Submitter : Mr. Ron Hogan **Date & Time:** 10/01/2004 02:10:52

Organization : Mr. Ron Hogan

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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-602

Submitter : Ms. Abbey Meyers **Date & Time:** 10/01/2004 02:10:23

Organization : National Organization for Rare Disorders

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

Please see PDF attached.

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

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3. The document was protected file and would not allow for CMS to attach the ile to the original message.

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CMS-4068-P-603

Submitter : Ms. Lisa Esgar **Date & Time:** 10/01/2004 02:10:12

Organization : Colorado Dept of Health Care Policy and Financing

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Attention: CMS - 4068 - P The Colorado Department of Health Care Policy and Financing administers the state Medicaid program. We have developed the attached responses to the draft regulation on the Medicare Prescription Drug Benefit. We are submitting our responses electronically on October 1, 2004 and submitting a follow-up hard copy. Thank you for this opportunity to comment.

CMS-4068-P-603-Attach-1.doc

Colorado Department of Health Care Policy and Financing
Responses to Draft Rules on the Medicare Modernization Act
October 2004
CMS-4068-P

B. Eligibility and Enrollment
2. Part D Enrollment Process
Page 46639, Federal Register August 3, 2004
§ 423.34 (d)

CMS has asked for comment from states on the options for automatic enrollment of full dual-eligibles into a PDP or MA-PD. The preamble suggests that either CMS could perform this function, using timely and accurate data from the states, or the states could perform this function with data from CMS and FFP for the administrative expenses.

Colorado's concern relates to resources. During a national teleconference call on August 13, 2004, CMS informed the states that states would be given 50% federal financial participation (FFP) for eligibility and enrollment related activities for Part D. If a state is performing an administrative function for the benefit of the federal government, the FFP should be 100%. This is not a Medicaid State Plan service. Because the intent is to only pay states 50% FFP, the Department requests that as many administrative functions for the Part D federal program as possible be performed by the federal government. As administrative functions expand and revise over time, it is increasingly possible that in the long run, the states will contribute more resources to the program than was intended by the law.

Other reasons for CMS performing this function include:

- Since the federal government should be responsible for appeals and problem resolution related to automatic enrollment, the activity should remain within the federal system;
- A uniform auto-enrollment process across the nation would be preferable; and
- CMS will be more familiar with the contractors available in each region, since the contracts with the PDPs will be with the federal government.

Colorado would be willing to work with CMS to provide reasonable and timely data as available in our current system or other federal reporting.

B. Eligibility and Enrollment
2. Part D Enrollment Process, Effective Dates
3.c. Special Enrollment Period
Pages 46812 and 46641, Federal Register August 3, 2004
§ 423.34 (d), § 423.38(c)

How will dual-eligibles who become eligible for Medicaid in mid-month be addressed? In Colorado, QMB, SLIMB, and QI clients become eligible for Medicaid benefits at the beginning of the month following the month in which they apply. All other Medicaid clients become eligible on the application date or on the date they meet the eligibility requirements, whichever is later, or in the case of long-term care clients, up to 90 days prior to the date of application if the client meets all of the eligibility requirements. Since the federal government determines when coverage is effective if someone enrolls during a special enrollment period, the rule must address timing with state enrollment processes.

B. Eligibility and Enrollment
2. Part D Enrollment Process
Page 46639, Federal Register August 3, 2004
§ 423.34 (d)

Section 423.34(d)(3) states that "nothing in this paragraph shall be deemed to prevent these full benefit dual-eligible individuals from (i) Affirmatively declining enrollment in a PDP or MA-PDP, or . . ." The preamble, at page 46639, middle column, states "[w]hile the statute prescribes an automatic enrollment process for full benefit dual-eligibles who fail to elect a PDP or MA-PD plan, it is important to note that such full benefit dual-eligible individuals *may decline the enrollment or change the enrollment if they so choose."* Emphasis added. This section of the proposed regulations and the language in the preamble contradict numerous statutory and proposed regulatory provisions requiring a full benefit dual-eligible to be enrolled in a Part D drug benefit plan. This language needs to be clarified. As written, the language indicates that dual-eligibles need not have Part D prescription drug coverage. If this is the case, the states may bear additional costs associated with dual-eligibles whose health deteriorates due to their failure to take necessary medication.

B. Eligibility and Enrollment
6. Disenrollment by the PDP
Page 46642, Federal Register August 3, 2004
§ 423.44

The proposed rules are not clear regarding what will happen to a dual-eligible who is disenrolled from a plan. CMS said in a teleconference call that if the client is disenrolled, the client will have time to sign up for another plan. However, this is not stated in the proposed rules.

In addition, it is not clear what will happen to a dual-eligible who has been disenrolled from every available plan. The rules state that if an individual is disenrolled from a PDP for disruptive behavior, the PDP sponsor has the option to decline future enrollment by the individual for a period of time specified by CMS. § 423.44(d)(2)(vi). Thus, under the proposed rules, for a period of time that is currently unspecified, the client may not be able to enroll in either plan. CMS stated during a teleconference call that dual-eligible clients cannot come back to the Medicaid rolls because the law states that Medicaid programs cannot pay for covered part D drugs for dual-eligible clients. If clients are not enrolled in any plan, they may have to visit emergency rooms to obtain medical care and a portion of those costs will be paid by the states. We suggest that the rules be clarified to state that a dual-eligible client can be disenrolled from a

plan so long as there is another plan available in that region that can enroll that client. The rules should also be clarified to explain that if a dual-eligible client is disenrolled, the client would be automatically enrolled in another plan if the client does not choose another plan within 30 days of disenrollment.

Finally, the rules should be clarified to indicate that a person cannot be disenrolled for disruptive behavior if his or her disruptive behavior is caused by the person's underlying disease. § 423.44(d)(2). CMS said in a teleconference call that a person could not be disenrolled for this reason but the proposed rules do not state this. In light of the concerns stated above, that CMS's stated intent should be included in the final rules.

B. Eligibility and Enrollment
Approval of Marketing Materials
Page 46813, Federal Register August 3, 2004
§ 423.50 (c) (5)

This proposed rule that states "[f]or markets with a significant non-English speaking population, [PDPs] provide materials in the language of these individuals," must be further defined. Will this be a percent of a population? If so, how will it be calculated? States should be aware exactly who is receiving materials in their primary language. In addition, it is unclear whether "significant" will be determined across an entire region (e.g., 10% of clients in Region 8), or, preferably, in pockets of the region that may have higher percentages of non-English speaking beneficiaries (e.g., 10% of clients in south-central Colorado).

B. Eligibility and Enrollment
11. Procedures to Determine and Document Creditable Status of Prescription Drug Coverage
Page 46645, Federal Register August 3, 2004
§ 423.56

On the middle of page 46645, it states: "any entity seeking to offer creditable prescription coverage must attest to this actuarial equivalence." In this proposed rule, Medicaid and state pharmaceutical assistance programs are considered creditable coverage. We believe that for the purposes of Part D, Medicaid should not be creditable coverage since there is no Medicaid benefit for these clients. This must be clarified in the final rule. We assume that states would not have to provide actuarial equivalence, should they choose to provide any type of state benefit.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections
1. Overview and Definitions, a. Covered Part D Drug
Page 46646, Federal Register August 3, 2004
§ 423.100

According to the proposed rules, the definition of a "covered Part D drug" closely follows the definition in the statute. However, this is not necessarily true. The definition of a "covered part D drug" contained in the statute states that a "covered part D drug" means "(A) a drug that may

be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); **OR** (B) a biological . . . **AND** such term includes a vaccine . . . and any use of a covered part D drug for a medically accepted indication (as defined in section 1927(k)(6). 42 U.S.C. § 1860D-2(e)(1)" (emphasis added). Although it is not clear, it seems that a drug need only meet subpart A of the definition to be considered a covered part D drug. Under the statutory definition, a "covered part D drug" may also be any covered part D drug that is used for a medically accepted indication.

However, proposed rule § 423.100 states that a drug (that is not a biological product or vaccine) is a "covered part D drug" if it meets the definition set forth in subpart A of the statutory definition (i.e., be available only by prescription) **AND** is used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). This distinction between the statute and the proposed rule is important when there is a drug that is available only by prescription, is FDA approved, has certain medically accepted indications but is being prescribed for an indication that does not meet the definition of a medically accepted indication in section 1927(k)(6) of the Act. Under the statute, it appears that the drug would still be a covered part D drug. However, under the proposed rules, the drug would not be a covered part D drug. If the drug would not be a covered part D drug, how would the plan make that determination and deny coverage of the drug? This would be important if any state decides to cover non-covered Part D drugs. According to proposed § 423.906 (b) & (c), Medicaid systems will not be able to pay for Part D drugs but states may choose to pay for non-covered Part D drugs. Thus, states need to know when a drug is a non-covered drug, including in the situation described above. (We note that some off-label uses meet the definition of a medically accepted indication while other off-label uses do not. It is not sufficient to simply refer to how prescribing drugs for off-label use will be handled.)

Colorado has another concern about the definition of the term long-term care facility. Clients residing in ICF/MRs should be included in this group, so that they are exempt from copayments. However, as described at 42 CFR 441.302 (c) (1), there is another group that should be included in this definition. These are clients in Home and Community Based Services waivers. These are clients who meet the nursing home level of care, but are in community settings. CMS emphasizes that these clients are to be equivalent for other purposes (such as spousal impoverishment and post-eligibility treatment of income), and the equivalence should translate into this regulation as well. The copayment exemption for nursing facility clients creates a bias against similar clients residing in the community. The waiver emphasizes that the Home and Community Based Services waiver is to avoid institutionalization. In fact, the exclusion of these clients from long term care definition affects the "choice" required at 42 CFR 441.302 (d) (2). This could also be an *Olmstead* violation as it favors institutionalized clients over similar clients in community placements.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections
4. Access to Covered part D Drugs
b. Formulary Requirements
Pages 46660-46661, Federal Register August 3, 2004
§ 423.120(b)

CMS has asked for comments on the limited formulary and how it may affect special populations such as long term care clients who are dual-eligibles. As the preamble states, the limited formulary proposed in the rules could adversely affect long-term care clients. Certain other populations such as mental health clients could be adversely affected because they too are more sensitive to, and less tolerant of, many medications.

The most appropriate way to protect these special populations and still allow a formulary system for PDPs and MA-PD plans to control costs is to establish formulary requirements that mirror the requirements that apply to state Medicaid programs. In other words, the PDP and MA-PD plans must have formularies that are no more strict than is allowed by federal law for states. 42 U.S.C. § 1396r-8(d)(4) states that a covered drug may be excluded from a preferred drug list with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling or based on the medically accepted indications for the drug, the drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of such treatment for such population over other drugs included in the formulary. The states must cover a drug excluded from the formulary pursuant to a prior authorization process. The states must also meet any other requirements set forth by CMS.

Thus, the state requirements imply that all drugs must be covered unless it can be determined that the drug is not therapeutically advantageous. Under the proposed rules, a plan is only required to cover two drugs in each category. All other drugs may be excluded unless it is determined by the pharmacy and therapeutic committee that it is necessary to include them. It seems that it may be a better system to require a similar structure to the state formulary systems. This would better protect special populations such as long-term care clients.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections
5. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies
Pages 46662-46663, Federal Register August 3, 2004
§ 423.124

Please clarify whether the general statement that enrollees are responsible for paying the difference between in-network and out-of-network pharmacy prescription costs applies to enrollees who qualify for subsidies. Specifically, proposed rule § 423.124(b) states that part D enrollees are financially responsible for the differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance for that drug. Subpart P of the proposed rules, which discusses premium and cost-sharing subsidies for low-income individuals, never mentions whether the subsidies cover the differential discussed in § 423.124(b). Thus, it is not clear in the rules whether low-income individuals would be required to pay this differential if they had to go to an out-of-network pharmacy.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections
6. Dissemination of Plan Information, a. Content of Plan Description
Page 46664, Federal Register August 3, 2004
§ 423.128

Although the rules are clear about the PDP and MA-PD obligations for informing consumers, it is probable that dual-eligible clients will contact Medicaid agencies for information regarding pharmacy benefits. This is particularly true because these clients will go from a comprehensive Medicaid benefit on one day, to a more restricted, Medicare benefit on the next. Therefore, the Department requests the following be added to the rules to clarify the plans' responsibilities in this matter.

1) As of the implementation date, a statement that Medicaid is no longer the primary provider of the pharmacy benefit for this client, and a phone number for dual-eligibles to contact for questions regarding all pharmacy benefit questions,
2) A statement that the Medicaid agency cannot answer questions about the Medicare benefit, and
3) A notice that some states may offer supplementary services, and that the client can contact the Medicaid agency for information regarding these services.

Without including these statements in the initial information sent to Medicare clients, the Medicaid state agency is likely to be subject to additional administrative costs which will require additional state funding, regardless of federal financial participation. Therefore, we request that all noticing take into account the special needs of dual-eligibles and be clear that the Medicaid benefit as they know it, has come to an end.

M. Grievances, Coverage Determinations, and Appeals
2. General Provisions
Page 46718, Federal Register August 3, 2004
§ 423.562(c)(1)

Please clarify the meaning of § 423.562(c)(1). This section states that an enrollee has no appeal rights if the enrollee has no further liability to pay for prescription drugs. The preamble on page 46718 essentially restates this without any explanation. We assume that copayments at any amount constitute a liability to pay for drugs. It is not clear whether institutionalized, full subsidy eligible clients (who have no copay or deductible according to proposed rule § 423.782) can appeal any decisions. Since the subsidy described in § 423.782 covers the costs of the drugs, does that meet the definition of a payment liability so that these clients have appeal rights? The preamble on page 46649 mentions that both the statute and proposed rule § 423.100 state that costs are considered incurred (for purposes of applicability toward client spending against the annual out-of-pocket limit) if they are paid on behalf of a low-income individual under the part D subsidy provisions. Although this section applies specifically to incurred costs for the out-of-pocket limit, the theory should also apply to appeal rights. These clients should have appeal rights at all times and this should be clarified in the final rules.

N. Medicare Contract Determinations and Appeals
4. Coverage Determinations
5. Formulary Exceptions Procedures
Pages 46718 -46721, Federal Register August 3, 2004
§§ 423.566 through 423.576, 42 CFR § 423.578

Please clarify whether enrollees can request determinations or exceptions for non-covered part D drugs that are covered as part of an enhanced alternative coverage plan. According to proposed rule § 423.906(c), supplemental benefits in an enhanced alternative coverage plan could include coverage of drugs that are specifically excluded as covered part D drugs. However, according to proposed rule § 423.566(b)(1), determinations can only be made for covered part D drugs. In addition, § 423.578(d) of the proposed rules states that the exceptions procedures cannot be used to request coverage of a non-Part D drug. Does this mean that if a plan offers supplemental benefits and covers excluded covered part D drugs that there is no appeal right or exceptions procedures if the plan decides not to cover them for a particular enrollee? This would be significant if any state decides to cover the excluded part D drugs. Once a final determination of coverage has been made, this information must be given to the states so that they can make their own determination about coverage. This coordination of coverage, as well as an enrollee's appeal rights with respect to a covered "non-covered part D drug" need to be addressed.

