this gap, and the new legislation must make sure to not limit this help. Finally, AIDS patients are very expensive to the helath care system-but AIDS patients on medications stay out of the hospital and ERs. However, private insurance plans are not going to eagerly sign up expensive AIDS patients for their Medicare HMO; the legislation must enusre they have access to the level of care they recieve now with Medicaid or ADAP.

Submitter : Mr. Dan Haase **Date & Time:** 09/11/2004 02:09:39

Organization : Not applicable-individual

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-4068-P

To Whom It May Concern:

In response 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.

For moral and ethical integrity, 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. Additionally, and

access to all medications at the preferred level of cost-sharing is both responsible economic stewardship for individuals who are challenged with hardships not allowing for quality of Life and reasonable pursuit for happiness. 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 we are to act in a responsible manner that provides a model of leadership for the world, it is essential we act in a manner that provides for noble and dignified care. To uphold the values of a compassionate Nation, of an honorable nation, our sense of humanity is demonstrated in the care we provide for citizens who are most vulnerable to hardship caused by diseases. Sufficient care is demonstrated by adequate means to medicate our fellow citizens who are infected with out current hope of cure.

Please recognize those of HIV/AIDS status as a group who suffers excessive economic, social and political scrutiny as this is not a disease of choice, those infected are victims who face challenge and burdens beyond that of average citizens and find an pattern of "falling behind" in a quality of life that all people should experience in our continue pursuit of health care that allows for a decent quality of life.

CMS-4068-P-38

Submitter : steve monroe **Date & Time:** 09/11/2004 07:09:10

Organization : steve monroe

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I understand Benzodiazepines are not a covered drug class under the medicare reform act of 2003....It's estimated by numeriuos studies that between 5-8% of the US population suffers from an anxiety disorder or panic attacks of which Benzodiazepines are commonly used to treat.....It's also estimated 1 in 5 medicare patients use Benzodiazepines for medical conditions of several kinds....6 Benzodiazepines are listed in the 2002 list of most commonly RX'd drugs in the US.....They are also very inexpensive drugs compared to more costly drugs still under patent protection...It would seem from a financial standpoint it's in both patients and the US governments best financial interests to include these widely RX'd drugs.....Millions of Americans depend on Benzodiazepines to treat existing medical conditions and to exclude them from part D coverage seems to me will be a both financial and medical hardship for many.....I also sence the US government would save millions of dollars to include this class of drugs due to there being less expensive that alternatives vastly more expensive.....I myself had been on this class of drug for years under medical supervision to control my medical condition.....I urge the dept. to include this vastly used and valueable class of drug under part D.....

Submitter : Dr. Susan Balter **Date & Time:** 09/11/2004 10:09:02

Organization : Dr. Susan Balter

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.

It is extremely important that people with HIV/AIDS have access to appropriate therapies to prevent worsening of their immune systems, opportunistic infections, increase in hospitalizations, and death. Appropriate medical care also helps protect others from contracting the disease.

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

Sincerely,

Susan Balter, M.D.
947 Jackson Ave.
River Forest, IL 60305

Submitter : Mrs. Jan Burnett **Date & Time:** 09/13/2004 01:09:22

Organization : Mrs. Jan Burnett

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

Please reconsider the medication for anxiety/panic disorder. They are a great need for many mental health consumers.

Submitter : Ms. Linda Crim **Date & Time:** 09/13/2004 04:09:47

Organization : Children's Hospital

Category : Nurse Practitioner

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

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.

All people with HIV deserve equal access to adequate treatment regardless of their ability to pay. Having provided medical care during the past 15 years to persons living with HIV, I have seen firsthand the positive impact full access to HIV medications can provide.

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

Sincerely,

Linda Crim, MSN, RN, CPN
Children's Hospital
700 Children's Drive
Columbus, Ohio 43205

Submitter : Dr. Carol Gerson **Date & Time:** 09/13/2004 07:09:14

Organization : Dr. Carol Gerson

Category : Physician

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

It is essential to be sure that HIV/AIDS drugs are covered under Medicare's prescription drug benefit. The cost of these drugs are prohibitive to all but the very rich, and especially for the elderly on fixed incomes, subsidies for these medications are critical.

CMS-4068-P-43

Submitter : **Date & Time:** 09/13/2004 08:09:10

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I'm currenlty a PharmD student. I want to express that pharmaceutical care plays a crucial role in the care of patients with drug therapy. Nowadays it is more than necessary to implement these guidelines due to our aging population as well as the complexity of drug therapy. Our citizens have not yet requested this kind of service because it was not available. Without fee-for-service type of plan, both patients and pharmacists would not benefit from this legislation.

Submitter : Mr. Mark Halverson-Wente **Date & Time:** 09/13/2004 08:09:37

Organization : Mr. Mark Halverson-Wente

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

To Whom It May Concern,

The Medicare benzodiazepine exclusion is an ill-considered and harmful approach to health care for America's older adults and must be remedied. Thank You.

CMS-4068-P-45

Submitter : Ms. Rhonda Ray **Date & Time:** 09/13/2004 09:09:43

Organization : David Powell Public Health Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

September 13, 2004

CMS-4068-P-45-Attach-1.txt

September 13, 2004

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

To Whom It May Concern:

I am 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 in the HIV medical community for many years and have seen the dramatic difference these medications make in the lives of patients living with this disease. Any barrier to access to these medications, either legislative or financial, would be a grave injustice on the part of our government. Thank you for considering my comments as you finalize the regulations.

Sincerely,

Rhonda Ray
Patient Assistance Coordinator
David Powell Public Health Center
4614 North Interstate 35
Austin, TX 78751
(512) 972-4901
Rhonda.ray@ci.austin.tx.us

CMS-4068-P-46

Submitter : Ms. Jennifer Kubic **Date & Time:** 09/14/2004 12:09:38

Organization : Ms. Jennifer Kubic

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,

Jennifer Kubic, LCSW
87 Gilbert St
Quincy, MA 02169

Submitter : Mr. Steve Detter **Date & Time:** 09/14/2004 02:09:32

Organization : Mr. Steve Detter

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

There are several points I would like to make as a pharmacist. Plans should include all pharmacies. There should not be preferred and non-preferred pharmacies (this confuses the patient about where to go). "Access" is not access if patients are coerced to use other pharmacies. There needs to be a level playing field. I do not have a problem with mail order (I use mail order {non pharmacy items}for convenience sometimes), but it is wrong to let the mail order charge a lower price than local retail pharmacies and/or force patients to use mail order as their only choice. If patients can get an extended day supply through mail order then they should be able to obtain the same at retail pharmacies at the same price.
To me the the most important part of this legislation is the Medication Therapy Management Program. If correctly implemented, it will save both the patient and the federal goverment money in the long run. So many times as a pharmacist I see prescriptions written for a drug when probably something else at a lower cost would be just as effective in the patient's drug regimen. In my opinion this occurs because physicians are 1. truly unaware of the cost of drugs, 2. a drug rep has just been in the office and detailed the physician on how great the drug is. Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS).
Plans will need to identify new targeted beneficiaries on a monthly basis. Once identified pharmacies should be notified that a patient is eligible for MTMS. Likewise, both pharmacist and physicians should be able to notify the plan and identify an eligible patient. Again pharmacist are the medication expert on the health care team and are the ideal provider of MTMS. CMS must clarify that plans can not require patients to use a specific provider for MTMS. This is akin to forced mail order. If MTMS is provided by someone the patient does not know and trust, then the likehood of optimal drug therapy outcomes decreases drastically. Fees should be the same to all providers. Again setting up preferred and non-preferred providers confuses patients. The fee schedule should be set high enough to make pharmacist want to do this. The fee schedule should be revisited annually for changes. I support the Medication Therapy Management Services Definition and Program Critera developed and adopted by 11 national pharmacy organizations in July 2004.
Thank you for consideration of my comments on this matter.