M. Grievances, Coverage, Reconsideration, and Appeals
Page 46720, Federal Register August 3, 2004
§ 423.578 (b)

Colorado is concerned that the exception process be clear, effective, and timely because, to the extent Medicare, a PDP, or an MA-PD denies a drug that is not on the formulary, and the absence of that drug results in unexpected medical care, such as physician, long-term, or hospital care, then Medicaid is affected by having to pick up the additional Medicaid portion of the costs. However, the exception rules do seem to provide the client with a process to obtain any medically necessary drug. We hope this is an area of close scrutiny by CMS of contracted PDPs and MA-PDs.

We believe that an additional requirement should be added under § 423.578(b)(2), to require that the PDP sponsor's exception procedures include "consideration of the other health care costs due to the absence of this drug." We agree and support the rule at § 423.578(c)(2) requiring refills of drugs approved for exceptions without the refiling of exceptions.

One issue seemed apparent in the review of the draft rules. For example, a beneficiary requests an off-formulary drug through the exception process because it is the only drug proven to be effective for that client. In the example, the PDP denies the request, and the client files for an appeal. In the meantime, the client needs the medication and purchases the drug out of pocket at an out-of-network provider, either because of the prohibitive cost or the network provider does not carry the drug. It seems that § 423.562(c)(2) would preclude the processing of the client's appeal. This does not seem practical.

Colorado's interest in this matter is the absence of a drug for a dual-eligible client that results in health care costs that would later need to be absorbed, at least in part, by Medicaid.

P. Premiums and Cost Sharing Subsidies for Low-Income Individuals
1. Eligibility for the Low Income Subsidy
Page 46725, Federal Register August 3, 2004
§ 423.773

Colorado is concerned that the eligibility process described in this section may differ from the current federally-approved process the Department uses to determine client eligibility for Medicaid. For instance, if a consumer contacts an eligibility site today to apply for Medicaid, information is entered into the Colorado Benefit Management System. The system processes that information under federally approved rules, and determines the applicable assistance programs for which the person is qualified.

Section 423.773 references people who are *similar* to dual-eligibles, but who are not dual-eligibles at the time of application. The preamble at pages 46725 and 46726 discusses a method to determine eligibility for those people. Because this system may be different than the Department's current eligibility determinations systems, the Department may incur programming costs to incorporate this new method. The FFP on these costs should be 100%.

P. Premiums and Cost Sharing Subsidies for Low-Income Individuals
2. Eligibility Determinations, Redeterminations and Applications
Page 46727, Federal Register August 3, 2004
§ 423.774
and
S. Special Rules for States - Eligibility Determination for Low-Income Subsidies and General Payment Provisions
1. Eligibility Determinations
Page 46751, Federal Register August 3, 2004
§ 423.904

Guidance received from CMS on August 13, 2004 indicated that states could "batch up applications" and send them to SSA for processing, and that SSA would make the determinations, send the notifications, and conduct the appeals. However, as proposed under §§ 423.774 and 423.904(a), and as directed under § 1935 of the Social Security Act, CMS has required states to "make eligibility determinations and redeterminations for low-income premium and cost sharing subsidies." These are contradictory statements, making comment difficult. Both the rule and preamble are relatively short on this topic, but it appears from review of the proposed rule that states could be required to perform the following Medicare administrative functions:

- Providing personnel resources for answering questions, assisting applicants, verifying completion of applications before submission to SSA;
- Making determinations and redeterminations;
- Making some type of system changes to at least record determinations and redeterminations made by the state;
- Programming costs associated with adding Subpart D eligibility to the CBMS;
- Printing applications;
- Conducting appeals;
- Sending notices to clients (includes the cost of printing and postage);
- Coordinating with financial institutions for verification; and

- Developing and sending various data reports to CMS and SSA.

These activities are not just for dual-eligibles, but for anyone applying for subsidies.

In addition, these resources will be required as of July 1, 2005, long before any relief from the pharmacy benefit is experienced. The costs for administration of the Medicare program could prohibit the provision of other State services, due to the lack of new General Fund in this state. These activities, spread to all Medicaid eligibility sites, will require a significant amount of General Fund since only 50% FFP is provided for administration of a Medicare program.

Colorado is unfunded for the costs associated with implementation of these federal program functions. While we understand that these duties are generally mandated by the law, we would appreciate any possible consideration of reducing the states' responsibilities due to the lack of funding for the current level of services.

In particular, we have the following comments related to §§ 423.774 and 423.904:

Administrative Costs

The statute requires that an application for subsidy assistance may be filed with either a state's Medicaid program office or SSA. While this is statutorily permitted, we believe that the FFP for the administrative costs for this activity must be 100%. CMS indicated that inquiries regarding application or eligibility should be referred to state agencies or SSA. Again, the concern is about resources. Since this is not a Medicaid State Plan service, the administrative functions for the Part D program should be fully funded by the federal government.

Colorado agrees that it would be beneficial for applicants to access applications and information at Medicaid eligibility sites, but believes that a cost allocation methodology should be developed to attribute the Part D administrative costs 100% to Medicare.

It is the Department's recommendation that the process include the use of either web-based applications, accessed with federally funded computers at Medicaid eligibility sites, or through paper applications that are batched and sent to SSA by the eligibility sites. Phone applications should be conducted directly with SSA.

Consistency in Appeals

Colorado is concerned that should the states process determinations, redeterminations, and appeals, as well as the SSA, it is not possible to create equal systems for clients. Even if the state follows federal guidelines, it does not seem likely that a beneficiary experiencing the state process will experience the same procedure as a client in the federal process. This not only seems confusing to the client, but could increase legal issues for the Department. We ask for a reconsideration of these issues, or at least, strong clarification about how continuity would be ensured.

It is unclear to the Department if CMS will accept state decisions as final (whether determinations, redeterminations, or appeals), or whether clients will be able to appeal state decisions to the federal government.

Coordination of Applications

In addition to all of the other coordination questions that arise from having both states and SSA process determinations, how will the federal government ensure that applicants do not apply at both locations? Since there will not be a common information system between SSA, CMS, and all 50 states, the Department cannot envision a data exchange process fast enough to prevent an applicant from receiving a denial from the SSA and walking across the street to the eligibility site to apply at the state. This could result in duplicative administrative work for the state and SSA. We ask that the rule clarify this coordination.

It is unclear whether the federal government will require subsidy applicants to show proof of Medicare enrollment in order to apply for the subsidy. If not, the Department expects extensive coordination problems and confusion as states are completely reliant on periodic (not real time) data matches to assess Medicare enrollment.

P. Premiums and Cost Sharing Subsidies for Low-Income Individuals
3. Premium Subsidy and Cost-Sharing Subsidy, a. Full Subsidy Eligible Individuals
Page 46728, Federal Register August 3, 2004
§ 423.780

Colorado notes that there are several new costs, in addition to a more restricted benefit, for the Medicaid dual-eligible. Primarily, there is the copayment for non-institutionalized clients. Currently, there is a co-payment on prescription medications for Medicaid clients, but they are not mandated to pay. Should the client be unable to pay, the pharmacy must provide the prescription nonetheless. As CMS is aware, many of these clients are extremely poor. What is the consequence to the client if the copayment cannot be paid?

There are other potential costs for the Medicaid client. He or she may unintentionally enroll in a plan where the maximum premium subsidy is less than the premium for the plan. Even though zero-premium plans would be available in the area, the client may not understand and enroll in error. The client would then be required to pay the difference in order to receive a drug benefit.

Another potential cost for the client is late enrollment fees. We thought that SSA would automatically enroll all dual-eligibles so there would be no late enrollment fee. However, the text on page 46729, first column, indicates that it is possible for a full subsidy eligible individual to experience late enrollment penalties.

Additionally, page 46732, first column, describes how a subsidy-eligible individual may have to pay for certain costs until eligibility for Part D is verified. The clients would be "reimbursed."

Another unexpected cost for dual-eligibles is the out-of-network penalty referenced at § 423.124. According to the proposed rule, dual-eligibles are responsible for the difference between the out-of-network's usual and customary price and the PDP's allowance for the covered Part D drug.

Although we understand the need and the purpose of these additional fees and penalties, these costs create barriers to prescription drugs that Medicaid clients do not currently experience. If clients do not receive the medications they need to prevent health decline, the costs for medical care would transition, at least in part, to the state Medicaid agency. Colorado is struggling to cover current needs based on caseload and utilization. No additional funding is available for extending services.

S. Special Rules for States - Eligibility Determination for Low-Income Subsidies and General Payment Provisions
1. Eligibility Determinations
Page 46751, Federal Register August 3, 2004
§ 423.906 (c)

We request clarification on the allowability of a state to pay for and receive a federal match for non-covered part D drugs, if a supplemental benefit plan is also covering some or all of these drugs. According to proposed rule § 423.906(c), states may cover drugs that are not covered Part D drugs. According to § 423.104(g)(1)(ii)(A), a plan's enhanced alternative coverage may include supplemental benefits such as coverage of non-covered part D drugs. We assume that if there is such a supplemental benefit plan in a region, the state(s) in that region may also cover the non-covered part D drugs but would be the secondary payor to the PDP or MA-PD plan. This should be clarified in the final rule.

S. Special Rules for States - Eligibility Determination for Low-Income Subsidies and General Payment Provisions
4. State Contribution to Drug Benefit Costs Assumed by Medicare
Page 46752, Federal Register August 3, 2004
§ 423.910 (c), (g)

Basing the clawback calculation on 2003 with an inflator is, in a sense, creating a very rough calculation of the actual costs that will occur in 2006. Colorado does not feel that this will adequately account for the utilization controls that have occurred in recent years. In fact, the states will be penalized for those actions. As unexpected additional administrative costs are added to the expected costs of 1) the clawback payment itself, 2) the assumptions for calculation of the clawback payment based on unavailable 2003 data, and 3) the costs for increased numbers of full-Medicaid, QMB, and SLIMB[1], the burden grows, and the margin of savings becomes questionable. It is not certain if the states can implement this program in a cost-neutral manner. During a time where states are recovering from significant budget reductions, this could be a substantial financial burden. CMS should allow for an adjustment to the 2003 base calculation to account for utilization controls implemented and/or experienced by the states since 2003. A

[1]Page 46785 of the Federal Register states that the increase will be 1.1 million clients nation-wide in calendar year 2006.

fairly objective way to accomplish this could be through reductions in the amount of the official fiscal estimate accompanying passed legislation, and applying a dual-eligible ratio to the total.

Although the law does not require CMS to notify states of the clawback calculation until the October 15 before the new year, this date does not allow states nearly enough time to plan for budgeting. Colorado requests that CMS change this date to August 15.

It is not clear when the first clawback payment is due. States must be made aware of this very soon to plan for budgeting.

It is still not known how CMS will handle HMO or other capitated costs that include drug coverage in the calculation. This is an important issue that must be clarified.

Although it is not discussed in any detail in the preamble, proposed § 423.910(f) states that the rebate factor will include rebates received during calendar year 2003. However, only rebates received on or before March 31, 2004 will be counted. This poses a problem for states because states have the ability to retroactively adjust the units of drugs for rebate purposes and do not receive rebate amounts for prescriptions until months after the prescriptions were filled. For example, Colorado has several hundred thousand claims from the last six months of 2003 that are now being sent for rebate. In addition, the money due to states through the rebate process is received months after the state actually paid for the prescriptions. Some states, such as Colorado, operate on a cash basis and will not record the rebate for drugs until months after the state has paid for the drugs. Thus, the rebate amounts will be tallied on subsequent CMS 64 reports and will not be reflected in the CMS 64 Medicaid expenditure reports filed in 2003 or through March 31, 2004.

If states so desire, states should be allowed to count rebates received for 2003 prescriptions through at least the end of 2004. Since the payments by the states reflect prescriptions that were filled in 2003, it would be more accurate to count the rebates that the states received for those prescriptions filled in calendar year 2003, rather than simply the rebate amounts that were received and recorded in calendar year 2003.

CMS must allow for an appeal process by states on the clawback amounts. As in any estimate, there could be a number of discrepancies that should be allowed for review and revision.

CMS-4068-P-604

Submitter : Mr. Lawrence Sage **Date & Time:** 10/01/2004 02:10:56

Organization : Indiana Pharmacists Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I have attached a file with the general comments of the Indiana Pharmacists Alliance.

CMS-4068-P-604-Attach-1.doc

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www.indianapharmacists.org

September 23, 2004

Comments on Proposed Medicare Part D Regulations

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

To Whom It May Concern:

I am writing on behalf of the Indiana Pharmacists Alliance (IPA). Our organization represents over 1400 pharmacists, students and technicians throughout the State of Indiana in all fields of the profession. We have several concerns and comments about the proposed Medicare Part D regulation as it relates to the practice of pharmacy.

Dispensing Fee
The regulation provides for three possible definitions of dispensing fee. The first definition only allows for the net cost of delivering the drug to the patient. We believe that this fee should not only recognize the act of preparing a prescription but also includes overhead costs incurred prior to the actual filling of the prescription. The pharmacy is assuming the risks inherent in stocking the drug, maintaining a facility and staffing it, etc. Any dispensing fee should take these factors into account. According to the NACDS 2004 Industry Profile, the estimated cost of dispensing a single prescription in the State of Indiana during 2003 was $7.27. It is the opinion of IPA that at minimum the dispensing fee should match this amount.

The second definition states that the fee should include amounts for supplies or devices necessary for administering covered drugs. The rule fails to state what "necessary" is. Without proper definitions of dispensing fees, the Prescription Drug Plans (PDPs) may deny patients access to devices such as nebulizers, inhaler spacers, since they are not a covered drug under Part D. These supplies or devices should be listed or defined.

The third definition includes monitoring by what is termed a "clinical pharmacist." With the exception of one state, there is no distinction drawn in any pharmacy practice acts between a pharmacist and a clinical pharmacist. All pharmacists take the same exam (NAPLEX) for

licensure in all states. We request that the term "clinical" be dropped and that the rule refer to a "pharmacist."

Equal Access to Retail Pharmacies
The proposed regulation requires that PDPs and Medicare Advantage-Prescription Drug Plans (MA-DPs) meet the minimum requirements of the Department of Defense's TriCare pharmacy access- 90% of beneficiaries live within two (2) miles of a pharmacy in urban areas, 90% within five (5) miles in suburban areas and 70% within fifteen (15) miles in rural areas. The problem with this standard is that it is an average by region. Thus, members in one region could have greater access to pharmacies than those people living in an adjacent region. This requirement also does not take into consideration that a patient may live four miles from a pharmacy geographically, but has to drive seven miles to actually get there. IPA asks that this standard be calculated on a state-by-state basis using well-traveled, commercial roadways rather than geography.

Preferred Pharmacies
Under the proposed rule, a PDP can avoid the minimum TriCare standard by creating networks of "preferred" pharmacies within a larger network. This could be accomplished by the PDP creating a network with the minimum number of pharmacies in it and then creating a smaller network of "preferred" pharmacies within that network, offering lower cost sharing or some other similar inducement to direct traffic to those "preferred" pharmacies. The rule doesn't specify how many preferred pharmacies there will be or how large the difference in price sharing might be. Creating preferred pharmacies will likely have the following effects:

1. Pharmacies that are labeled as "non-preferred" could be seen as professionally sub-par.

2. The creation of preferred pharmacies accomplishes a single goal: <u>to direct and control the flow of prescriptions and other purchases.</u> The creation of these preferred pharmacies makes it possible for a PDP to discriminate against pharmacies within the larger network because the distinction will be made at the discretion of the Plan Sponsor.

3. Labeling a pharmacy as "preferred" could limit access to patients in impoverished or rural areas where multiple pharmacies do not exist. The net result will be the lowest-income patients having to pay higher prices simply because they cannot travel to a preferred pharmacy.

The concept of preferred pharmacies negates the "any willing provider" provision written into the law. <u>IPA strongly objects to allowing PDPs to create these intra-network distinctions</u>.

Level Playing Field
Under the proposed regulation, a PDP cannot require patients to use a mail-order pharmacy. However, according to the proposed rule, a PDP that owns mail-order pharmacies can negotiate with manufacturers for rebates to increase benefits; retail pharmacies cannot. This could allow PDPs that own mail-order pharmacies to attempt to use these rebates, based on their entire book

of business, (including community pharmacy outlets) to offer lower prices through their owned mail order pharmacies. Rebates and discounts generated by business through all channels of retail pharmacy distribution could then be used to subsidize moving patients to mail order pharmacy. This will inevitably lead to negative effects on those patients with complex medication schedules, chronic diseases and those who self-administer certain drugs via devices. For these patients, face-to-face counseling with a pharmacist is not just preferred- it is necessary. Some things simply cannot be accomplished over the phone. It was not Congress's intent to allow the plans to coerce their patients into using certain pharmacies- as evidenced by Senators Grassley and Enzi's opposition.

IPA feels that the rebates PDPs receive should be applied equally to all drug-dispensing pharmacies- not just the PDP owned mail pharmacies. This will eliminate some of the difference in drug costs between preferred and non-preferred providers. Retail community pharmacies must be allowed to provide patients with 90 day supplies of their medications, if the patients so desire.

We also feel that the proposed rule is too vague regarding the term "negotiated price." We ask for a clarification or more exact definition of the term.

Electronic Prescribing
IPA is in support of the use of electronic prescribing given the following conditions:

1. The prescribing of medications through electronic means complies with all State laws and regulations.

2. Electronic prescribing is performed through a uniform and reliable system such as ProxyMed or SureScripts.

3. Incentives are provided to help pharmacists and pharmacies prepare to receive prescriptions electronically. There are software and other technical issues that will require solutions before implementation can be accomplished.

4. Any electronic prescription is sent to the pharmacy of the patient's choice.

Cost Effective Drug Utilization Management
IPA supports the goal of reducing medication errors and increasing cost-effectiveness. We advocate the adoption of quality assurance standards and criteria. We recommend using standards and criteria developed by NCQA as a reference.

If PDPs are to use formularies, IPA supports the creation of P&T Committees, and that they are required to have pharmacists in an equal number to other committee members. Our preference is that pharmacists should make up a majority of the committee's members- given the acknowledged expertise of pharmacists with the proper use of prescription drugs.

Medication Therapy Management

The regulation requires that each PDP and MA-PD provide a MTM program for Medicare patients with high drug costs, chronic medical conditions and chronic medications. However, there is no standard service that each PDP will have to offer. The regulation does not define "chronic medications" or "chronic medical conditions." The inevitable result will be patients in one region qualifying for services and identical patients in another region being denied those same benefits. We believe that the rules should define a standard for services that must be offered by PDPs, so that there is not a patchwork of differing services offered by different plans.

The regulation does not specify the amount of a minimum payment to be made. IPA believes the fee should be paid to the pharmacist and should be high enough as to encourage pharmacists to provide these services.

IPA wishes to stress that MTM's primary goal is the proper utilization of drugs. Therefore we are of the opinion that MTM should be available to ANY patient with high drug costs and/or chronic medical conditions who is taking two (2) or more drugs, regardless of OTC or Rx status. Pharmacists are the ideal health care professionals to provide MTM services and to determine which services each beneficiary needs. Plans should be encouraged to use our services- to let us help our patients make the best use of their medications. We are concerned that leaving that decision to the PDPs may allow plans to choose less qualified providers of MTM services.

Coordination of Benefits
IPA believes that Part D should not automatically cover drugs not covered in Medicare Part B due to a lack of Medicare Supplier Number. Rather, an incentive for obtaining a Medicare Supplier Number should be made available. If pharmacists are going to be required to perform the coordination of benefits, there must be a standardized process for all plans to use, and the pharmacist should be compensated for performing this service.

Self-Referral Prohibition
IPA supports the rule preventing referrals for Part B drugs when a financial relationship exists between the physician and the entity furnishing the drugs. We also feel that PDPs should NOT be allowed to refer patients to their own mail-order pharmacies. IPA supports the inclusion of Part D outpatient prescription drugs into this rule to curb the risk of anticompetitive and unethical behavior.

Home Infusion Pharmacies
Patients should always have access to home infusion pharmacies. It is the opinion of the IPA that the PDPs and MA-DPs not include home infusion pharmacies in their routine community pharmacy access standards. Rather, a new standard should be created specifically for home infusion pharmacies.

Lawrence J. Sage
Executive Vice President
Indiana Pharmacists Alliance

CMS-4068-P-605

Submitter : Mr. George Maurer **Date & Time:** 10/01/2004 02:10:40

Organization : Community Pharmacies of Indiana

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I have attached a file with the general comments of the Community Pharmacies of Indiana Inc.

CMS-4068-P-605-Attach-1.doc

Community Pharmacies of Indiana

729 N. Pennsylvania St.
Indianapolis, IN 46204
Phone 317-634-4968
Fax 317-6321219
cpi@indianapharmacists.org

September 23, 2004

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

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George Maurer
President
Community Pharmacies of Indiana

CMS-4068-P-606

Submitter : Dr. Geri Foster **Date & Time:** 10/01/2004 02:10:42

Organization : VUMC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

October 1, 2004

Center for Medicare and Medicaid Services
Dept. Health and Family Services
Att: CMS-4068-P
Baltimore, MD 21244-8014

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As the Investigational Drug Service Pharmacist and Co-ordinator of Compounding Services at Vanderbilt University Hospital and Clinics, I am deeply concerned with the rules as they are currently proposed.

Pharmacists want this program to work. Pharmacists are professionally motivated to provide any medication in a safe and effective manner, which includes proper preparation of the product, but very importantly, provides the product with personalized education to assure effective use.

In order for this program to be successful, I urge CMS to incorporate rule language that will
1) ensure incentives (compensation) for all pharmacy providers that perform medication therapy management (MTM) services, and 2) allow for any willing pharmacy to serve as a prescription product provider for Medicare beneficiaries. Below are specific recommendations for rules concerning MTM services and prescription access that will ultimately do the right thing for the patient:

MTM Services

1. CMS rules must allow for all pharmacists to be included not precluded. Pharmacists are an integral part of the health care team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary medications and hospitalizations. Examples include anticoagulation therapy management, diabetes monitoring and education, asthma teaching, cholesterol monitoring, anemia therapy management, management of epilepsy disorders, dosing of medication therapies in the elderly, compliance management education for HIV patients with complex medication regimens and assuring patients with chronic diseases such as heart failure are taking the right medications. Health care literature, and managed care literature includes MANY examples of how pharmacists manage these complex therapies very well.

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

3. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services. They should not be allowed to discriminate by removing pharmacists from this professional responsibility!

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

5. MTM services should be able to be provided in conjunction with and outside of product dispensing.
6. An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims, similar to the electronic system f

CMS-4068-P-607

Submitter : Dr. Barbara Johnston **Date & Time:** 10/01/2004 02:10:41

Organization : HIV Center St. Vincent's-Manhattan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

To Whom It Concerns:

Patients with HIV/AIDS constitute a unique population which requires a specialized approach. Unlike in other conditions, in which slightly different agents within a class of drugs may be used without detrimental clinical effect, in HIV/AIDS drugs have to be highly tailored to an individual. For that reason, patients and their physicians must have access to the complete range of HIV medications that are available at any given time. As new agents become available, they may make the difference between life and death for those already resistant to current drugs, and they should be rapidly incorporated as well. It is imperative that these factors be kept in mind as the regulations are being written and implemented.

Thank you for your attention

Barbara Johnston MD
Deputy Director HIV Medicine
St.Vincent's-Manhattan

CMS-4068-P-608

Submitter : Susann Dahlquist **Date & Time:** 10/01/2004 02:10:58

Organization : DaVita Dialysis

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

I would like to voice my request that you reconsider including water soluble vitamin supplements under the Medicare Prescription Drup Benefit for the hemodialysis population. These vitamins are lost during dialysis and absolutely necessary for improving the health of these people.

CMS-4068-P-609

Submitter : Mrs. Rebecca Snead **Date & Time:** 10/01/2004 03:10:45

Organization : Mrs. Rebecca Snead

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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. In talking to my member of Congress, this was their intent. 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.

Any Willing Provider - The preferred and non-preferred

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. CMS should require plans to offer a standard contract to all pharmacies.
In addition, I would assert if this designation sticks, only preferred pharmacies should count when evaluating whether a plan has meet the pharmacy access standards.

Regarding the issue of differential copayments allowed for 90 days supply, 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.

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

SUBPART D ? COST CONTROL & QUALITY IMPROVEMENT REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Pharmacists are the most qualified, accesible health care professionals to provide medication therapy management services (MTM) services and determine which services each beneficiary needs. MTM services should be face to face with their community pharmacist. Patients with two or more chronic diseases and two or more drugs should qualify for MTM services.
Who will benefit from MTM services will change, so plans should be required to identify new targeted beneficiaries on a monthly basis. In addition, if a patient qualified for MTM services, and because of proper managment they no longer meet the criteria - services should not be discontinued for at least one year. Without proper continued management they may revert back to an uncontrolled state. One additional key pont is that CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.
MTM Services should comply with the principles adopted by the profefssion on the attached document.

CMS-4068-P-609-Attach-1.pdf

CMS-4068-P-609-Attach-2.pdf

CMS-4068-P-609-Attach-2.pdf

CMS-4068-P-609-Attach-1.pdf

Medication Therapy Management Services
Definition and Program Criteria

Original: 4-May-04 (APhA MTM Services Working Group)
Last Revised: 7-Jul-04 (Pharmacy Profession Stakeholders)

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

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

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

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

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

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

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

CMS-4068-P-610

Submitter : **Date & Time:** **10/01/2004 03:10:33**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

October 1, 2004

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

Re: CMS-4068-P

To Whom It May Concern:

I would like to take this opportunity to express my concerns on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for
consideration as CMS develops the final regulation.
SUBPART C ? BENEFITS & BENEFICIARY PROTECTIONS
First, I am very disappointed that CMS did not provide for pharmacist?s fees as they do for other health care providers. Dispensing fees are at a critically low level and patient care is being challenged. Although CMS believes that the plans will negotiate with pharmacists for their dispensing fees, this does not currently occur and will have a huge impact on the viability of the smaller community pharmacies. Plans should pay pharmacists for the cost of goods plus a percentage of profit plus a true cost of dispensing. In the State of Connecticut, the cost of dispensing is estimated to be over $9.00 per prescription. Current reimbursements are inadequate.
Second, I am concerned that the proposed regulation allows plans to establish preferred and nonpreferred pharmacies; this could affect my ability to continue to serve my patients. Allowing plans to distinguish between pharmacies based on cost of product could allow plans to drive beneficiaries to a particular pharmacy. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice. A preferred network should be based on added services not on cost of product. Also, allowing a preferred network places smaller community pharmacies at a distinct disadvantage. Since they are unable to collectively negotiate contracts with plans, they will not be able to compete. In a small state like Connecticut, plans could contract with one national chain pharmacy and patients will no longer be able to choose their pharmacy. Even if smaller pharmacies would be allowed access, if the fees that the larger corporations negotiate are so low, the smaller pharmacies will not be able to afford to participate. This will eventually affect access and care.
Thank you for your time and consideration of my concerns.

Sincerely,

Laura Soule

12 Eric Dive
Granby, CT 06035

CMS-4068-P-611

Submitter : Mr. Fred Cowell **Date & Time:** 10/01/2004 03:10:13

Organization : Paralyzed Veterans of America

Category : Other Association

Issue Areas/Comments

GENERAL

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Please see the attached Microsoft Word file from the Paralyzed Veterans of America re: MMA.

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

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CMS-4068-P-612

Submitter : Mrs. Anngela Moreno **Date & Time:** 10/01/2004 03:10:45

Organization : Sooner Success

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-612-Attach-1.doc

SOONER SUCCESS
State Unified Children's Comprehensive Exemplary Services for Special Needs

October 1, 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:

Sooner Success welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. Sooner Success is a comprehensive, unified system of health, social and education services supporting children and youth with special needs and their families. Sooner Success is a program through the Child Study Center, Department of Pediatrics, College of Medicine at the OU Health Science Center. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

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

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. We strongly urge CMS to develop a

specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic

substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

Require plans to dispense a temporary supply of drugs in emergencies:

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

Anngela Moreno
Sooner Success
Logan County Coordinator
405.742.8404 405.372.8529
soonersuccess@yahoo.com

Submitter : Dr. Richard Lecher **Date & Time:** 10/01/2004 03:10:59

Organization : SCARC, Inc.

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-613-Attach-1.doc

scarc, Inc. 11 US Route 206, Suite 100, Augusta, NJ 07822 • (973) 383-7442 • Fax (973) 383-8330

Richard Olsen, *President*
Richard C. Lecher, Ph.D., *Executive Director*

October 1, 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:

SCARC, Inc. welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and

safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

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

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

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

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

concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

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

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Sincerely,

Richard C. Lecher, Ph.D.
Executive Director

RCL:bh/1-Yrcl11

CMS-4068-P-614

Submitter : Mrs. Deborah Mammosser **Date & Time:** 10/01/2004 03:10:17

Organization : Genesee Region Independent Living Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Docket ID-CMS 4068P regarding the proposed rule "Medicare Program; Medicare Prescription Drug Benefit", 69FR46632.

This proposed rule doesnot provide sufficient protection for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. There are 7 million dual-eligible who will lose all Medicaid prescription drug benefits the currently utilize.

I would recommend that you delay implementation of this program for part D, regarding those with dual eligibilities until its impact on such programs as TWWIIA-Ticket to Work/Work Incentives improvement Act, PASS-Plan for Achieving Self Support, and other social security work incentives is determined.

Advocates and the Social Security Administration have worked hard for over 10 years to remove disincentives to work for beneficiaries. Almost all indicated that the loss of health care coverage was the greatest disincentive to work.

Extend this legislation to allow citizens with disabilities the right and privilege of working without fear of losing their Medicaid coverage.

Thank you.