Submitter : Mr. Robert S. Johannsen **Date & Time:** 09/14/2004 03:09:13

Organization : Family Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Changes need to be made. Prescription drug companies have a closed market. Prices are extremely inflated due to lack of competition. We need to use medicare dollars wisely. The bargining power of our medicare people needs to be utilized. It's good business! I personally did not want the original bill passed due to the drug benefit inspite of fee cuts for me and continuation of the cap.

CMS-4068-P-49

Submitter : Michael Nan **Date & Time:** 09/15/2004 09:09:05

Organization : Heritage Valley Health System

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

IF YOU WANT TO HAVE A SUCCESSFUL PLAN INTRODUCED TO THE PLAN - BE STRAIGHT FOWARD - BE EXTREMELY SIMPLE - THERE IS NO NEED TO COMPLICATE THE PLAN IN ORDER TO AVOID EXCESSIVE EXPENSES TO MEDICARE - IF THERE IS A MAX. BENEFIT THAT MEDICARE WANTS TO IMPOSE UPON EACH INDIVIDUAL - JUST SPELL IT OUT- NO DEDUCTIBLES, NO MAX. OUT OF THE POCKET, ETC. - JUST SIMPLE. THE SIMPLER THE PLAN - THE MORE SUCCESSFUL - IT WON'T BE PERFECT AT FIRST, BUT WILL BE THAT MUCH CLOSER TO BEING RIGHT IF IT IS SIMPLE!! THANKS FOR YOUR EFFORTS TO ACCOMPLISH THIS MONUMENTAL TASK.

MICHAEL NAN, RPH

CMS-4068-P-50

Submitter : Mr. Joel Farley **Date & Time:** 09/15/2004 09:09:40

Organization : American Pharmacist Association

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

September 15th, 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:

In regards to the part D amendments to the Medicare program, I am concerned about a number of issues that may adversely impact the profession of pharmacy.

First, in regards to subpart C of the benefits and benficiaries protection section, 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 all patients are able to continue to use local pharmacy services.

I also 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.

My second concern is in regards to 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. 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.

In conclusion, I would urge CMS to revise the aforementioned regulations to allow patients access to Pharmacist services on the local level. I also would encourage revisions to part D which mandate health plans to include Pharmacist's as the sole provider of MTM services. As the experts in pharmacology and pharmacotherapy related issues, Pharmacist's should be seen as an invaluable resource in MTM services utilization.

Thank you very much for considering my view.

Sincerely,

Joel Farley, R.Ph.
University of Minnesota
7-174 Weaver-Densford Hall
308 Harvard St. S.E.
Minneapolis, MN 55455
612-625-7691

farl0032@umn.edu

CMS-4068-P-50-Attach-1.doc

CMS-4068-P-50-Attach-2.doc

September 15th, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068-P

Baltimore, MD 21244-8014

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Thank you very much for considering my view.

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Joel Farley, R.Ph.
University of Minnesota
7-174 Weaver-Densford Hall
308 Harvard St. S.E.
Minneapolis, MN 55455
612-625-7691
farl0032@umn.edu

September 15th, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-4068-P

Baltimore, MD 21244-8014

Re: CMS-4068-P

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In conclusion, I would urge CMS to revise the aforementioned regulations to allow patients access to Pharmacist services on the local level. I also would encourage revisions to part D which mandate health plans to include Pharmacist's as the sole provider of MTM services. As the experts in pharmacology and pharmacotherapy related issues, Pharmacist's should be seen as an invaluable resource in MTM services utilization.

Thank you very much for considering my view.

Sincerely,

Joel Farley, R.Ph.
University of Minnesota
7-174 Weaver-Densford Hall
308 Harvard St. S.E.
Minneapolis, MN 55455
612-625-7691
farl0032@umn.edu

Submitter : Mr. Ben Smith **Date & Time:** 09/15/2004 11:09:28

Organization : Carolina Association of Pharmacy Students

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Thank you for allowing me to submit comments on CMS-4068-P. I have the following comments on Subpart C:

Pharmacy Access Standards: As a student pharmacist, I know I will value the ability to serve patients. The relationship between the pharmacist and patient is very valuable to the patient's health and they should be allowed to choose their pharmacist. If CMS will require plans to meet the access standard on a local level then it can be ensured that ALL beneficiaries will have convenient access to a local pharmacy. This revision should be made from the current access standard of meeting the TRICARE reqquirements overall service level. Plans will have less incentive to offer pharmacies acceptable contracts to enroll them in their pharmacy network. Congress made the promise to provide all patients fair access to their pharmacy, and CMS should comply with this request.

Any Willing Provider: The proposed regulation allows plans to designate and to specify "preferred" and "non-preferred" pharmacies within the network. This could reduce a patient's co-pay at preferred pharmacies. However, establishing preferred and nonpreferred pharmacies could likely inhibit my ability to serve patients when I am in practice. Patients could be persuaded to go to particluar pharmacies. However, Congress waned to ensure that patients could utilize the pharmacist and pharmacy of their choice. Patients should not be coerced or persuaded to go to particular pharmacies. This will NOT allow patients to have TRUE ACCESS to the pharmacy of their choice, as they will be persuaded to choose their pharmacy.

Level Playing Field: Legislation states that plans must allow beneficiaries the same benefits at a community pharmacy as through mail order. The benefits could include an extended supply of medication, which have in the past unfortunantly only been allowed through mail order for many plans. However, the plans can charge more when beneficiaries get an extended supply at a local pharmacy. I feel that if the plans can charge a higher price for an extended supply at a community pharmacy then CMS should clarify that the price difference must be directly related to the difference in service costs and not the cost of the medication. This is another mechanism that is utiized to coerce patients away from their pharmacy of choice. The Congressional intent opposses making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice , as identified in the colloquy of Senators Grassley and Enzi. Patients should be allowed to get the same services at a similar price from the pharmacist that they trust in their community as they do from a mail order pharmacy. At the mail order pharmacy the beneficiary does not have no face to face interaction with a pharmacist and the pharmaceutical care that the pharmacist can provide the patient.