CMS-4068-P-615

Submitter : Dan Drake **Date & Time:** 10/01/2004 03:10:10

Organization : OPERS

Category : Other Government

Issue Areas/Comments

Issues 1-10

BACKGROUND

See Attachment

CMS-4068-P-615-Attach-1.doc

Ohio Public Employees Retirement System
Medicare Modernization Act
Comments on Proposed Rules Published in Federal Register Dated August 3, 2004
Submitted electronically to http://www.cms.hhs.gov/regulations/ecomments

September 20, 2004

Introduction

We appreciate the opportunity to comment on specific aspects of the Medicare Modernization Act and the implementation of the new Part D prescription drug benefits. The Ohio Public Employees Retirement System (OPERS) currently provides pension and health care benefits, including prescription drug coverage, to approximately 188,000 retirees and dependents, approximately 62% of whom are currently eligible for Medicare benefits. An additional 370,000 active employee members and their dependents will receive OPERS benefits upon their retirement, based on current membership. Our primary mission is to provide pension benefits to our benefit recipients. We are authorized but not required to provide health care benefits to the extent funding allows. While not required to do so, we believe in the importance of providing affordable health care benefits to our retirees, both current and future. We have recently created and adopted our Health Care Preservation Plan (HCPP) to provide an organized and systematic approach for the long term solvency of our health care program, including a structure for ongoing evaluation of the program and its solvency and identification of desirable changes to ensure a lasting program.

Because of the size of our health care expenditures (approximately $1.1 billion annually), the significant level of cost increases and the expected growth of our retired population, both in actual numbers and relative to the number of active employees, we value the new Part D benefits and believe that it will help us in our mission to preserve our health care program for the long term. While we have not determined what our approach will be upon implementation of the new program in 2006, we are considering either accepting the subsidy in exchange for continuation of our program or coordinating with a PDP to provide benefits. As a result, we are very interested in all aspects of the program, including the valuation rules, the implementation process and the administrative complexity of potential alternative approaches and have specific comments in that regard. We include our comments below, designated by the proposed rule section title, as instructed.

I. Background

We appreciate the flexibility for plan sponsors to offer drug plans with plan designs that differ from the coverage levels to be included in Part D, including the use of a formulary, and we strongly encourage the continuation of this flexibility as the regulations are finalized. We have worked very hard over many years to design a program, together with our pharmacy benefit manager, that best balances the needs of our retirees with the appropriate cost management techniques and appreciate the flexibility to continue to do so to the extent it continues to be appropriate in light of the new Part D benefit.

II. General Provisions

Documentation of Creditable Coverage Status

We understand the need to document the creditable status of prescription drug coverage and the need for an established process for disclosure of this information to CMS and to each eligible beneficiary. Given our size and complexity, we are concerned about any new administrative requirements and the level of simplicity versus complexity that those requirements include. We also believe that the simpler the required administrative processes, the more likely other plan sponsors will be to consider continuation or enhancement of their non-Medicare prescription drug coverage. As a result, we strongly encourage flexible processes that allow the plan sponsor to utilize already established communications vehicles and distribution processes for documentation of creditable status, as well as other administrative details of the program.

While the specific process has not yet been defined, the proposed rules outline several approaches that will be considered. One of these is to allow the required disclosures to be included into materials routinely disseminated, perhaps providing standard language for this purpose. Alternatively, the proposed rules mention requiring each entity to issue a separate notice to each eligible enrollee. Given the direct paper and postage costs and the indirect administrative staffing costs of producing separate notifications, we believe that incorporating the certification into already existing communication vehicles is the best approach for documenting creditable coverage. If separate notifications are required, we encourage you to consider the requirement only for plans that are <u>not</u> considered creditable coverage initially and those losing creditable coverage status over time.

Establishment of Prescription Drug Plan Service Areas

The OPERS plan provides prescription drug coverage to individuals retiring from active employment status in the state of Ohio. While many of these individuals remain in the state once retired, many do not. As a result, we provide coverage to individuals residing across the country. If OPERS chooses to coordinate coverage with an existing PDP, we request that CMS grant waivers from the normal PDP service areas and regions defined in the proposed rules to enable OPERS and other groups providing coverage to beneficiaries across the country to work with a single PDP of our choice, rather than requiring coordination with a number of PDPs across the country, an administratively complex and costly approach if required.

Coordination Under Part D Plans With Other Prescription Drug Coverage

Section 1860D-22(b) refers to “employment-based retiree health coverage.” The proposed rules indicate that this includes coverage for individuals under a group health plan based on their status as retirees and includes the spouses and dependents of retirees. The proposed rules include the following definition.

> "We use the term "employer-sponsored group prescription drug plan" to mean a prescription drug plan under a contract between a PDP sponsor and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage."

OPERS is created by statute for the purpose of providing benefits to retirees of Ohio public sector employees and their dependents and is not created by "employers, labor organizations or the trustees of funds established by employers or labor organizations." It is our understanding based on conversations we have had with regulatory officials and from references in other areas of the proposed rules that a public retirement system such as OPERS is also an "employer-sponsored group prescription drug plan" for purposes of the Part D benefits. However, we request that this be referenced explicitly in writing since we do not meet the definition shown above.

Tracking True Out-of-Pocket (TrOOP) Costs

As noted in the proposed rules, CMS is considering a number of options to track the calculation of TrOOP, including mandatory versus voluntary reporting and centralized versus decentralized tracking. OPERS has not decided whether to receive the federal subsidy or coordinate with a PDP. As we and other group plans consider which alternative is best, we again encourage the simplest level of administrative complexity. We agree that TrOOP tracking is potentially very administratively burdensome and are concerned about what would be required if we choose to coordinate with a PDP. We encourage elimination of this provision as a way to simplify administration and encourage plan sponsors to choose the coordination alternative.

To the extent that elimination of this provision is not feasible, we support the alternative presented in the proposed rules to establish a central clearinghouse as it does currently for Parts A and B. We do, however, request that CMS not exercise its authority to charge the plan sponsor user fees for the transmittal of information for tracking purposes. We believe increasing plan sponsor costs in this regard may produce an unintended consequence of additional groups reducing or eliminating existing levels of coverage.

Payments to Sponsors of Retiree Prescription Drug Plans

We agree that it is important to maximize the number of retirees receiving generous prescription drug benefits, in whole or in part, by non-Medicare plan sponsors, to the extent that finances allow. We also understand the need to limit federal budget outlays for Part D benefits. The determination of actuarial equivalence is one of the most important components of the regulations and was intended to provide incentives for plan sponsors to continue or enhance their existing coverage.

Our primary concern with calculation and ultimate acceptance of the federal subsidy rests with the calculation and administration of the actuarial equivalence relative to our OPERS-paid allocation toward the cost of medical versus prescription drug coverage. Under our newly designed program, individuals will receive an allocation toward the cost of their coverage based on their number of years of pre-retirement service and their family status under the plan. This allocation is provided for medical and prescription drug coverage combined, rather than separate allocations for prescription drug versus medical coverage. Based on CMS comments during open conference calls and other reactions to the proposed rules, we believe that CMS will be flexible in how OPERS defines the allocation when evaluating the actuarial equivalence of our prescription drug coverage separate from our medical coverage, but we request explicit written assurance of this flexibility as the rules are finalized.

The second concern we have is relative to the administration and payment of the federal subsidy. Given our significant level of expenditures toward the cost of prescription drug coverage and the importance of cash flow, we strongly encourage monthly payment of the subsidy, assuming an automated process of reporting and payment, rather than annual payments as described under one alternative. Because of the very small claims lag due to the high level of automation of prescription drug plans, we believe that this is achievable. We also encourage the annual reporting and reconciliation after the close of the plan year of the amounts of rebates reimbursed to the plan, since these amounts are not known at the time of the prescription drug purchase and cannot be incorporated into the monthly reporting and payment process in an accurate way. We also believe that the cash flow issues are significant enough that payment of less than the full subsidy calculation during the year, with reconciliation after the close of the plan year, could be costly for plan sponsors and produce unintended consequences of plans exiting from coverage. This is particularly significant as many retiree plans, including the OPERS plan, expect to grow in the number of covered beneficiaries as the population increases. This potentially exacerbates the cash flow issue if estimates are used for payment of the subsidy.

With regard to actuarial testing, we agree with the “two-prong” test to avoid financial windfalls, utilizing both a gross value test and a net value test for determining actuarial equivalence. We believe that it presents a balanced approach for evaluation and determination of equivalence when applied at the single plan level, as described.

Lastly, we encourage the most straight-forward approach to data collection and transfer and encourage CMS to focus on the reporting of aggregate claims cost data, rather than individual beneficiary claim detail, whenever possible. We understand the need for data retention for auditing purposes for a defined period of time, but believe the most efficient process for subsidy verification, given time constraints to develop a process by 2006 and the amount of data that would be transmitted if line item detail is required, is to define the standard data set and procedures for reporting of aggregate data, and defining the detailed data set to be retained by the plan sponsor or its business associate for use during a potential audit.

Closing

Again, we understand the level of complexity in establishment of a new Part D benefit and appreciate the opportunity to influence the creation of such a program through public comment. We are committed to preserving our health care program, both medical and prescription drug coverage, for as many of our retirees and dependents for as long as possible. We believe that Medicare Part D can help us accomplish this mission and hope that other plan sponsors will feel the same. We encourage CMS to establish final procedures and subsidy calculations to maximize the number of plan sponsors continuing to provide benefits to their retirees. At the same time, we encourage the highest level of simplicity with regard to the sharing of information between plan sponsors and other parties involved in the administration of the program.

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Submitter : Mrs. Shirley Singletary **Date & Time:** 10/01/2004 03:10:36

Organization : Mrs. Shirley Singletary

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file from the disability community.

CMS-4068-P-616-Attach-1.doc

Date

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

To Whom It May Concern:

The name of organization welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The name of organization is standard description of your organization. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning

of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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- people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and

appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Submitter : Rhonda Peterson **Date & Time:** 10/01/2004 03:10:51

Organization : Peterson Pharmacy

Category : Nurse

Issue Areas/Comments

Issues 1-10

BACKGROUND

I write today to offer comments regarding the proposed Medicare Part D rules. As an owner of Peterson Pharmacy, I am deeply concerned with the rules as they are currently proposed.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns expressed by pharmacists around the nation are being considered. All pharmacists want this program to work. Private sector health plans have far too often targeted pharmacies and pharmacy reimbursement in cost containment measures rather than working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow that path.

BENEFITS AND BENEFICIARY PROTECTIONS

? Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Recipients should not be economically coerced into using one pharmacy over another unless the plan sponsor for defined quality reasons prefers the preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

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

? Plan sponsors should be required to establish specified MTM services.
CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

ELIGIBILITY, ELECTION, AND ENROLLMENT

? Medicare recipients must be able to choose their own pharmacies
It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. The access standards should be applied at a level no broader than a county to ensure that recipients have ready access to the pharmacies in their community. Furthermore, plan sponsors should be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans have often used their market force to drive down pharmacy reimbursement below a pharmacy?s operational costs, thereby forcing the pharmacy providers to cost shift to other business sectors. Medicare must not allow this business practice to continue.

GENERAL PROVISIONS

I write today to offer comments regarding the proposed Medicare Part D rules. As an owner of Peterson Pharmacy, I am deeply concerned with the rules as they are currently proposed.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns expressed by pharmacists around the nation are being considered. All pharmacists want this program to work. Private sector health plans have far too often targeted pharmacies and pharmacy reimbursement in cost containment measures rather than working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow that path.

CMS-4068-P-618

Submitter : Ms. Nancy McGowan **Date & Time:** 10/01/2004 03:10:57

Organization : Ms. Nancy McGowan

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Pharmacists should be able to serve their patients. CMS should revise the pharmacy access standard (PAS) to require plans to meet the TRICARE requirements on a local level, which is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.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 regulation allows plans to establish preferred & non-preferred pharmacies, which could affect pharmacists' ability to continue to serve their patients. Allowing plans to distinguish between pharmacies goes against Congress' intent, which was to ensure that patients could continue to use the pharmacy & pharmacist of their choice.Only preferred pharmacies should count when evaluating if a plan's network meets the PAS. This will help patients access a local pharmacy for their full benefits. Access isn't access if patients are forced to use other pharmacies. 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 drug's cost. Congressional intent opposes making the cost difference a tool for coercing beneficiaries away from the pharmacy of their choice. Patients with 2 or more chronic diseases and 2 or or drugs should qualify for MTMS. Who will benefit from MTM can change so plans should be required to inform pharmacists and doctors which of their patients are eligible.Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their pharmacy choices for these services.Once a beneficiary becomes eligible for MTMS, he should remain eligible for MTMS for the entire year.Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services. Pharmacists are the ideal providers of MTMS. Requiring beneficiaries to get 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. CMS must evaluate each plan's application to provide MTM benefit and examine if the proposed fee is pay for MTM services is high enough to entice pharmacists to provide MTMS. Face to face interaction between beneficiary and pharmacist is the preferred method of delivery and the initial assessment should be face-to-face. I support the MTMS Definition and Program Criteria developed & adopted by 11 national pharmacy organizations in July 2004.

CMS-4068-P-619

Submitter : **Jeff Patchett** **Date & Time:** **10/01/2004 03:10:29**

Organization : **NorthEast Medical**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

attched

CMS-4068-P-619-Attach-1.wpd

September 30, 2004

Center for Medicare and Medicaid Services
Dept. Health and Family Services
Att: CMS-4068-P
Baltimore, MD 21244-8014

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As the Director of Pharmacy at NorthEast Medical Center, I am deeply concerned with the rules as they are currently proposed and the negative impact they could have on the services provided to Medicare beneficiaries by my five medication management clinics.

I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. My suggestions mirror those of other pharmacists and include additional thoughts and suggestions. I hope that my concerns and the concerns being expressed by pharmacists around the nation are being considered.

In order for this program to be successful, I urge CMS to incorporate rule language that will 1) ensure compensation for all pharmacy providers that perform medication therapy management (MTM) services, and 2) allow for all willing pharmacy to serve as a prescription product provider for Medicare beneficiaries. Below are my specific and detailed recommendations for rules concerning MTM services and prescription access that will ultimately do the right thing for the patient:

<u>MTM Services</u>

1. **CMS rules must allow for all pharmacists to be included not precluded**. Pharmacists at NEMC are an integral part of the health care team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve the quality of patient outcomes, they also dramatically lower total medical costs via avoiding unnecessary hospitalizations and ER visits. Examples include anticoagulation therapy management, diabetes monitoring and education, asthma teaching, cholesterol monitoring, anemia therapy management, dosing of medication therapies in the elderly, compliance management education for patients with complex medication regimens and assuring patients with chronic diseases such as heart failure are taking the right medications.
2. All pharmacists practicing within a region (regardless of practice setting) should be afforded the opportunity to provide and be paid for MTM services such that **plan sponsors should be directed to allow any pharmacist who receives a physician order for an MTM service to provide and be reimbursed for that service**. Furthermore, all prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM

920 Church Street, North • Concord North, Carolina 28025 ✆ 704.783.1566 ✆ 704.783.3157 ✉ jpatchett@northeastmedical.org

services to a pharmacist provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

3. **MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist**. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services. They should not be allowed to discriminate and leave pharmacists out in the cold.
4. **Pharmacists should be able to identify eligible beneficiaries with multiple chronic diseases and drug therapies who need MTM services** and be eligible to provide MTM services to these patients. Identification of targeted beneficiaries should not be left solely to the plan. Plans should also be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription.
5. MTM services should be able to be provided **in conjunction with <u>and</u> outside of product dispensing**.
6. **An efficient electronic MTM claims process** should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.
7. **Plan sponsors should be required to establish at CMS-specified set of MTM services**. The specified set of services should be a <u>minimum</u> set while additional services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management and adverse drug event assessment and prevention should be included.
8. CMS should consider developing a **program to accredit plans** that agree to meet the above stated conditions that add value to and lower the cost of care.

<u>Access to Pharmaceuticals – Drug Product Provisions within Part-D</u>

1. Plans should be required to offer standard contract language to all pharmacies willing to participate in the program as a prescription and MTM services provider. **Plans need to make it easy for patients to have convenient access to their pharmacy of choice**. They should not be able to limit the number of pharmacy providers as this would negatively impact patient access to needed medications and pharmacy services. North Carolina, like many states, has a number of rural counties where access to health care is often limited. The isolation and transportation issues faced by the elderly may be exacerbated if access is defined at the county or regional level. Furthermore, in order to provide the highest quality care and service to Medicare beneficiaries who receive their care at NEMC, it is absolutely essential that our pharmacies are able to dispense prescription medications for beneficiaries as an approved/preferred pharmacy provider.
2. **Co-payment reductions should not be provided to coerce beneficiaries into using "preferred" pharmacy providers solely on the basis of pricing or cost**. This will provide incentives for beneficiaries to use low cost, low quality providers and ultimately increase the cost of patient care and will produce a "chasm" in that it will disrupt existing pharmacist-patient relationships resulting in improved drug therapy outcomes. While steering patients to a limited number of pharmacies that are willing to accept deep-discount reimbursement rates may result in reduced “drug-silo” costs for the plan (which under the current legislation may in fact be in the plan’s best interest as they may only be at risk for the cost of the drug product), this savings will undoubtedly be offset by much higher medical costs to Medicare as a result of poor quality pharmaceutical care and poor patient medication therapy management and medication regimen non-compliance. This practice could also result in pharmacies that specialize in accepting the lowest reimbursement formula but develop “schemes” to shift patients to high-profit margin regimens that ultimately increase costs to the plan.

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3. CMS must act responsibly by assuring an **adequate reimbursement formula** that at a minimum covers the average cost of filling a prescription or providing a service. The excessive costs in pharmaceuticals appears to be at the manufacturer level.
4. It would be an acceptable approach for plan sponsors to provide beneficiaries with incentives for using "preferred" pharmacies over others based on **well-defined quality principles** related to providing a high level of pharmaceutical care and MTM services for patients. It would be advantageous for all pharmacy providers to strive to achieve and adhere to the defined quality standards and they should be allowed to become designated as preferred when they achieve those standards, as compared to being excluded. It would seem plausible to modify reimbursement similarly to hospital reimbursement based on compliance with CMH quality indicators. Those that meet quality indicators get paid more those that don't meet the indicators.
5. **Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies**. There are safety and medication management concerns when beneficiaries are required to use mail order pharmacies. If mail service is offered as an incentive to lower costs, all pharmacies should be offered standard contract language and allowed to participate as a mail service provider. Beneficiaries should not be required to use mail service pharmacies.
6. To prevent conflict of interest, **plan sponsors should be prohibited from promoting or requiring the use of pharmacies in which they have an ownership interest**.

In closing, pharmacies must be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Physicians are frequently inaccessible by design. Pharmacists will be able to assist in making this new benefit successful. Medicare must make specific requirements of the plan sponsors otherwise many of the nation's foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully, and all licensed pharmacists within a designated region should be considered an MTM provider. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration, and please feel free to contact me if I can be of further assistance in helping to craft specific rules.

Sincerely,

Jeffrey A. Patchett, MBA RPh
Director of Pharmacy Services
NorthEast Medical Center
Concord, NC 28081
704-783-1028
704-783-3157 fax
jpatchett@northeastmedical.org

CMS-4068-P-620

Submitter : Mrs. Susan Lefstead **Date & Time:** 10/01/2004 03:10:43

Organization : Mrs. Susan Lefstead

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

People cannot be cold turkeyed off benzodiazapenes, especially the elderly! I was cold turkeyed off of klonopin in 12/02 and almost died! Benzo withdrawl is a long long process, taking years to get off safely. Even then, it is hellish as I had to be reinstated and am now slowly tapering and very sick. This would literally kill thousands of people. You better wake up and educate yourselves on this matter and the doctors better get with it. It is their fault for getting people dependent on this poison in the first place and not even knowing the risks of these drugs and potentially fatal withdrawl. I pray to God that this will not pass. If it does the blood is on the hands of those responsible for this. Thank-you. Susan.

CMS-4068-P-621

Submitter : Mr. Glenn Cavanaugh **Date & Time:** 10/01/2004 03:10:44

Organization : Westmoreland County Food Bank

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Concerning the proposed rule "Medicare Program:medicare Prescription Drug Benefit, "69FR46632, I feel that the current rule doesn't provide sufficient protection for individuals diagonosed with either HIV or AIDS who will receive their treatment through this benefit.

CMS must designate peoplel 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, iin all approved formulations, as is recommended by the Public Health Service HIV treatmentn guidelines.

Please give this issue your fullest consideration. Many of our clients struggle to put food on their tables, and with proposed medication price increases, several will be devastated. The daily stresses of just the illness alone are difficult to endure, but imagine knowing that treatment is available for prolonging life, but with no availability of the necessary money to purchase those medications. Long survivors who are treatment experienced andn likely to have drug resistance problems will suffer greatly.

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

Sincerely yours,

Glenn R. Cavanaugh
Westmoreland County Food Bank
100 Devonshire Drive
Delmont, PA 15626

Submitter : Mr. Michael Dunn **Date & Time:** 10/01/2004 04:10:35

Organization : Independent Living, Inc.

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

I am concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. I am especially concerned with the 7 million dual eligible who will lose all Medicaid prescription drug benefits they now have. The following are critical recommendations:

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

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

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today?s technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.

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

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Thank you for your consideration of my views.

Yours sincerely,

Michael P. Dunn
Advocacy Services Manager
Independent Living, Inc
5 Washington Ter.
Newburgh, NY 12550

CMS-4068-P-623

Submitter : Mrs. Doris Pitre **Date & Time:** 10/01/2004 04:10:54

Organization : The Alliance of Louisiana Developmental Centers (F

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

THE ALLIANCE OF LOUISIANA DEVELOPMENTAL CENTERS
(FAMILIES & FRIENDS)

October 1, 2004

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

RE: Comments relating to Medicare Part D proposed Regulations ?
69 Fed. Reg. 46632 (Aug. 3, 2004).

Our organization supports the comments submitted by Voice of the Retarded (VOR). We feel strongly that:

- The definition of ?long term care facility? must include Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR).

- ?Institutionalized? should include all individuals eligible for ICF/MR placement, including current residents, home and community-based services (HCBS) waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

The regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives.

Thank you for your consideration.

Sincerely,

Doris Pitre, Chairperson
The Alliance of LA. Developmental Centers (Families & Friends)
939 Landreneau Rd.
Eunice, LA. 70535
337-457-8792 Ph & Fax
dorispitre@earthlink.net

CMS-4068-P-624

Submitter : Brad Lueneburg **Date & Time:** 10/01/2004 04:10:20

Organization : Family Rexall Drug Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation, by allowing the establishment of preferred and non preferred pharmacies by the pharmacy benefit plans, will hamper competition and take away seniors' freedom to choose their pharmacy. This was definately not Congressional intent when they passed the Medicare prescription drug benefit. I feel that all pharmacies in any plan region be allowed to participate in the plan and be reimbursed at the same equal amount as any other pharmacy. This would much better exemplify the Congressional intent of "any willing provider." It would also serve to maximize competition which would in turn give the best value for the seniors.

Thanks for your consideration,

Brad Lueneburg

Submitter : Mr. William Butler **Date & Time:** 10/01/2004 04:10:32

Organization : Q Care International, LLC

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Q CARE INTERNATIONAL LLC
680 ATLANTA COUNTRY CLUB DRIVE
MARIETTA, GEORGIA 30067
770/953-2011 FAX 770/951-8860

September 16, 2004

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

RE: CMS-4068 ?p, ?General Provisions?

Dear CMS:

We welcome the opportunity to comment on the proposed rule issued by CMS to implement the Medicare Prescription Drug Benefit under the Medicare Program. The proposed rule in its current form defines ?medical supplies associated with the injection of insulin? as syringes, needles, alcohol swabs, and gauze. While we support the inclusion of those items, we urge CMS to expand that list to include needle destruction devices (NDD) in the final rule.

Health statistics indicate that a significant portion of the diabetes population who self inject insulin shots neglect an essential part of their treatment, that is the safe disposal of contaminated needles. Diabetics are the largest group of self injectors. Because of a common secondary complication of the disease, peripheral neuropathy, an accidental needle stick injury can be far more serious to a diabetic than the general population. The loss of nerve sensation brought on by peripheral neuropathy numbs the body, most commonly the feet of diabetics, to feeling. As a result, injuries on the lower limbs are often unnoticed and untreated. This can lead to serious infections which can be very costly to address.

Medical practitioners continue to caution home injectors, particularly diabetics, about the dangers of improper needle disposal. Historically, patients who administer their own insulin treatments have not had practical options to dispose used needles responsibly. The development of NDD?s however, provides a way for diabetics to safely complete their insulin treatment.

Handling the used needle, a form of medical waste, is in fact the last step in self treatment but is usually ignored. Providing diabetic seniors with access to NDD?s as an insulin associated item will further their health and safety while providing a cost saving preventative benefit. Needle stick injuries compounded by peripheral neuropathy can lead to very costly medical treatments, including lower limb amputations. A simple needle stick, that could have been prevented, creates the need for increased medical services and impacts Medicare expenditures for diabetic beneficiaries. Providing diabetic Medicare beneficiaries affordable access to NDD?s will save money in the program by helping to reduce injuries caused by used needles that are not properly disposed.

We urge you to carefully consider the medical benefits of NDD?s to the senior diabetic population, in addition to savings to the Medicare program, and include these medical items as associated insulin supplies in your final rule to implement the Medicare Prescription Drug Benefit.

Sincerely,

William F. Butler,
President
Q Care International, LLC

CMS-4068-P-626

Submitter : Mrs. Doris Pitre **Date & Time:** 10/01/2004 04:10:17

Organization : Voice of the Retarded - Louisiana State Coordinato

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

October 1, 2004

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

RE: Comments relating to Medicare Part D proposed Regulations ?
69 Fed. Reg. 46632 (Aug. 3, 2004).

I, as the Louisiana State Coordinator for VOR, support the comments submitted by Voice of the Retarded (VOR). I feel strongly that:

- The definition of ?long term care facility? must include Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR).

- ?Institutionalized? should include all individuals eligible for ICF/MR placement, including current residents, home and community-based services (HCBS) waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

The regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives.

Thank you for your consideration.

Sincerely,

Doris Pitre
LA. VOR State Coordinator
939 Landreneau Rd.
Eunice, LA. 70535
337-457-8792 Ph & Fax
dorispitre@earthlink.net

CMS-4068-P-626-Attach-1.doc

Voice of the Retarded
5005 Newport Drive, Ste 108 * Rolling Meadows, IL 60008 * 847-253-6020 *
847-253-6054 fax * vor@compuserve.com * http://www.vor.net

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21224-8014

Sent by regular mail and
electronically (http://www.cms.hhs.gov/regulations/ecomments)

On August 3, 2004, the Centers for Medicare & Medicaid Services released proposed regulations relating to section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Included within this new law is a shift of payment authority from the states to the federal government for the purpose of providing medication coverage to people eligible for both Medicare and Medicaid ("dual eligibles"). Starting in 2006, this new Medicare prescription medication benefit will replace Medicaid prescription coverage for low income beneficiaries. Although a state may continue to provide "wrap around" prescription medication benefits through its Medicaid plan to compliment the new Medicare coverage, any such supplemental coverage will be at the state's option.

Long term care facilities receive special mention in the new law. Although certain dual eligibles will be subject to Medicare premiums and cost sharing, full dual eligibles, including dual eligibles in "long term care facilities," are exempt from co-payments. According to the proposed regulations, the definition of "long term care facility" is in question:

"We request comments regarding our definition of the term long-term care facility in §422.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in §440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs." [69 Fed. Reg. 46648-49 (Tuesday, August 3, 2004)].

VOR strongly agrees. As noted later in the regulations --

"It is particularly important to ensure that the drug needs of institutionalized Part D enrolles -- most of whom are dually eligible for Medicare and Medicaid -- are met. The institutionalized population is

generally more sensitive to and less tolerant of many medications." [69 Fed. Reg. 46661 (Tuesday, August 3, 2004)].

CMS, in this statement, makes the best claim for including in the definition of "long term care facilities" ICFs/MR. Residents of ICFs/MR are the most fragile of the population with mental retardation (see attached, "Characteristics of Large State MR/DD Facilities"). In addition to severe and profound mental retardation and multiple functional limitations, most ICF/MR residents also experience chronic medical conditions requiring prescription medication intervention (e.g., seizures, psychosis, etc.). Although the exact number of ICF/MR residents that are also dually eligible for Medicare and Medicaid is difficult to quantify statistically, existing information indicates that they are a significant number. This hypothesis is especially compelling when one considers that nearly 66% of all individuals in public ICFs/MR are more than 40 years old and may receive Medicare survivor benefits from a deceased parent(s), in addition to their Medicaid eligibility (see attached, "Characteristics of Large State MR/DD Facilities").

With regard to accessing medications, most ICFs/MR contract with long term care pharmacies and it is critical that individuals continue to access prescription medications through these established vendors. For any population, continuity of medication benefits is critical.

Given that ICFs/MR are the present safety net of the system for persons with mental retardation who also experience complex medical conditions -- the "intensive care unit" of our service system -- VOR also supports including individuals receiving home and community-based waiver supports in the definition of "institutionalized." Waiver placement eligibility criteria is identical to eligibility for ICF/MR placement. Due to ongoing, wholesale efforts to serve almost all of the ICF/MR-eligible population in less restrictive waiver settings, it seems misguided and even dangerous to transfer or divert these individuals from ICF/MR supports and then also restrict their prescription medication options simply because of where they are now living. As established, the severity of cognitive disabilities and related medical conditions in community waiver settings will mirror the conditions of ICF/MR residents. Furthermore, as individuals age, or the severity of a medical condition worsens, some waiver participants will be (re)admitted to ICFs/MR. Continuity of benefits would be enhanced if the definition of "institutionalized" includes our waiver population.

For all the above reasons, eligible individuals on waiting lists for ICFs/MR and HCBS services should also be included.

Thank you for the opportunity to comment and for your consideration of VOR's submission. For more information please contact:

Mary McTernan
President
Voice of the Retarded
201 Brooksby Village Dr., Apt. 508
Peabody, MA 01960

978-535-2472 phone
978-535-0472 fax

Tamie Hopp
Executive Director
5005 Newport Drive, Suite 108
Rolling Meadows, IL 60008
605-399-1624 direct
605-399-1631 direct fax
847-253-6054 alternate fax
vor@compuserve.com

CHARACTERISTICS OF RESIDENTS OF LARGE STATE MR/DD FACILITIES
June 30, 2004

Source: Residential Services for Persons with Developmental Disabilities: Status and Trends Through 2002," Research and Training Center on Community Living, Institute on Community Integration/UCEDD, University of Minnesota (June 2003).