Ben Smith
PharmD Candidate Class of 2006
UNC-Chapel Hill School of Pharmacy
Chairman, Carolina Association of Pharmacy Students
smithbh@email.unc.edu
704-657-8698

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

I have the following comments for Subpart D of CMS-4068-P concerning the Medication Therapy Management Program. Thank you for considering these comments:
I am pleased that plans are required to establish a MTM program and that the purpose of the program is provide services to optimize therapeutic outcomes for targeted beneficiaries.
Beneficiaries and Providers: I do feel that pharmacists should be the primary provider for the services based on our educational background and this should be in the guidelines. It is very important that CMS does not leave this decision to the plans and that plans are allowed to choose less qualified providers. Pharmacists have a very clinical training with all student pharmacists receiving a Doctor of Pharmacy degree and to allow the MTM services to optimize their benefit to patients, pharmacists should be ensured that we can provide our skills to patients as the primary provider of MTM. I have seen many instances in ambulatory care settings during school of pharmacists providing diabetes, anticoagulation, heart failure, hypertension, and other chronic disease services. Please ensure that pharmacists will be the primary provider so that we will have the opportunity

to expand theses important services through MTM services. Patients that have two or more chronic diseases and two or more drugs should qualify for these important services that pharmacists can provide. Plans should be required to identify new targeted beneficiaries on a monthly basis since the patients who can benefit from MTM will change. Pharmacists and physicians should also be able to identify eligible beneficiaries. I think that the plans should be required to let pharmacists know which patients that they see are eligible for MTM services. Plans must also inform the beneficiaries when they qualify for MTM services and about their choices in receiving these services. An eligible beneficiary of MTM services should remain eligible for an entire year so, that a continuity of services may be maintained in order to optimize the patient's health. I feel taht is is VERY IMPORTANT that CMS clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should, without question, be allowed to provide MTMS to non-targeted beneficiaries. Pharmacists should be able to bill patients directly for the services since MTMS is not a covered benefit for non-targeted beneficiaries. This is very important to enhancing the health care status of non-targeted patients.
Fees: It is important that plans are required to pay the same fee for MTMS to ALL providers. Plans should not be allowed to pay pharmacists at non-prederred pharmacies less than pharmacists at preferred pharmacies for the same service. Also, since pharmacists are highly qualified and highly trained healthcare professionals, CMS should examine each plan's application and ensure that the proposed fee for MTMS is high enough to convince pharmacists to take the time to provide these important services.
Services:
It is important to recognize the fact that MTM services are independent of the distribution of medication. However, they can occur in conjuntion with the distribution. Face-to-face interaction is the best method for delivering services. The first assessment should always be face-to-face. The Medication Therapy Management Services Definition and Program Criteria that was developed and adopted by 11 national pharmacy organizations in July of 2004 should be relied on for important information concerning MTMS. I fully support this document. I am also glad that CMS recognizes that different beneficiaries will need different MTMS. Examples include performing a health assessment, creating a medication treatment plan, and monitoring and evaluating a patient's response to therapy etc.

Ben Smith
PharmD Candidate Class of 2006
UNC-Chapel Hill School of Pharmacy
Chairman, Carolina Association of Pharmacy Students

Submitter : Dr. Timothy Lahey **Date & Time:** 09/16/2004 01:09:21

Organization : Beth Israel Deaconess Medical Center

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.

As a physician caring for people with HIV, I cannot emphasize enough to you the vital importance of making sure enough funding exists to support the treatment of this disenfranchised group. Every clinic I have, I see someone who without insurance benefits would lack the proven, lifesaving benefits of HIV medications and other services.

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

Sincerely,

Timothy Lahey, MD
Beth Israel Deaconess Medical Center
Massachusetts General Hospital

CMS-4068-P-53

Submitter : Mr. inder rakalla **Date & Time:** 09/16/2004 02:09:39

Organization : polyclinic pharmacy inc

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

regarding Sec. 423.120(a)(5) the pproposed rule to allow rx plan sponsors to arbitrarily creat smaller subsets of "preferred pharmacies" i have a few comments about that

1. it will completely go against any willing provider provision of the law.
2. why do we have continuously fight for our rights again and again . this govt supposedly is for the people by the people of th people. Maybe we are not the right kind of people. We
3. I would like you to follow the intebt of the law as it was meant to be so that this valuable benefit can be implemented with fairness to all.

thank you inder rakalla

CMS-4068-P-54

Submitter : Dr. Terri Jackson **Date & Time:** 09/16/2004 02:09:28

Organization : Midwestern University Chicago College of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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.

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

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.

CMS-4068-P-54-Attach-1.doc

September 16, 2004

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

Dear Sir or Madam:

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

Subpart C: Benefits & Beneficiary Protections

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

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

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

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

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I have provided the following MTM services in my practice lipid management and asthma management. 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,

Terri L. Jackson, Ph.D., R.Ph.
Assistant Professor of Pharmacy Administration
Chicago College of Pharmacy
Midwestern University
555 31st Street
Downers Grove, Illinois 60515
Phone 630-515-6168
E-Mail: tjacks@midwestern.edu

CMS-4068-P-55

Submitter : Mr. David Poirier **Date & Time:** 09/16/2004 02:09:31

Organization : Michigan Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

PHARMACY ACCESS STANDARDS; CMS should revise the pharmacy access standard to requir plans to meet the TRICARE requirements on a LOCAL level, not on the plan's overall service level. This would ensure that all beneficiaries have convenient access to a local pharmacy, and increase competition to ensure quality service. Congress promised patients fair access to their pharmacy.
ANY WILLING PROVIDER; The proposed regulation should not allow plans to make distinctions and designate pharmacies as "preferred" or "nonpreferred", with reduced copays at preferred pharmacies. Patients will be driven to preferred pharmacies, not necessarily the pharmacy of their choice. 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.
ANY WILLING PROVIDER: Plans must allow beneficiaries to obtain the same benefits at a community pharmacy as through a mail order house. Plans should NOT be allowed to charge a higher price for as extended supply obtained from a community pharmacy. 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.

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

MEDICATION THERAPY MANAGEMENT program;
Patients with two or more chronic diseases and drugs, should qualify for medication therapy management services(MTMS).
Plans should be required to identify new targeted beneficiaries for MTMS on a monthly basis. Plans should be required to notify the patient, physician, and pharmacist of their eligability.
CMS must clarify that MTMS can be received from ANY WILLING PROVIDER, and Plans must pay the same fee to ALL providers of MTMS.
MTMS FEES FROM PLANS MUST BE ADEQUATE ENOUGH TO ENTICE PHARMACISTS TO PROVIDE MTMS.

Submitter : Mr. **Date & Time:** 09/16/2004 03:09:48

Organization : Mr.

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Consider revising the pharmacy access standard so plans meet the TRICARE pharmacy access requirements. Meeting TRICARE standard on a local level will ensure beneficiaries have convenient access to the pharmacy of their choice. It appears the proposed regulation will allow 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 meets the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congressional 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 CMS recognizes different beneficiaries require different MTM services such as medication treatment plans, and monitoring and evaluating response to therapy. I also appreciate CMS? apparent recognition of pharmacists as primary providers; however, leaving the decision to plan contractors may allow less qualified providers to provide MTM services. Pharmacists are ideal health care professionals to provide MTM services and determine which services beneficiary needs. Plans should encourage pharmacists to develop such services in order to maximize patient health and optimize proper medication usage.

Submitter : Mrs. Geraldine Burns **Date & Time:** 09/16/2004 04:09:06

Organization : Benzodiazepine Awareness Network, Int'l.

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am writing on behalf of the Benzodiazepine Awareness Network which was started a few years ago. We are dedicated to the responsible and informed use of addictive prescription drugs. We believe that education, advocacy, research, and support are vital to people who prescribe and have been prescribed this class of drugs.

I have been made aware of the fact that as of January 2006, you will be excluding benzodiazepines from the Medicare drug benefits. I am outraged that a class of drugs which has been prescribed now for over forty years, can be excluded like this. Many of the elderly who are on these medications, even at low doses to sleep at night, will suffer greatly because of these drugs being excluded. These drugs are addictive and cannot be stopped. We know that most of the elderly will not pay out of pocket for these drugs and their physicians will switch them to another class of drugs. This will, in the long run, cost Medicare much more money.