AGE OF RESIDENTS

0-21: 4.5%
22-39: 30.9%
40-62: 55.4%
63+: 9.2%

LEVEL OF MENTAL RETARDATION

Mild/No MR: 10.4%
Moderate: 9.9%
Severe: 16.7%
Profound: 63%

ADDITIONAL CONDITIONS

Cerebral Palsy: 19.4%
Behavior Disorder: 52.4%
Psychiatric Disorder: 45.7%
Blind: 13.5%
Deaf: 6.6%
Epilepsy: 45%
Two or more: 47%

FUNCTIONAL LIMITATIONS

Walking: 37%
Verbal: 58.1%
Toileting: 56.1%
Eating: 51.4%
Dressing: 62.6%

CMS-4068-P-627

Submitter : Mr. Dennie Baker **Date & Time:** 10/01/2004 04:10:50

Organization : NAMI Bucks county Pennsylvania

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, M.D., Ph.D

Administrator

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention: CMS-4068-P

P.O. Box 8014

Baltimore , MD21244-8014

Dear Dr. McClellan:

I , Dennie G. Baker, 863 Euclid Ave. Warrington Pennsylvania 18976, welcome the opportunity to submit comments on the proposed rule recently published by the Centers for Medicare and Medicaid Services (CMS) for the new Medicare prescription drug benefit.

As advocates for people with or at risk of mental illness, we recognize that access to psychiatric medications is a critical component of community-based care, and deem it critical that the Medicare drug benefit provide coverage for all medically necessary mental health medications. We appreciate the enormous challenges associated with implementing this new benefit, but urge that CMS substantially revise the proposed rule in accordance with these comments to ensure adequate access to mental health medications for the many Medicare beneficiaries who need them. As Congress itself recognized in the conference report on the Medicare Modernization Act, Medicare beneficiaries with or at risk of mental illness have unique, compelling needs that must be given special consideration in implementing this important new benefit.

Many Medicare beneficiaries face mental illness. Research has shown that some 37% of seniors show signs of depression when they visit their primary care physician. Yet most are not receiving the mental health services they need. In fact, seniors have the highest rate of suicide of any age group in the country. It is estimated that only half of older adults who acknowledge mental health problems actually are treated by either mental health professionals or primary care physicians (US DHHS, 2001). Beneficiaries who qualify for Medicare based on a disability also frequently experience mental illness and studies have shown that over half of all under-65 disabled beneficiaries have problems with mental functioning (Kaiser Family Foundation, 1999).

We urge CMS to address the following concerns (discussed more fully below) in the final rules for the Medicare Part D drug benefit.

Coverage of Dual Eligibles. Ensure continuity of care for dual eligibles by:

extending the deadline for switching their coverage from Medicaid to Medicare; and
grandfathering coverage of medications on which mental health consumers have been stabilized.

Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses . For other Medicare beneficiaries with mental health needs and particularly dual eligibles , require plans to use alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution.

Involuntary Disenrollment for Disruptive Behavior. Establish greater protections for beneficiaries threatened with and subjected to involuntary disenrollment by their drug plans for disruptive behavior.

Appeals Procedures. Simplify the grievance and appeals procedures to prioritize ease of access and rapid results for beneficiaries and their doctors and provide a truly expedited process for individuals with immediate needs, including individuals facing psychiatric crises.

Outreach and Enrollment. Partner with and provide resources to community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.

Coverage of Dual Eligibles (? 423.34)

Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. There is a high rate of mental illness among this segment of Medicare beneficiaries: according t

CMS-4068-P-628

Submitter : Mr. David Yurdin **Date & Time:** 10/01/2004 04:10:28

Organization : Primary Health Care, Inc.

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

I have been providing a HIV healthcare to many individuals for the past 20 years. Many of those patients are insured by Medicare and receive Medicaid benefits. Creation of a prescription program for Medicare will pose new financial challenges to these largely indigent individuals. Our Ryan White title 3 program has limited funds to help with medications and we largely depend on title 2 AIDS drug assistance program (ADAP) for those that are uninsured. Currently our AIDS drug assistance program is closed to new applicants. We're very concerned about copayments that will be required in order to obtain these very costly antiretroviral medications. Many of the patients survive on a few hundred dollars a month. For some of them the $3 copay for each of several medications is challenging enough. So, how our patients going to be able to afford these medications under the new program if the traditional Medicaid is not available? This will place a tremendous strain on our grant budget.
David L. Yurdin, PA-C

CMS-4068-P-629

Submitter : Mr. Praveen Fernandes **Date & Time:** 10/01/2004 04:10:25

Organization : Human Rights Campaign

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4068-P-629-Attach-1.doc

HUMAN
RIGHTS
CAMPAIGN

September 29, 2004

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

RE: Comments on Proposed Rule implementing the Medicare Prescription Drug Benefit, 42 CFR Parts 403, 411, 417, and 423

To Whom It May Concern:

On behalf of the Human Rights Campaign's more than 550,000 members nationwide, we write to voice our concerns to the Center for Medicare & Medicaid Services (CMS) regarding the Proposed Rule published August 3, 2004, that would implement the prescription drug benefit program adopted in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), with respect to Medicare benefits for people living with HIV and AIDS.

HRC recognizes the importance of the prescription drug benefit program to the many Americans who depend on Medicare to help them with the enormous costs of healthcare, including the increasingly important role of often-costly prescription drugs. We also recognize that many individuals living with HIV and AIDS depend on assistance from Medicare and Medicaid to obtain the costly medicines necessary to fight the disease.

In reviewing the proposed regulations, we have identified several serious issues with respect to ensuring adequate prescription drug access and coverage to these poorest and sickest members of the HIV/AIDS population. Beginning in 2006, all individuals who are currently recipients of Medicare and Medicaid, known as dual eligibles, will be transferred solely into the MMA's Medicare plan. Currently, Medicaid provides the largest source of highly active antiretroviral therapy (HAART) drug coverage (and a significant amount of the over-the-counter drug benefits) to people with HIV/AIDS. When they are transferred to Medicare, which relies heavily on private health plans, these beneficiaries may not receive the same level of critical protections. It is imperative that CMS adopt provisions for the HIV/AIDS population to ensure that, under the new Medicare-only arrangement, dual eligibles will continue to have affordable access to all available FDA-approved medications.

WORKING FOR LESBIAN, GAY, BISEXUAL AND TRANSGENDER EQUAL RIGHTS
1640 RHODE ISLAND AVENUE, NW WASHINGTON, D.C. 20036
PHONE (202) 628 4160 *FAX* (202) 347 5323 *E-MAIL* HRC@HRC.ORGT

SPECIFIC COMMENTS:

Special Population Designation: We appreciate CMS's acknowledgment in the Proposed Rule (as at Section II.C.4.b. of the introductory materials) that individuals living with HIV and AIDS are a "vulnerable population" that may be financially impacted by the new Medicare provisions. CMS is undoubtedly aware that the HIV/AIDS population utilizing Medicare and Medicaid includes mostly poor, very ill individuals who may lack external support mechanisms. Such recognition, however, should also come with some measure designed to alleviate the potential fiscal consequences of the transition. We recommend that the Proposed Rule designate people with HIV/AIDS as a special population and provide special protections from cost-sharing requirements (such as copayments, deductibles and coinsurance) and formulary restrictions.

Dual Eligible Protections: Nearly 60,000 persons with HIV and AIDS are dual eligibles who will lose their Medicaid drug coverage on December 31, 2005. We are concerned that the Proposed Rule does not appear to ensure that these individuals will not be left, even temporarily, without drug coverage during the transition from Medicaid to a Medicare Part D prescription drug plan. Failing to enroll dual eligibles who do not select a plan by May 15, 2006, as § 423.36 of the Proposed Rule seems to indicate, potentially leaves HIV/AIDS patients facing a four-month lapse in access to critical medication. We are concerned that the date set to begin enrollment, November 15, 2005, leaves dangerously little time to transition all dual eligibles before Medicaid coverage is terminated. We recommend that the Proposed Rule ensure that dual eligibles are at no time left without sufficient drug coverage during the transition, even if this requires the use of federal matching funds or the implementation of a special enrollment schedule for the HIV/AIDS population.

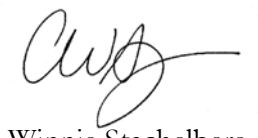
Formularies: Formularies are the cost-assessed tier systems used by many plans which stipulate to doctors and other medical professionals which drugs may be prescribed to whom and when. HIV/AIDS patients deal with a broad range of health issues and may, at one time or another, require FDA-approved drugs that their private plans do not include in their formularies. The Proposed Rule does not adequately address this critical issue for the HIV/AIDS population. For example, § 423.120 only requires a prescription drug plan (PDP) to include two covered drugs per therapeutic category and class. The complexities of HIV/AIDS treatment, especially with an increasing number of viral strains resistant to particular drugs, mandate physician freedom in prescribing different drugs in different combinations at different times. Allowing PDPs to have limited formularies could curtail the ability of physicians and other medical professionals to provide the best possible treatment to their HIV/AIDS patients. We recommend that the Proposed Rule at least reflect the principle that doctors have primary control over prescribing drugs, whether they be formulary, non-formulary or off-label. As stated above, a special population status for HIV/AIDS patients, which frees them from formulary limitations entirely, would be a better solution.

AIDS Drug Assistance Programs: State ADAPs are a critical part of the safety net for HIV/AIDS patients, often making up shortfalls left by Medicaid and Medicare. As noted in Section II.C.2.a. of the introductory comments, the Proposed Rule would penalize an individual who seeks help from an ADAP when he or she cannot afford his or her Medicare PDP's deductible or cost-sharing by prohibiting that assistance from counting as an incurred cost and helping the patient qualify for low-income cost-sharing. ADAPs are already having difficulty keeping pace with the demands for assistance from the low-income HIV/AIDS population. With this demonstrated need for additional aide from ADAPs, we are concerned that the Medicare prescription drug benefit program would

make use of those funds by low-income patients more difficult and even detrimental to their eligibility for other financial assistance.

The Human Rights Campaign appreciates having the opportunity to weigh in on these regulations. Thank you for considering our comments. If you have any questions regarding our comments, please do not hesitate to contact Praveen Fernandes on my staff at 202.216.1559.

Sincerely,



Winnie Stachelberg
Political Director

CMS-4068-P-630

Submitter : Mr. Tim Weippert **Date & Time:** 10/01/2004 04:10:54

Organization : Mr. Tim Weippert

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the regulations that will govern Medicare Part D in 2006.

I believe that there are 3 areas that need more pinpoint and definitive information included.

1. Tri-Care pharmacy access standards- being more a very rural area it is of UTMOST importance that patients have accessibility to coverage and to be able to work with THEIR pharmacist's who have been part of their health care team for many years. As it stands now, that is VERY much in question. We cannot have of patients expected to go distances of 30, to 40 to 100 miles to access services when they are right their within their own local community. Patients will suffer and the cost of healthcare will continue to rise if this allowed to happen. Let's make sure people can have access to their local community pharmacist.

2. PBM's- Their should be NO UNFAIR advantage for them to use economic incentives to drive the patient away from their community pharmacist. Again, if allowed to happen, this will lead to the demise of the local pharmacies and MORE IMPORTANTLY again reduce patient care and drive health care upwards and patients will have less access to the REAL healthcare professional they need to take care of them.

3. MTM- It is FINALLY time that the pharmacist is recognized in the health care world and is of UTMOST importance and of UTMOST knowledge in the management of patient care. With that needs to come fair reimbursement for services rendered by the pharmacist to their patient. This again will drive costs of health care down. It not allowed to happen, the reverse will be in order again.

As you can see, these 3 main points will be the avenue to effective, patient care driven and cost maintained services. If not allowed, the system will continue to see increased health care costs and will fail and Medicare will not be their for future generations.

Thank you for considering these comments

Tim Weippert, RPh.

CMS-4068-P-631

Submitter : Ms. Fae Hicks **Date & Time:** 10/01/2004 04:10:40

Organization : Ms. Fae Hicks

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please delay the implementation of the Part D program for dual elibibles. Individuals with mental retardation or developmental disabilities are numberous and have more extensive needs thatn the rest of the Medicare population. Also, other critical recommendations are:
1. designate special populations who will receive affordable access to an alternative,flexible formulary.
2. Fund collaborative partnerships with organizations representing people iwth disabilities
3. Impose new limits on cost management tools
4. Strengthen and improve inadequate and unworkable exceptions and appeals processes
5.Require plans to dispense a temporary supply of drugs in emergencies.

These are critical issues to individuals with special needs. Please give them your careful consideration.

Thank you,

CMS-4068-P-632

Submitter : Ms. Patricia Myslicki **Date & Time:** 10/01/2004 04:10:50

Organization : Parent and professional

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As the parent of a daughter with disabilities who resides in a great residential program/ICF-MR, I want you to remember the potential impact upon lives of people like my daughter Kathy. I have advocated for her special needs for almost forty years-schools, medical providers, insurance providers, faith communities, mental health care systems...she needs now and will for many years need affordable, appropriate services. Kathy can no longer tolerate some medical procedures without special arrangements-will this be possible in the future under the system changes? She's not currently using medications but as she ages, this may change-will her medical providers be able to treat her using appropriate services or medications? Will there be private plans who follow MMA guidelines who will welcome and understand the needs of individuals with disabilities who now receive Medicaid and Medicare/from family members? I know there are copayment issues in the Medicare system. Will that continue and if so, how will people like Kathy pay such amounts? Will that become my responsibility when I am retired and living with minimal income? As Kathy's guardian I have always been confident that however my advocacy and feedback efforts have assisted Kathy, my voice has possibly helped other individuals with special needs. As a case manager and former special educator, I know there are many vulnerable people within the aging population, within the population with unique health and mental health/brain disease issues, within the population who can not access health care due to illiteracy or other barriers, within families who fear for their person's future...these people need to be considered and assured of ongoing services which benefit them in an affordable fashion.

CMS-4068-P-633

Submitter : Mr. George Amann **Date & Time:** 10/01/2004 04:10:15

Organization : Kankakee Association for the Mentally Retarded

Category : Other Association

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Comments relating to Medicare Part D proposed regulations-69 Fed. Reg. 46632 (August 3,2004): I support the comments submitted by Voice of the Retarded(VOR). * The definition of "long term care facility" must include Intermediate Care Facilities for Persons with Mental Retardation (ICF/MR). As a parent of a mentally retarded son who resides in an ICF/MR, it is crucial to his survival that the regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives. * "Institutionalized" should include all individuals eligible for ICF/MR placement, including current residents, home and community based services waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements. Let's stop going after the most vulnerable population. CMS can do much better.

Thank you for your consideration.

Respectfully submitted,

George Amann
President, Kankakee Association for the Mentally Retarded
5901 Willow Court
Crystal Lake, Illinois 60014
Phone: 815-455-5213
E-mail: georgea1@msn.com

CMS-4068-P-634

Submitter : Miss. Chris Visalli **Date & Time:** 10/01/2004 04:10:08

Organization : Miss. Chris Visalli

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

I am writing to provide comments on the proposed rule ?Medicare Program; Medicare Prescription Drug Benefit, ?69 FR 46632. I am concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. I am especially concerned with the 7 million dual eligible that will lose all Medicaid prescription drug benefits they now have.