I have seen the suffering first hand. I started the first online support group in 1999 for people coming off of this class of drug. It can cause such illness and devastation to one?s life, let alone the cost you will have with people having all kinds of tests done, running doctor to doctor to find out in the end, that the drug they were taken off of had caused their problems. A slow taper is necessary along with support from physician and family to successfully come off of these drugs. Please look at the information at a website dedicated to this class of drugs a www.benzo.org.uk where you will see from Prof. Heather Ashton, one of the world?s leading experts on these drugs how important a slow taper from these drugs are. Especially, the elderly, who sometimes cannot taper and must remain on these drugs.

Those of all ages that are on Social Security Disability will also be effected tremendously by this decision. Many in our groups have had their lives ruined by these drugs and working with a slow taper is their only method of gaining some sense of life again. For some, they are not even able to stop the drugs, because the withdrawal is too difficult.

This decision is by far, one of the most careless decisions I have ever heard about. For all these 40 plus years, these drugs have been prescribed and now we have 1 out of every 5 Americans on this medication. Total mayhem would breakout if this were to come to fruition.

Sincerely,

Geraldine Burns,
Benzodiazepine Awareness Network,
Boston, MA 02132

Submitter : Lou deBottari **Date & Time:** 09/16/2004 06:09:16

Organization : FAIR

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Comments on MMA Title 1 Proposed Regulations
CMS-4068-P

Introduction
FAIR (Fairness for Already Insured Retirees) is a group of seniors who are concerned about the impact on them of the MMA (Medicare Modernization Act) and a recent EEOC (Equal Employment Opportunity Commission) ruling. The FAIR group already has good prescription drug coverage provided by their previous employer or union.

MMA:
FAIR's concern is that corporate America will not be persuaded to retain existing prescription drug plans by the subsidy as it is currently structured. Evidence of this is presented in a typical corporate letter to retirees.

EEOC Ruling:
FAIR's concern is that this ruling provides corporate America the mechanism to freely discriminate senior retirees from active employees and drop their coverage entirely.

FAIR has suggested solutions to these two issues. These solutions are advantageous to both corporate America and the retiree, furthermore, they are affordable. The MMA solution revolves around a restructuring of the subsidy. The EEOC solution does not require a change in the recent ruling, simply a 'grandfather' clause exempting a relatively small and rapidly diminishing group from its adverse impact and Congress to legislate that an employer can use the Medicare benefits to make a showing that the benefits provided to the grandfather group are equal to those under 65.

FAIR has reviewed the entire document of proposed regulations for the MMA Title 1. The following comments pertain only to those sections that impact FAIR. Page 419 of the proposed regulations is of such significance that our response includes a proposal showing our recommended solution.

General
1-FAIR is concerned that new organizations will be approved to operate as PDP's, receive premiums and within the audit period place many retirees? funds at risk. The bonds required under the proposed regulation are far from what could be lost. The stated value of $100,000 for each person handling the money (pg. 1163 (iv) would cover the loss of premiums of less than 250 members. A bond of at least a value to cover the premiums for the number of members in the plan. The bond should be inflation proof and be posted for at least 6 years. The past track record of white-collar crime is of big concern.

2- Page 13- line 1; The new prescription drug plans will create another level of administration. The additional cost to the Medicare program has not been stated but in the opinion of FAIR will not be insignificant.

General Provisions

3-Page 160-b- Formulary Requirements: FAIR questions and wonders why the law has been established that creates the PDP?s. Each one will have to have their formulary approved by Medicare. Each PDP will have a pharmaceutical and therapeutic (P&T) committee. This again will increase the overhead cost. This entire plan continues to increase the administrative cost. FAIR concludes that this additional administrative cost goes against the idea of creating a system with a low delivery cost of prescription drugs. An entire new industry is being created that will not help reduce the overall cost.

4-Page 161-Last sentence: The administrative problem of enforcing this regulation efficiently is costly. CMS is correct that the P & T committee members must be free of conflict. This is a noble idea but based on the record today of many government agencies it is doubtful that it will be possible to enforce. Penalty for failure to meet the requirements should be high enough so that self enforcement will be the norm. Perhaps a security bond of a large enough value would be the solution.

5-Page 162 Second to last sentence: The entire formulary decision and revision does not take into account the experience of a patient?s doctor who may have more expertise that anyone on the committee, thus the doctor?s opinion should carry substantial weight.

6-Page 163 Second paragraph: The use of the U.S. Phar

Submitter : Mr. Eddie Madden **Date & Time:** 09/16/2004 07:09:56

Organization : Madden's Pharmacy, Inc

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

In Sec.423.120(a)(5), you propose a rule that would allow Prescription Drug Plan Sponors to arbitrarily create smaller subsets of pharmacy providers, called preferred pharmacies, within the confines of any region plan.

This system would absolulely negate the participation guarantee provided an individual pharmacy under the "any willing provider" provision written into the law and extended in your rule under Sec.423.120 (a)(4)(i).

This unauthorized provision would simply allow the Plan Sponor to enroll the sufficient number of pharmacies to statify the Tricare requirements and then, at its own discretion, pick and choose one or more of those participants to make up a smaller "preferred" group of pharmacies providing reduced cost sharing to the Part "D" enrollee.

Pharmacies not selected to be a part of the "preferred" list by the Plan Sponor would not have available the option of joining that group, as that make-up would be enirely determined by the Plan sponsor. This would, in effect, keep the pharmacy from the rights provided by the "any willing provider" provision.

While the excluded pharmacy may well be a participate in the region, the use of the "Preferred Pharmacies" provision has one-and only one-purpose for its existence-to drive traffic and purchases to those pharmacies in the "preferred" list. To argue otherwise is senseless.

Your belief that the law allow these intra-network distinctions and artificial classifications is absolutely wrong and most certainly strikes exactly into the heart of the "any willing provider" guarantee in the law. This rule gives full power of the determination of the "Practical Pharmacy Make-up" of the actual region network exclusively to the Plan Sponsor and denies the rights and gurarantees of " Practical Participation" as a choice of the individual pharmacy as written into the law.

I call on CMS to completely withdraw the provisions entitling the Plan Sponor to have sole determination of the true, active pharmacy participates in a region by allowing the Plan Sponor to create preferred subgroups of pharmacies under SEc.423.120(a)(5).

Madden's Phamacy, Inc.
101 College Ave
Elberton, Georgia 30635 706-283-1701

Eddie M. Madden, R.PH.

Submitter : Dr. Steven Paulson **Date & Time:** 09/16/2004 07:09:14

Organization : Texas Oncology PA

Category : Physician

Issue Areas/Comments

Issues 1-10

BACKGROUND

I am a practicing medical oncologist in a large group

GENERAL PROVISIONS

I am very concerned about the impact of the MMA on Oncology services. The CBO's initial analysis indicated an approximate 8% reduction in physician reimbursement over 2004, however, the final analysis shows this to be more like 15-20%. Since this is greater than the intended impact, I would hope CMS will relook at the regulations governing this provision.

CMS-4068-P-61

Submitter : Mr. PHILLIP MARKWAY **Date & Time:** 09/16/2004 08:09:34

Organization : PHARMACITS FOR THE PROTECTION OF PATIENT CARE

Category : Congressional

Issue Areas/Comments

Issues 1-10

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

My name is Phillip J. Markway and I am a pharmacist at The Carroll Apothecary. 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 reimbursed 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.