Dual eligible (Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes that the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicaid beneficiaries.

Please delay the implementation of the Part D program until its impact on TWWIIA (Ticket to Work/Work Incentives Improvement Act), PASS (Plan for Achieving Self Support), and other Social Security work incentives is determined.

Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need. Thank you for your consideration of my views.

CMS-4068-P-635

Submitter : Mr. W.J. Francis **Date & Time:** 10/01/2004 04:10:15

Organization : Public Policy Network

Category : Individual

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Subpart K?Application Procedures and Contracts with PDP Sponsor
Comment on the proposed rule for establishment of the Medicare Prescription Drug Benefit
October 1, 2004

Dear Sirs:

This comment applies to proposed section 423.505(h), ?Requirements of other laws and regulations,? and also to sections 423.504(b) and (c). I propose that the former section be removed in its entirety and that these others be removed or significantly modified. I am sending a similar comment on the parallel sections in the Medicare Advantage (MA) regulation. The actual comment is attached as a Word file.

CMS-4068-P-635-Attach-1.doc

CMS-4068-P-635-Attach-2.doc

Subpart K—Application Procedures and Contracts with PDP Sponsors
Comment on the proposed rule for establishment of the Medicare Prescription Drug Benefit
October 1, 2004

Dear Sirs:

This comment applies to proposed section 423.505(h), "Requirements of other laws and regulations," and also to sections 423.504(b) and (c). I propose that the former section be removed in its entirety and that these others be removed or significantly modified. I am sending a similar comment on the parallel sections in the Medicare Advantage (MA) regulation.

1. In your proposed rule on Prescription Drug Plans (PDPs), you incorporate verbatim a section from the Medicare Advantage regulation that would require PDPs to comply with "all Federal, State, and local laws and regulations" (your preamble language explaining the proposed 422.505(h)), which in its subsection (7) requires compliance with "all other applicable laws and regulations." On its face, this requirement would add an additional enforcement sanction to potential violations of thousands of Federal laws and regulations. These would include the DOJ and FTC antitrust rules, DOL minimum wage rules, IRS tax enforcement, NLRB labor relations requirements, OSHA safety requirements, SEC securities laws, FEC campaign finance laws, EPA environmental rules, government-wide debarment regulations, EEOC and DOJ civil rights rules, and innumerable others. Likewise, state and local governments enforce thousands of laws and regulations, including zoning laws, gun control laws, tax laws, traffic laws, and a host of others.

The origin of this "any law" requirement lies in language that then-HCFA regulations drafters routinely included in Conditions of Participation (CoP) regulations two and three decades ago. During the 1990s, and since then, these provisions have been removed piecemeal as CoP regulations were revised, by agreement of CMS drafters and OS regulations reviewers. Today, few if any remain.

The bloated interim final Medicare+Choice regulation issued in 1998 did not receive the normal intensity of scrutiny applied previously and subsequently to HCFA regulations, and included among its many gratuitous requirements this "any law" provision carried over into the proposed MA and PDP regulations. (So poorly drafted was that regulation that within a year an amended rule was issued to remove requirements that HCFA admitted were impossible for any health plans to meet.) The provision was not explained or defended in the preamble, and health plans commenting on the regulation did not realize its implications.

This provision has a halo feel. Who could object to a provision simply stating the obvious fact that companies are expected to obey all laws? But in fact it is a radical provision. It presumes that CMS has the expertise and resources to review company compliance with statutes for which CMS has no statutory responsibility or expert competence. It further presumes that CMS has some form of Solomonic wisdom and may exact an additional

penalty (loss of a PDP contract) if in CMS's subjective judgment the company has not paid a high enough penalty under some other law or fails to comply with some other law. And it presumes that CMS has competence and legal authority to impose this penalty even though another Federal or State agency was assigned exclusive authority to administer that law, to determine compliance under that law, and to determine applicable penalties. In cases where the company remains in alleged noncompliance after an initial adverse finding by another agency, under appeal by the company, it assumes that CMS should be allowed to intervene in the middle of a case under the stewardship of another agency and exact a draconian penalty before all other legal procedural avenues are exhausted.

No coherent reason, let alone evidence, has ever been advanced (and no reason is advanced in this preamble other than that of "copy catting" the MA regulations) why any Federal agency, under any program, should ever have such powers to unilaterally impose its subjective notions of justices for its own interpretations of alleged or adjudicated violations of other laws. Nor has any Medicare-specific reason ever been advanced as to why only Medicare's MA and PDP programs (not even other Medicare programs) need this power, alone among the entire panoply of thousands of Federal programs issuing grants and contracts that choose not to impose such a requirement. Certainly the other major Federal health insurance programs that contract with health plans, including FEHBP and TriCare, have never felt the need to impose such a requirement.

On its face, this provision violates the legal obligation on CMS, imposed by EO 12866, to "promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need."

Proposing to retain this provision also violates settled Administration policy. In 2001 the Bush Administration identified as a candidate for repeal, and subsequently repealed (FR pages 66984-86, December 27, 2001), the so-called "blacklisting rule" under which all Federal contractors were required to comply with any applicable law or lose eligibility for future contracts. The stated reasons for repeal included some of those above, e.g. lack of contracting officials' competence to deal with laws administered by other agencies. In addition, the unstated reason for repeal was the very issue that prompted virulent opposition from Federal contractors: the "blank check" given to contracting officials to use their own subjective judgment in determining whether companies were in satisfactory compliance with tax, labor, employment, environmental, antitrust, etc. laws, and to "blacklist" companies they unilaterally determined to warrant additional penalties.

By conflicting with government-wide contracting policy and other insurance agencies' policy, this provision also violates the EO 12866 directive that "each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies, " and is potentially a significant regulatory action by virtue of creating "a serious inconsistency … with an action taken or planned by another agency."

For the same reasons that this provision should be eliminated, and for additional reasons discussed below, the requirement that PDP organizations commit themselves and have a compliance plan "to comply with all applicable Federal and State standards" (section 423.504(b)(6)(A)) should also be deleted.

2. Subsection (6) of this section would require PDP plans to comply with "other laws applicable to *recipients of Federal funds*" (emphasis added). Doesn't that include every recipient under every Federal and State law? This provision is unclear in intent, but appears to be subject to all the debilities above. In addition, it essentially duplicates the proposed provision that PDP organizations commit themselves and have a compliance plan "to comply with all applicable Federal and State standards" (section 423.504(b)(6)(A)). It also appears to contradict the regulatory provision, itself unclear, that "CMS may enter into contracts under this part … without regard to Federal and Departmental acquisition regulations" (423.504(c)).

Most fundamentally, it conflates two entirely separate bodies of regulations. Under longstanding legal and practical distinctions, the Federal government, HHS, and CMS distinguish between Federal rules applied to "grantees" and "contractors." A huge *corpus* of statutes and rules apply to contractors (for example, the Federal Acquisition Regulations, or FAR), and another huge and distinct *corpus* applies to grantees. This proposed provision would lump the two sets of laws and rules together under the rubric of "recipients of Federal funds." There is no legal or policy justification for subjecting PDPs to Federal grant rules. PDPs will be Federal contractors, and the FAR rules encompass the relevant universe of potential applicability under the rubric of receipt of funds.

Astoundingly, these two requirements in effect impose the entire panoply of FAR requirements on PDP plans. But Section 1857(c) of Title 18 of the SSA gives CMS explicit authority to waive the applicability of all FAR rules to PDP and MA contractors. And the proposed rule seems to say in yet another unexplained and confusing provision (423.504(c)) that nothing in the FAR will apply to PDP plans, but that the FAR will apply only to fallback plans. Nothing in the preamble indicates what CMS intends, or why. The explanation, of course, is simple. CMS copied and updated longstanding and mindless M+C regulatory language without considering its implications. CMS surely does not want all FAR rules to apply to PDP plans.

What is even worse, the proposed regulation requires "written policies, procedures, and standards of conduct articulating the organization's commitment to comply with *all* applicable Federal and State standards" (423.504(b)(vi)) (emphasis added). This clearly implies that PDPs identify each of the tens of thousands of applicable statutes and regulations and write a compliance procedure dealing with each. How else would plans even know what standards apply? Nothing in the Regulatory Analysis or Paperwork Reduction Act analysis even hints at the potential costs involved. A serious effort to comply would cost millions of dollars for each participating plan. This provision alone would create an economically "significant" rule. And nothing in this provision meets EO

12866 standards. Surely CMS has intended no such result, a consequence of careless drafting rather than policy intent.

The policy conclusion is simple. HHS should eliminate all of this expansive language. None of it serves any demonstrable purpose, or meets any demonstrated need. It all violates EO 12866 standards, and the stated goals of the CMS Administrator.

I have two additional suggestions. First, since HHS has the authority to selectively determine which FAR standards apply, HHS should add one simple requirement to replace the existing proposals. HHS should not allow firms to participate that have been debarred under the FAR standards. Debarment is a simple and clear standard that will prevent fraudulent firms from obtaining PDP contracts. It is inexcusable for HHS to have left this loophole while imposing mindlessly expansive and empty standards.

Second, a simple fix will eliminate 99 percent of the ambiguity and cost of the provision on "written policies, procedures, and standards," while focusing it on the only demonstrably important concern central to the administration of Medicare. CMS should limit 423.504(b)(4)(vi) to compliance with "Federal standards aimed at preventing or ameliorating waste, fraud, and abuse." This change will not only eliminate excessive requirements of no real world relevance, but also focus plan efforts where they belong: on prevention of fraud and abuse.

3. Sections 423.505(h)(1) through (5) would require PDPs to comply with five specifically named Federal laws. Nothing in the preamble indicates any conceivable reason why these five laws, out of thousands, should be emphasized by specific naming. As written, these provisions are on their face entirely duplicative of the "any law" standard discussed above. On that ground alone, these provisions should be eliminated along with the "any law" standard, simply as a matter of parsimony in drafting.

These five laws include four civil rights statutes and the HIPAA Administrative simplification rules. Nothing in the administrative record regarding Federal health insurance contractors suggests that these laws should have been singled out as of particular concern from among the thousands of applicable Federal statutes. The HIPAA reference is justified under the rationale that "we have updated the list." Pardon me, but the list omits 99.9 percent of all applicable laws and regulations. And elsewhere in this proposed rule HIPAA requirements are discussed extensively. Under the Administrative Procedure Act, and normal regulatory drafting practice, nothing requires that regulations list, or "update," the myriad other laws and regulations that apply to contracting firms. This is an entirely gratuitous and unnecessary provision.

The same argument applies to the listing of the Americans with Disabilities Act. This statute applies to employers of 15 or more persons and providers of public accommodations in interstate commerce. It no doubt applies to PDPs. Nothing in the ADA or routine Federal regulatory procedures requires that CMS list the ADA in this NPRM as one of the myriad laws applying to PDPs. This is also an entirely unnecessary provision (unless, unknown to me, there is an issue of coverage as described below).

The remaining three laws are all civil rights statutes that apply, in their own terms, to "recipients of Federal financial assistance." Nothing in the preamble indicates why they are listed, and potential PDP sponsors and health care providers have no reason to suspect a deceit, but that is indeed what is going on, perhaps unknown to the drafters and reviewers of this provision. To only slightly oversimplify, all Federal civil rights statutes apply either to firms operating in interstate commerce, to the Federal government itself, or to Federal grantees and other recipients of Federal subsidies. Nothing in standard delegation and governance procedures requires or even encourages individual regulations to name other regulations that may apply to Federal contractors. Why then, are these statutes specifically named?

None of the three cited statutes, title VI of the Civil Rights Act of 1964, the Age Discrimination Act, and section 504 of the Rehabilitation Act applies on its face to Federal contractors. Under Federal administrative law, Federal contractors are never or almost never recipients of "assistance;" rather, they carry out Federal functions on a contractual basis that does not include any purpose or intent to provide "financial assistance" to the contractor. In sharp contrast, Federal grantees, who are given funds with an assistance purpose (and likewise recipients of Federally subsidized loans) are recipients of "assistance." For example, States receiving Medicaid funds, and universities receiving NIH research grants, are recipients of "assistance." However, nothing in the MMA indicates any purpose to provide PDP plans Federal financial assistance. They are subject to civil rights and other laws that apply to interstate commerce and to Federal contractors, but not to laws applicable only to Federal grantees and other recipients of "assistance." Accordingly, the three referenced statutes are among the subset of Federal laws that most clearly do **NOT** apply to PDPs. I do not believe that there exists today a single legal memorandum arguing that the MMA or predecessor program creates a program of financial "assistance." Absent any such justification, and its presentation to the public in an NPRM requesting comment, the proposed expansion of these statutes to entities that were never contemplated as subject to them, would be a badly flawed rulemaking.

In this context, the issue takes on a serious interagency dimension. Any line of reasoning that PDP contractors are receiving "assistance" is likely to be a line of reasoning that would apply to all or most Federal contracts. That would be a radical change in interpretation of these civil rights law, one with government-wide implications and potentially very substantial costs. (In this regard it is important to note that most hospitals, physicians, and pharmacies are already subject to these statutes as subrecipients of Medicaid funds. But the vast majority of Federal contractors are not grantee subrecipients and would face an entirely new panoply of requirements and costs.)

It is possible that some in HHS may have a different view. If so, you still have a simple alternative in accommodating these comments without lengthy debate that might delay the final rule. Explain the legal issue as to "assistance" in the final rule preamble, eliminate the proposed regulatory language from the final rule, and explain that you will at a later time consider issuing a proposed rule dealing specifically, and in detail, with the

possible applicability of these and other laws to PDPs (the three named statutes are not the only ones that hinge on the term “financial assistance”). In that proposed rule, should it ever be issued, present a Regulatory Impact Analysis laying out estimated compliance costs, and alternatives. In that NPRM include written opinions from the civil rights and administrative law components of the Justice Department and other affected agencies (e.g., OPM and the Federal Acquisition Regulatory Council). But do not place these requirements in regulation without a candid and complete APA rulemaking presenting the issues squarely and fairly, or without an analysis complying with EO 12866.

4. The preceding comments are complex. But you have a truly simple expedient. You need only delete proposed section 423.504(h) in its entirety (and make the accompanying changes discussed above), explaining in a preamble paragraph or two that the proposal presents unforeseen problems, is not necessary to implement Title I, and that any remaining issues will be attended to in the future if necessary. You can take this simple step even if you do not agree with all of the specific arguments made above, and without creating a lengthy and complex analysis of your own.

Some might argue that in practice these provisions have caused little or not problem or burden in the M+C, because they have been unused or unenforced. That argument leads to an inexorable conclusion under EO 12866: eliminate unused and unenforced provisions as obviously unnecessary.