Submitter : Mr. james colonel **Date & Time:** 09/16/2004 08:09:42

Organization : specialty pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

my name is JAMES COLONEL AND I AM A PHARMACIST AT SPECIALTY PHARMACY. PHONE # 954-537-2027.
MY RESPONSE TO MEDICARE DRUG BENEFIT (CMS-4068-P) IS AS FOLLOWS...
MTMP ARE DIRECT PROACTIVE INTERVENTIONS DESIGNED TO ENHANCE PATIENT'S ABILITY TO TAKE MEDICATIONS. THIS IS A SPECIAL SERVICE THAT PHARMACISTS PROVIDE NOT INCLUDED IN THE FEE FOR SERVICE OF FILLING PRESCRIPTIONS. THE FEE IS A SEPERATE AND IMPORTANT ONE FOR THE PHARMACIST TO BE ABLE TO CONTINUE TO PROMOTE POSITIVE OUTCOMES.

CMS-4068-P-63

Submitter : Mr. John Sykora **Date & Time:** 09/16/2004 08:09:43

Organization : Mr. John Sykora

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

I am a pharmacist and owner of a community pharmacy. My concerns are related to the cost of the drugs to me and the reimbursement rates to me. Currently, the existing plans all use preditory pricing against my business. This is done in the form of kickbacks (i.e. rebates) to plan organizers which supports their mailorder programs and in the higher drug costs by the manufacturers in the American market. This results in my profit margins being given to the plan organizers who do not purchase any drugs. And it results in my customers purchasing their drugs in a foreign market where they are less expensive.

The elimination of kickbacks and an open international drug market would even the competition and make the medicare programs viable for my business and allow the people in my community to buy locally rather than out of the country or through mailorder pharmacies.

CMS-4068-P-64

Submitter : **Date & Time:** 09/16/2004 09:09:51

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

test

CMS-4068-P-64-Attach-1.doc

Attachment # 064-1

Test2

Submitter : Dr. Rebecca Wilson **Date & Time:** 09/16/2004 09:09:22

Organization : Dr. Rebecca Wilson

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am responding in regards to the following issues:
Subpart C: Benefits & Beneficiary Protections
Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Benefit Plans

CMS-4068-P-65-Attach-1.doc

September 15, 2004 **Attachment # 065-1**

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

Re: CMS-4068-P

Dear Sir or Madam:

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

Subpart C: Benefits & Beneficiary Protections

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

I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could affect the ability of pharmacists 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" is not "access" if patients are coerced to use other pharmacies instead of the pharmacy they have used for many years.

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

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

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 can 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.

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. 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.

MTM services are independent of, but can occur in conjunction with, the provision of a medication product. I appreciate the 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).

Thank you for considering my view.

Sincerely,

Rebecca Dawn Prevette Wilson, PharmD
2921 Kudrow Lane
Morrisville, NC 27560
(919) 466-0952
rxdawnp@aol.com

Submitter : Dr. John Leuck **Date & Time:** 09/16/2004 10:09:20

Organization : Dr. John Leuck

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

My name is John Leuck and I am a pharmacist(Doctor of Pharmacy degree) at SavMart Pharmacy.
My resposne to 'Medicare Prescription Drug Benefit' (CMS-4068-P) is as follows:
1. MTMP are direct proactive interventions designed to enhance patients ability to take mecicine 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 USP standards.
4. MTMP are ghenerally of an ongoing nature, involving an initial patient in-take assessment, followed by routine patient monitoring at regular intervals.
5.MTMP must be reimbursed as a management fee, NOT as a dispensing fee. Costs associated with MTMP are seperate and distinct from those costs associated with dispensing.
In-take assessment:30-45 minutes of pharmacists tiem per occurrence;
MOnitoring and following up: 15-20 minutes of pharmacists time per occurrence.

Submitter : Dr. Catherine Ann Dargin **Date & Time:** 09/17/2004 02:09:51

Organization : Bergan Mercy Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am writing in support of the proposed Medicare Prescription Drug Benefit regulation that includes Medication Therapy Management Services (MTMS). The fact that plans are required to establish a medication therapy management (MTM) program for the purpose of providing services that will optimize therapeutic outcomes for patients is finally a step in the right direction for increasing positive patient outcomes directly related to the proper use and management of their medications. Individuals with multiple chronic disease states, who are taking multiple drugs, and are likely to incur annual costs that exceed payment levels of most insurance plans, are the perfect candidates for medication management services. I believe that pharmacists are the most well educated memebers of the healthcare team when it comes to proper use, monitoring and selection of medications. It is a good idea that the plans should be required to inform pharmacists who among their patients are eligible for medication management services so that a pharmacist is easily able to target their services to the patients who would benefit from the service the most. Patients should also be told when they are eligible so they can come to their pharmacists for medication management. As stated above, pharmacists are the medication experts on the health care team, and they are the ideal providers of MTMS. Patients must be allowed to go to their favorite pharmacists for medication management and not required to go to a specfic pharmacy. This regulation is a wonderful foundation for the beginning of a new era in the area of medication management, allowing patients to get the most out of their medications and improve their quality of life. Thank you for your time and support of the Medicare Prescription Drug Benefit regulation.

Catherine Ann Dargin, PharmD
Pharmacy Practice Resident
Bergan Mercy Medical Center
7500 Mercy Road
Omaha, NE 68124
402-398-5597
catherine@creighton.edu

Submitter : Dr. Jeffery Spray **Date & Time:** 09/17/2004 02:09:55

Organization : Dr. Jeffery Spray

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Pharmacists should be empowered to provide medication management services for patients and be reimburses for this service through the MMA. Pharmacists are the best trained and positioned to provide this cost saving service for patients. This will also allow pharmacists to become more involved in patient care and enhance patient outcomes. There are numerous studies that have demonstrated the impact pharmacist management of medication with improved outcomes and cost savings.

Submitter : Mrs. Janie Owen **Date & Time:** 09/17/2004 03:09:04

Organization : none

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

I object to Patients receiving chemo to have to go to the hospital for administration. We are already established at this one place and it is hard enough having the cancer and then have to move to different people in a hospital is not very considerate of the patients. Thank you

Submitter : Dr. Leticia Jones, PharmD, R.ph. **Date & Time:** 09/17/2004 04:09:02

Organization : Dexter Professional Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

September 17,2004

Re: CMS-4068-P

Dear Sir or Madam,

I appreciate the opportunity to sumbit the following points concerning the implementation of the Medicare prescription drug benefit.

I have been a pharmacist since 1992, completed my advanced PharmD in 1998, and currently practice clinical pharmacy in both the hospital and ambulatory care settings. I am fortunate to be able to utilize my clincal skills to help my patients manage their health (everything from dyslipidemia to smoking cessation). Many of our elderly patients would benefit considerably if pharmacists were able to offer Medication Therapy Management Services.

I really believe that pharmacists are the ideal health care professional to provide MTM services. Why? Because we are highly trained experts on medications, we are accessible, and because we are trusted by our patients. Many of our seniors need consistent management with their health and undoubtedly their quality of life would improve if they had a caring pharmacist helping manage their medications.

I appreciate that CMS recognizes that different beneficiaries will need different MTM services, including monitoring and assessing response to therapy, etc. Hopefully, pharmacists will be the primary providers of these services, but it concerns me that leaving the decision to the plans will allow less qualified probviders to provide MTM services. Pharmacists across the nation, I know, would love the opportunity to provide MTM services, and would take pride in enabling our seniors to enjoy a healthier life.

Lastly, 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. My patients really depend on my colleagues and myself for their pharmacy services and they want to continue to use our pharmacy (we are the last independent in our county and provide services that none other can). Requiring plans to meet the standard on a local level is the ONLY way to ensure that ALL beneficiaries have convenient access to "their" pharmacy.

Thank you for consideration of my comments. You have an enormous job in front of you, and wish you well as you develop the final regulation.

Sincerely,

Leticia K. Jones, PharmD, R.Ph.
Clinical Consultant Pharmacist
Dexter Professional Pharmacy
800 Fulton St.
Logansport, IN 46947
hme@dexterpropharmacy.com

CMS-4068-P-71

Submitter : Dr. Phil Rushing **Date & Time:** 09/17/2004 04:09:09

Organization : San Diego County Pharmacists Association

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

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 medicines corrrectly 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 asssessment, followed by routine patient monitoring at regular intervals.
5) MTMP must be reimbursed as a mnagement fee, NOT as a dispensing fee. Costs associated with MTMP are seperate and distinct from those costs associated with dispensing:
* In-take assessment 30 to 45 minutes of pharmacists'time per occurrence
* Monitoring and follow-up: 15 to 25 minutes of pharmacists' time per occurrence.

Thank you

Submitter : Ms. Roberta Armstrong **Date & Time:** 09/17/2004 05:09:55

Organization : Felpausch Pharmacies

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Concerning CMS 4068 P, I have concerns relating to quality and access of the proposed regulations isued Aug 3, 2004. The ability of our patients to access our pharmacies may be seriously impacted since the proposed regulations do not properly implement the so-called TriCare pharmcy access standards included in the MMA. Requiring plans to meet the standard on the local level is the only way to ensure that ALL beneficiaries have convenient access to a trusted local community pharmacist.

I am concerned the plans are allowed to have preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in their network. A plan could select one preferred pharmacy and thru a lower copay drive all the business to one pharmacy, which would negate the access standards. CMS should require plans to offer a standard contract to all pharmacies.

I appreciate that CMS recognizes that one size does not fit all and beneficiaries have different needs and also recognizes pharmacists will likely be the primary providers . However I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Pharmacists have face to face consultation with Medicare beneficiaries and they use their pharmacist to help them sort out MTM problems, which is common . Pharmacists have the most training in medication management and are the ideal halth care professionial to provide MTM services and decide which services each person needs. I currently provide MTM service in my practice at Felpausch Pharmacy. A recent Rx for an antidepressant was for a 75mg strength, which indicates the short acting version, while the child had been taking the 75mg long acting form. With teen sucide in the news, today, 09-15-04, it is imperative that the child receive the correct dose as the 75mg in the short acting could have caused serious side effects as the patient was used to the slow release, however more importantly, the child would not have had full coverage during the entire 24 hours. In This same situation I have intervened for the over 65 crowd as again they need the long acting coverage and their bodies would have serious problems metabolzing the 75mg in the whole dose... Plans should be encouraged to use my services, to let my patients make the best use of their medications. In summary, I urge CMS to revise the regualtion to revise the pharmacy access standards to require plans to meet the requirements on a local level, not on the plans overall service level. Also, only preferred phamacies should count when evaluating whether a plan meets the acces standards and a standard contract should be offered to all pharmacies. Pharmacists in the community setting are in an ideal situation to monitor patients since they see the patient more often than any other health care provider and are already providing MTM servies in many different ways. Our 'greatest generation' is counting on the pharamcists to continue and expand the help that they have been giving to them for years, lets not let them down.
A provider must have a face to face consultation with the patient for maximum effectiveness of MTM services. A Pharmacist by seeing a patient at least monthly may see that the patient needs a dosage adjustment or has other side effects that are only apparent if a health care professional has a direct face to face relationship with the patient.

Thanks you for considering my view,

Roberta Armstrong, RPh
517-629-4590

Submitter : Mr. mark recktenwald **Date & Time:** 09/17/2004 05:09:29

Organization : Giant Food Stores LLC

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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.

Submitter : Ms. Darlene Hughes **Date & Time:** 09/17/2004 07:09:20

Organization : Louisiana Medicaid Eligibility Section

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

423.34 Enrollment process

Although Part D will be voluntary for most, this referenced regulation indicates that dual eligibles will be auto enrolled if they do not voluntarily enroll in a PDP or MA-PD. However; 423.34 (d)(3) contains provisions for full benefit dual eligibles to decline enrollment and disenroll.

423.906(b) Medicare as primary payer. Medicare is the primary payer for covered drugs for Part D eligible individuals. Medicaid assistance is not available to full benefit dual eligible individuals including those not enrolled in a PDP or MA-PD.

If they opt out or disenroll and will not have any drug coverage, this needs to be clearly communicated in all literature concerning the declination to enroll or disenrollment by full benefit dual eligibles.

423.772 Definitions
Family size:
Income/resource unit for the Medicare Savings Programs has been the individual and ineligible spouse or eligible couple. This rule would provide that for the drug benefit, other relatives living in the same household and dependent on the applicant or app?s spouse for ? of their financial support can be included when determining HH size for comparison to the applicable FPL.
Why can this be consistent with the methodologies for the other Medicaid programs that assist with payment of Medicare premiums. This will add complexity to eligibility determination for subsidies.

423.773 requirements for eligibility

(b)(2)(ii) and (d)(2)(ii)

Indicates for subsequent years, the amount of resources allowable for the previous year will be increased by the annual percentage increase in the CPI as of September of that previous year, rounded to the nearest multiple of $10.

This will add complexity to the state eligibility determination. It would be preferable for the resource standards for all subsidies/premium assistance for Medicare parts (B, D) be consistent among the federal poverty levels used to their determine eligibility.

423.774 Eligibility Determinations, redeterminations and applications.

Among Part D eligibles, how will coordination, uniformity and comparability be ensured between initial eligibility determinations, redeterminations and the appeals processes conducted by the State under its State Plan under Title XIX, versus, those done by the Commissioner of SSA in accordance with the RQ?s of Section 1860D-14(a)(3) of the Act?

Also, nothing thus far has indicated these subsidies will be a Medicaid eligibility group (included in the State Plan).

423.884 Requirements for qualified retiree prescription drug plans.

Will the state Medicaid agency have any responsibility /involvement in sponsor

CMS-4068-P-75

Submitter : Mr. Robert Sack **Date & Time:** 09/17/2004 09:09:38

Organization : Widner Drug Store

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Question 5: The MTMP must be reimbursed as a management fee, not as a dispensing fee. Costs associated with MTMP are separate and distinct from those cost associated with dispensing.
The in-take assessment is only a 15-25 minutes long occurrence not the 30-45 minutes as stated in the letter that was faxed.

Thank you,
Robert A Sack
Widner Drug Store

Submitter : Mr. Scott Orton **Date & Time:** 09/17/2004 11:09:02

Organization : DaCoconutWireless

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 on Medicare, and I am very afraid of these regulations that will affect myself and others that depend on their medication. Living with HIV has put me in a special catagory, the one that means that I MUST take my HIV drugs, or I WILL DIE. 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,

Scott Orton
1130 Hassinger St. #3A
Honolulu, Hawaii 96822
Ph:808-383-2016

Submitter : Dr. Sam James **Date & Time:** 09/17/2004 11:09:39

Organization : University of Arizona

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Patients should be eligible for all medication including medication that does not have generic equivalent drugs. Policies that exclude new (modern) medications will result in adverse patient outcomes, which will ultimately be more expensive to the system. It should be clear that co-pays should not be prohibitive so that the patient cannot afford the co-pay and is forced to decline appropriate therapy - resulting in an adverse outcome. Increasing co-pay by health insurance industry is a common practice, resulting in many of my patients being unable to afford the medication prescribed for them. I regard this practice as giving with one hand and taking with the other. The Medicare drug benefit progam is a huge step forward, but is discriminatory in its present form. If the intension is to provide all patients with equivalent care, then withholding medication base on lack of generic equivalent drugs is discriminatory.

CMS-4068-P-78

Submitter : Mr. Jimmy Garner **Date & Time:** 09/17/2004 11:09:17

Organization : Mr. Jimmy Garner

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.

CMS-4068-P-79

Submitter : Chris Longstaff **Date & Time:** 09/17/2004 11:09:25

Organization : Schnucks Pharmacy

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Being a pharmacist I interact with many elderly people. Making them use mail order instead of direct pharmacy care would be difficult and dangerous for the patients. Mail-order is hard to understand, confussing and non-productive with respect to drug therapy compliance.
Older patients need one 0n one contact to keep them taking the medicine they need. If they happen to be forgettful or in the early stages of Alzheimer's disease drug therapy would suffer greatly. Why not give retail pharmacies the same break on drug prices that you give mail-order. Sounds a little discriminatory. Retail pharmacies could charge the same as mail order and the patients care wouldn't suffer. Please consider other alternatives, or pharmacists will lose there jobs and the whole economic situation would continue downward.

Thank you very much Chris Longstaff

CMS-4068-P-80

Submitter : Mr. Tim De Vargas **Date & Time:** 09/18/2004 04:09:56

Organization : New Mexico POZ Coalition

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 citizen and person living with full blow a AIDS status, co-infected with Hepatitis C and a history of Cancer (plasma cytoma)and making a transition from the workforce to early Disability Retirement (after long career with New Mexico State Government) Social Security Disability Insurance I am concerned with barriers to participation the proposed action may create.

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

Tim De Vargas
P.O. Box 2808
Espanola, New Mexico 87532\
Phone 505-753-0741

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-81

Submitter : Ms. **Date & Time:** 09/18/2004 06:09:15

Organization : Ms.

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

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

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

I am a single parent who, given my state of health, will never be able to make a living on my own again. I am 49 years old and HIV+ since 1988; A gift from my daughter's father.

I will get right to the point. I believe that if we have billions to fight with, billions for NASA, billions to give to other countries to help their HIV/AIDS citizens then we have enough money to provide any american who can not get them through insurance, medication free of charge.

Thank you

CMS-4068-P-82

Submitter : Dr. Patrick Nemechek **Date & Time:** 09/18/2004 01:09:26

Organization : Nemechek Health Renewal

Category : Health Care Professional or Association

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.

As a board certified specialists in Internal Mediciane and a physician who has specialized for 15 years in the care of persons infected with HIV, I am convinced that many of my patients will be unable to afford their life sustaining medications and will result in certain death of many of them.

Although the annual expense of these medications will exceed the maximum cap set forth in the law, these patients, many whose sole income is from disability, will still be exposed to over $5000 of medication expenses per year. This will equal approximately 30-50% of the total annual income. This added financial burden is unsustainable, and will certain be the cause of death in many of my patients.

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,

Patrick M. Nemechek, D.O.
Medical Director
Nemechek Health Renewal
4010 Washington
Kansas City, MO 64111

CMS-4068-P-83

Submitter : Mr. Barry Margolin **Date & Time:** 09/18/2004 02:09:35

Organization : Mr. Barry Margolin

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

As a family living with disability from advanced AIDS and dependent on a combination of Medicaid and Medicare for health care, we are terrified that in 2006 we will lose access to the widest possible combination of antiviral therapies. It is an enormous challenge for us and our physicians to create a viable combination regimen to treat HIV/AIDS; we began therapy in 1993, before doctors had an effective set of drugs and before they understood the significance of HIV's rapid mutation towards drug resistance. It will mean pain, costly hospitalizations and early death if our doctors cannot prescribe the best possible combination from the full range of anti-retroviral drugs. People living with HIV and AIDS must be designated a special population eligible for coverage for any approved anti-retroviral treatment for HIV and AIDS, as we are under the existing Medicaid system.

Submitter : Lillian Thiemann **Date & Time:** 09/18/2004 03:09:33

Organization : Visionary Health Concepts

Category : Media Industry

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 am a person living with HIV and at one time I relied on Medicaid /Medicaire for my antiretroviral drugs. I became healthy enough to start my own business and move into private healthcare as well as employ several people living with HIV and provide them with health insurance, including drug coverage. There are no words to describe to you how important it was for me to be able to obtain whatever drugs I needed to improve my health. Many people I know are highly treatment experienced and they need to have totally unrestricted drug access to survive. Please help, and thank you for considering my comments as you finalize the regulations.

Sincerely,

Lillian Thiemann
Co-Founder/President
Visionary Health Concepts
1062 Bruynswick Road
Gardiner, NY 12525

Submitter : Dr. Charles Burnett **Date & Time:** 09/18/2004 04:09:33

Organization : Costco Pharmacies

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The final regulations should ensure that beneficiaries have the ability to chose any willing provider without a penaly to utilize a local Pharmacy and by-pass mail order. Their should be a very vigorus oversight of any PBM involved in the program to ensure that they do not retain excessive profits at the expense of providers and the government.

Submitter : Mr. John Snyder **Date & Time:** 09/18/2004 06:09:16

Organization : Mr. John Snyder

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I have already suffered from the lack of coverage in the current plan and the decrease of coverage with the new plan will put an even greater hardship on me. I worked for thirty-six years paying taxes. Please consider the needs of people with AIDS.

CMS-4068-P-86-Attach-1.txt

CMS-4068-P-87

Submitter : Frank Jackson **Date & Time:** 09/18/2004 08:09:14

Organization : Frank Jackson

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Your proposed plan to stop benefits for people living with HIV/AIDS is genocide, plain and simple. Thousands of taxpaying American citizens count on THE COMBINED resources of Medicare, Medicade, and ADAP to get the drugs that are keeping us alive. I DO NOT HAVE ANY FINANCIAL RESOURCES TO PAY FOR THESE DRUGS ON MY OWN. Please don't make a decision that could kill me.

Submitter : Mr. Robert Gotcher **Date & Time:** 09/18/2004 08:09:26

Organization : Mr. Robert Gotcher

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please be aware of the intricacies of Persons With Aids when you are forming these regulations. We have already had some treatments taken from us and if you keep it up, you are going to have more deaths on your hands

CMS-4068-P-89

Submitter : Mr. John McNesby **Date & Time:** 09/18/2004 08:09:30

Organization : Mr. John McNesby

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-89-Attach-1.rtf

CMS-4068-P-90

Submitter : Mr. Stu Smith **Date & Time:** 09/18/2004 08:09:05

Organization : Shanti

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.

I have lived with disabling HIV for more than 15 years and can not work and social security disability income leaves nothing for me to be able to purchase the life saving medications and services I need to live. I live below the federal poverty guideline already and need medicare and medicaid prescription assistance just to stay alive.

Submitter : Mr. Andrew Gerwitz **Date & Time:** 09/18/2004 09:09:13

Organization : Schnucks Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I AM CONCERNED THAT MY PATIENTS WOULD HAVE RESTRICTED ACCESS TO THEIR PRESCRIPTION DRUG AT THEIR LOCAL PHARMACY. aLSO, THESE REGULATION SHOULD PROHIBIT PLANS FROM USING USING ECONOMIC INCENTIVES THAT COERCE BENEFICIARIES TO USE MAIL ORDER SERVICES TO OBTAIN THEIR MEDCATIONS. aLSO, THESE REGULATIONS MUST INCLUDE MORE SPECIFICITY IN THE MEDICATION MANAGEMENT PROGRAM (MTM.

CMS-4068-P-92

Submitter : Mr. Stan R. Lee **Date & Time:** 09/18/2004 09:09:41

Organization : Mr. Stan R. Lee

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

We must protect the current Medicaid Rx plan that covers perscriptions that are vital to People with Aids. Because of the nature of the disease, and drug tolerances, we can not limit or prevent access of these already approved Medicaid Drug Benefits to a Medicare Prescpritption Drug Benefit plan. This plan may not all ready cover life essential medications that are now available through current Medicaid programs. The Ryan White Act is all ready under funded and most state ADAP programs are being stretched, capped or dagerously near collapse. This diesease, HIV/AIDS is notting going to go away or cured anytime in the near future!! Infections rates, sadly, are increasing and HIV/AIDS medication costs are raising. We can not have one of the world's "wealthiest" civilizations and populations, be adversely effected by an epidemic disease, that we can be manage through drug therapy. We are talking human life. Fathers, Mothers, Grandmothers, Grandfathers, Brothers, Sisters, children of all sorts. Let this disease "rage" accross our nations because our government has limited funds. Then as HIV/AIDS takes large amount of people who could continue to pay taxes and continue funding of Medicare and Medicaid, longer...this will add to the end of Medicare and Medicaid programs. Less able working people, less taxes paid to such programs.

Instead of focuses on how to save money by prescription care cuts by Medicare and Medicaid, let us focus on helping people gain their health back & get them back to the work force. Without a healthy workforce, we will not have a healthy source for funding social and health programs. No human life, no taxes need, and no need for any form of government anywhere.

CMS-4068-P-93

Submitter : Dr. rajeev winfred **Date & Time:** 09/18/2004 10:09:13

Organization : preston taylor comm hlth ctrs

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I AM CONCERNED THAT PATIENTS WITH NO INSURANCE WILL NOT VOLUNTEER TO SIGN UP FOR DISCOUNT CARDS BECAUSE THEY ARE AFRAID OF LOSING FREE INDIGENT DRUGS THAT ARE PROVIDED THROUGH DRUG COMPANIES. I THINK DRUG COMPANIES SHOULD CLARIFY THEIR POSITION REGARDING PTS WHO SIGN UP FOR THE DISCOUNT PHARMACY CARDS. I WORK FOR A FEDERAL COMM HLTH CTR IN WV WHERE WE SEND APPLICATIONS ON BEHALF OF PATIENTS TO DRUG COMPANIES ROUTINELY FOR FREE MEDICATIONS. WHAT WILL BECOME OF THESE PATIENTS ONCE THE ENROLLMENT PROCESS IS CLOSED???

Submitter : Ms. DAN WALTERS **Date & Time:** 09/19/2004 02:09:08

Organization : PHARMACY SOCIETY OF WISCONSIN

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription benefit. As it relates to 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 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 anc ocerce patients to use it through lower copayments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress' intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies. As it relates to 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 health assessment, a medication treament plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition of 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 MTM services for a number of patients in my practice at The Medicine Shoppe Pharmacy in Two RIvers, Wisconsin. 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 require plans to meet the TRICARE pharmacy standard on the local level and to require plans to offer a standard contract to all pharmacies. MTM services, under Subpart D of the proposed regulation, must require that pharmacists be the primary providers. Only then will the drug use system truly deliver the desired outcomes that it is capable of. We, as a country, spend an exhorbitant amount of money on fixing problems that result from an inefficient health care system. According the Instiutue of Medicine (IOM) Report , for every $1 spent on prescription drugs, we spend between $3 and $4 dollars for failed outcomes and adverse events. The cheapest pill on the block will not deliver savings if people are not educated and informed on how best to adhere and monitor their drug therapy. Pharmacists are the most accessible health care providers but are also the most underutilized. We as a country have a chance to change the landscape and deliver on the promise that our seniors need. Let's get it right!!! Thank you for considering my view. Sincerely, Dan Walters, R.Ph.

CMS-4068-P-95

Submitter : Dr. Merrill Cole **Date & Time:** 09/19/2004 02:09:19

Organization : Dr. Merrill Cole

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

I would like to respond to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. It deeply concerns me 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 die without access to appropriate treatment and medication. Sometimes they die, or get very sick, in the process of working through bureaucratic red tape. Many HIV-positive individuals in this country depend upon Medicare to afford the services they need. Please do all that you can to assure that your plan does not cause irreparable harm to an extremely vulnerable population.

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

Submitter : Mr. carl norris **Date & Time:** 09/19/2004 05:09:05

Organization : PWA

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,
carl norris
10014 T plaza apt 1
omaha, NE 68127

CMS-4068-P-97

Submitter : Mr. Randal Stoffer **Date & Time:** 09/19/2004 06:09:30

Organization : BonnieTree Productions, Inc.

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 HIV pos, but presently not on Medicare, but should or when there is a need for health care and I am unable to work to pay for it I would like to know all treatments will be available to me regardless of my ability to pay. I believe all American's deserve to know that they will receive medical care. Especially, at a time when they should not have that to worry about at al.

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

Submitter : Tim Deen **Date & Time:** 09/19/2004 10:09:07

Organization : Tim Deen

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.

The eventual personal effect on me will be that as a treatment experienced HIV + the current proposal would sentence me to death in the very near future.

Sincerely,

Tim Deen
5126 Denton Dr.
Dallas, Texas 75235
Age 50

Submitter : Dr. Sarz Maxwell **Date & Time:** 09/19/2004 02:09:19

Organization : Chicago Recovery Alliance

Category : Physician

Issue Areas/Comments

Issues 1-10

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:

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.

Clinically, people living with HIV/AIDS are a "special population" and CMS must designate them as such to 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 physician, I find more and more that my biggest problem is not making a diagnosis or choosing the appropriate treatment. My biggest problem is finding a way for my patients to access adequate treatment. Please help to see that this problem does not extend to my patients with HIV/AIDS receiving the antiretrovirals they so desperately need!

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

Sincerely,

Sarz Maxwell MD
1020 W Ardmore #2M
Chicago IL 60660
sarzmaxmd@yahoo.com

CMS-4068-P-100

Submitter : Dr. Timothy Koch **Date & Time:** 09/19/2004 03:09:21

Organization : UFMCC

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

It is essential and humane practice to ensure that persons living with HIV who rely upon Medicare/Medicaid to obtain their very specific and non-generic medications in order to continue living: and some of these medications that are needed because of drug resistance to other meds are NOT on the approved formulary. Do NOT let this happen to these persons (estimated at greater than 80,000)! We ALL know that they will not be able to afford to get these medications otherwise. Please do the Right Thing for those who are at risk.