To implement this “just say no” policy decision, you need not wait until the final stages of regulatory clearance or even resolve any legal questions. Inclusion of the regulatory language I criticize in these comments was never required by law, but a voluntary policy decision. The language can be removed on the same basis it was included: by policy fiat. Instead, you should explain your intention of accepting these comments to relevant HHS components (Inspector General, Planning and Evaluation, Administrative Law Division, and Civil Rights) and OMB. You should tell OMB that if it wishes to subject these changes to interagency review it should do so immediately (in October), and require any dissenting view to be presented in October. No last minute vetoes by HHS components or other agencies should be allowed. In other words, these burdensome and unnecessary regulatory provisions should be disposed of immediately, so that serious work on the many substantive issues can proceed and the MMA regulations can be issued timely at the end of December or early January.

I have sent a copy of this comment to OMB, because of the serious regulatory policy and burden issues that it raises. I recommend that OMB take steps to assure that any interagency policy issues not be allowed to delay promulgation of the final rule.

Sincerely, W.J. Francis
Public Policy Network
703-278-0041

Subpart K—Application Procedures and Contracts with PDP Sponsors
Comment on the proposed rule for establishment of the Medicare Prescription Drug Benefit
October 1, 2004

Dear Sirs:

This comment applies to proposed section 423.505(h), "Requirements of other laws and regulations," and also to sections 423.504(b) and (c). I propose that the former section be removed in its entirety and that these others be removed or significantly modified. I am sending a similar comment on the parallel sections in the Medicare Advantage (MA) regulation.

1. In your proposed rule on Prescription Drug Plans (PDPs), you incorporate verbatim a section from the Medicare Advantage regulation that would require PDPs to comply with "all Federal, State, and local laws and regulations" (your preamble language explaining the proposed 422.505(h)), which in its subsection (7) requires compliance with "all other applicable laws and regulations." On its face, this requirement would add an additional enforcement sanction to potential violations of thousands of Federal laws and regulations. These would include the DOJ and FTC antitrust rules, DOL minimum wage rules, IRS tax enforcement, NLRB labor relations requirements, OSHA safety requirements, SEC securities laws, FEC campaign finance laws, EPA environmental rules, government-wide debarment regulations, EEOC and DOJ civil rights rules, and innumerable others. Likewise, state and local governments enforce thousands of laws and regulations, including zoning laws, gun control laws, tax laws, traffic laws, and a host of others.

The origin of this "any law" requirement lies in language that then-HCFA regulations drafters routinely included in Conditions of Participation (CoP) regulations two and three decades ago. During the 1990s, and since then, these provisions have been removed piecemeal as CoP regulations were revised, by agreement of CMS drafters and OS regulations reviewers. Today, few if any remain.

The bloated interim final Medicare+Choice regulation issued in 1998 did not receive the normal intensity of scrutiny applied previously and subsequently to HCFA regulations, and included among its many gratuitous requirements this "any law" provision carried over into the proposed MA and PDP regulations. (So poorly drafted was that regulation that within a year an amended rule was issued to remove requirements that HCFA admitted were impossible for any health plans to meet.) The provision was not explained or defended in the preamble, and health plans commenting on the regulation did not realize its implications.

This provision has a halo feel. Who could object to a provision simply stating the obvious fact that companies are expected to obey all laws? But in fact it is a radical provision. It presumes that CMS has the expertise and resources to review company compliance with statutes for which CMS has no statutory responsibility or expert competence. It further presumes that CMS has some form of Solomonic wisdom and may exact an additional

penalty (loss of a PDP contract) if in CMS's subjective judgment the company has not paid a high enough penalty under some other law or fails to comply with some other law. And it presumes that CMS has competence and legal authority to impose this penalty even though another Federal or State agency was assigned exclusive authority to administer that law, to determine compliance under that law, and to determine applicable penalties. In cases where the company remains in alleged noncompliance after an initial adverse finding by another agency, under appeal by the company, it assumes that CMS should be allowed to intervene in the middle of a case under the stewardship of another agency and exact a draconian penalty before all other legal procedural avenues are exhausted.

No coherent reason, let alone evidence, has ever been advanced (and no reason is advanced in this preamble other than that of "copy catting" the MA regulations) why any Federal agency, under any program, should ever have such powers to unilaterally impose its subjective notions of justices for its own interpretations of alleged or adjudicated violations of other laws. Nor has any Medicare-specific reason ever been advanced as to why only Medicare's MA and PDP programs (not even other Medicare programs) need this power, alone among the entire panoply of thousands of Federal programs issuing grants and contracts that choose not to impose such a requirement. Certainly the other major Federal health insurance programs that contract with health plans, including FEHBP and TriCare, have never felt the need to impose such a requirement.

On its face, this provision violates the legal obligation on CMS, imposed by EO 12866, to "promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need."

Proposing to retain this provision also violates settled Administration policy. In 2001 the Bush Administration identified as a candidate for repeal, and subsequently repealed (FR pages 66984-86, December 27, 2001), the so-called "blacklisting rule" under which all Federal contractors were required to comply with any applicable law or lose eligibility for future contracts. The stated reasons for repeal included some of those above, e.g. lack of contracting officials' competence to deal with laws administered by other agencies. In addition, the unstated reason for repeal was the very issue that prompted virulent opposition from Federal contractors: the "blank check" given to contracting officials to use their own subjective judgment in determining whether companies were in satisfactory compliance with tax, labor, employment, environmental, antitrust, etc. laws, and to "blacklist" companies they unilaterally determined to warrant additional penalties.

By conflicting with government-wide contracting policy and other insurance agencies' policy, this provision also violates the EO 12866 directive that "each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies, " and is potentially a significant regulatory action by virtue of creating "a serious inconsistency … with an action taken or planned by another agency."

For the same reasons that this provision should be eliminated, and for additional reasons discussed below, the requirement that PDP organizations commit themselves and have a compliance plan "to comply with all applicable Federal and State standards" (section 423.504(b)(6)(A)) should also be deleted.

2. Subsection (6) of this section would require PDP plans to comply with "other laws applicable to *recipients of Federal funds*" (emphasis added). Doesn't that include every recipient under every Federal and State law? This provision is unclear in intent, but appears to be subject to all the debilities above. In addition, it essentially duplicates the proposed provision that PDP organizations commit themselves and have a compliance plan "to comply with all applicable Federal and State standards" (section 423.504(b)(6)(A)). It also appears to contradict the regulatory provision, itself unclear, that "CMS may enter into contracts under this part … without regard to Federal and Departmental acquisition regulations" (423.504(c)).

Most fundamentally, it conflates two entirely separate bodies of regulations. Under longstanding legal and practical distinctions, the Federal government, HHS, and CMS distinguish between Federal rules applied to "grantees" and "contractors." A huge *corpus* of statutes and rules apply to contractors (for example, the Federal Acquisition Regulations, or FAR), and another huge and distinct *corpus* applies to grantees. This proposed provision would lump the two sets of laws and rules together under the rubric of "recipients of Federal funds." There is no legal or policy justification for subjecting PDPs to Federal grant rules. PDPs will be Federal contractors, and the FAR rules encompass the relevant universe of potential applicability under the rubric of receipt of funds.

Astoundingly, these two requirements in effect impose the entire panoply of FAR requirements on PDP plans. But Section 1857(c) of Title 18 of the SSA gives CMS explicit authority to waive the applicability of all FAR rules to PDP and MA contractors. And the proposed rule seems to say in yet another unexplained and confusing provision (423.504(c)) that nothing in the FAR will apply to PDP plans, but that the FAR will apply only to fallback plans. Nothing in the preamble indicates what CMS intends, or why. The explanation, of course, is simple. CMS copied and updated longstanding and mindless M+C regulatory language without considering its implications. CMS surely does not want all FAR rules to apply to PDP plans.

What is even worse, the proposed regulation requires "written policies, procedures, and standards of conduct articulating the organization's commitment to comply with *all* applicable Federal and State standards" (423.504(b)(vi)) (emphasis added). This clearly implies that PDPs identify each of the tens of thousands of applicable statutes and regulations and write a compliance procedure dealing with each. How else would plans even know what standards apply? Nothing in the Regulatory Analysis or Paperwork Reduction Act analysis even hints at the potential costs involved. A serious effort to comply would cost millions of dollars for each participating plan. This provision alone would create an economically "significant" rule. And nothing in this provision meets EO

12866 standards. Surely CMS has intended no such result, a consequence of careless drafting rather than policy intent.

The policy conclusion is simple. HHS should eliminate all of this expansive language. None of it serves any demonstrable purpose, or meets any demonstrated need. It all violates EO 12866 standards, and the stated goals of the CMS Administrator.

I have two additional suggestions. First, since HHS has the authority to selectively determine which FAR standards apply, HHS should add one simple requirement to replace the existing proposals. HHS should not allow firms to participate that have been debarred under the FAR standards. Debarment is a simple and clear standard that will prevent fraudulent firms from obtaining PDP contracts. It is inexcusable for HHS to have left this loophole while imposing mindlessly expansive and empty standards.

Second, a simple fix will eliminate 99 percent of the ambiguity and cost of the provision on "written policies, procedures, and standards," while focusing it on the only demonstrably important concern central to the administration of Medicare. CMS should limit 423.504(b)(4)(vi) to compliance with "Federal standards aimed at preventing or ameliorating waste, fraud, and abuse." This change will not only eliminate excessive requirements of no real world relevance, but also focus plan efforts where they belong: on prevention of fraud and abuse.

3. Sections 423.505(h)(1) through (5) would require PDPs to comply with five specifically named Federal laws. Nothing in the preamble indicates any conceivable reason why these five laws, out of thousands, should be emphasized by specific naming. As written, these provisions are on their face entirely duplicative of the "any law" standard discussed above. On that ground alone, these provisions should be eliminated along with the "any law" standard, simply as a matter of parsimony in drafting.

These five laws include four civil rights statutes and the HIPAA Administrative simplification rules. Nothing in the administrative record regarding Federal health insurance contractors suggests that these laws should have been singled out as of particular concern from among the thousands of applicable Federal statutes. The HIPAA reference is justified under the rationale that "we have updated the list." Pardon me, but the list omits 99.9 percent of all applicable laws and regulations. And elsewhere in this proposed rule HIPAA requirements are discussed extensively. Under the Administrative Procedure Act, and normal regulatory drafting practice, nothing requires that regulations list, or "update," the myriad other laws and regulations that apply to contracting firms. This is an entirely gratuitous and unnecessary provision.

The same argument applies to the listing of the Americans with Disabilities Act. This statute applies to employers of 15 or more persons and providers of public accommodations in interstate commerce. It no doubt applies to PDPs. Nothing in the ADA or routine Federal regulatory procedures requires that CMS list the ADA in this NPRM as one of the myriad laws applying to PDPs. This is also an entirely unnecessary provision (unless, unknown to me, there is an issue of coverage as described below).

The remaining three laws are all civil rights statutes that apply, in their own terms, to "recipients of Federal financial assistance." Nothing in the preamble indicates why they are listed, and potential PDP sponsors and health care providers have no reason to suspect a deceit, but that is indeed what is going on, perhaps unknown to the drafters and reviewers of this provision. To only slightly oversimplify, all Federal civil rights statutes apply either to firms operating in interstate commerce, to the Federal government itself, or to Federal grantees and other recipients of Federal subsidies. Nothing in standard delegation and governance procedures requires or even encourages individual regulations to name other regulations that may apply to Federal contractors. Why then, are these statutes specifically named?

None of the three cited statutes, title VI of the Civil Rights Act of 1964, the Age Discrimination Act, and section 504 of the Rehabilitation Act applies on its face to Federal contractors. Under Federal administrative law, Federal contractors are never or almost never recipients of "assistance;" rather, they carry out Federal functions on a contractual basis that does not include any purpose or intent to provide "financial assistance" to the contractor. In sharp contrast, Federal grantees, who are given funds with an assistance purpose (and likewise recipients of Federally subsidized loans) are recipients of "assistance." For example, States receiving Medicaid funds, and universities receiving NIH research grants, are recipients of "assistance." However, nothing in the MMA indicates any purpose to provide PDP plans Federal financial assistance. They are subject to civil rights and other laws that apply to interstate commerce and to Federal contractors, but not to laws applicable only to Federal grantees and other recipients of "assistance." Accordingly, the three referenced statutes are among the subset of Federal laws that most clearly do **NOT** apply to PDPs. I do not believe that there exists today a single legal memorandum arguing that the MMA or predecessor program creates a program of financial "assistance." Absent any such justification, and its presentation to the public in an NPRM requesting comment, the proposed expansion of these statutes to entities that were never contemplated as subject to them, would be a badly flawed rulemaking.

In this context, the issue takes on a serious interagency dimension. Any line of reasoning that PDP contractors are receiving "assistance" is likely to be a line of reasoning that would apply to all or most Federal contracts. That would be a radical change in interpretation of these civil rights law, one with government-wide implications and potentially very substantial costs. (In this regard it is important to note that most hospitals, physicians, and pharmacies are already subject to these statutes as subrecipients of Medicaid funds. But the vast majority of Federal contractors are not grantee subrecipients and would face an entirely new panoply of requirements and costs.)

It is possible that some in HHS may have a different view. If so, you still have a simple alternative in accommodating these comments without lengthy debate that might delay the final rule. Explain the legal issue as to "assistance" in the final rule preamble, eliminate the proposed regulatory language from the final rule, and explain that you will at a later time consider issuing a proposed rule dealing specifically, and in detail, with the

possible applicability of these and other laws to PDPs (the three named statutes are not the only ones that hinge on the term “financial assistance”). In that proposed rule, should it ever be issued, present a Regulatory Impact Analysis laying out estimated compliance costs, and alternatives. In that NPRM include written opinions from the civil rights and administrative law components of the Justice Department and other affected agencies (e.g., OPM and the Federal Acquisition Regulatory Council). But do not place these requirements in regulation without a candid and complete APA rulemaking presenting the issues squarely and fairly, or without an analysis complying with EO 12866.

4. The preceding comments are complex. But you have a truly simple expedient. You need only delete proposed section 423.504(h) in its entirety (and make the accompanying changes discussed above), explaining in a preamble paragraph or two that the proposal presents unforeseen problems, is not necessary to implement Title I, and that any remaining issues will be attended to in the future if necessary. You can take this simple step even if you do not agree with all of the specific arguments made above, and without creating a lengthy and complex analysis of your own.

Some might argue that in practice these provisions have caused little or not problem or burden in the M+C, because they have been unused or unenforced. That argument leads to an inexorable conclusion under EO 12866: eliminate unused and unenforced provisions as obviously unnecessary.

To implement this “just say no” policy decision, you need not wait until the final stages of regulatory clearance or even resolve any legal questions. Inclusion of the regulatory language I criticize in these comments was never required by law, but a voluntary policy decision. The language can be removed on the same basis it was included: by policy fiat. Instead, you should explain your intention of accepting these comments to relevant HHS components (Inspector General, Planning and Evaluation, Administrative Law Division, and Civil Rights) and OMB. You should tell OMB that if it wishes to subject these changes to interagency review it should do so immediately (in October), and require any dissenting view to be presented in October. No last minute vetoes by HHS components or other agencies should be allowed. In other words, these burdensome and unnecessary regulatory provisions should be disposed of immediately, so that serious work on the many substantive issues can proceed and the MMA regulations can be issued timely at the end of December or early January.

I have sent a copy of this comment to OMB, because of the serious regulatory policy and burden issues that it raises. I recommend that OMB take steps to assure that any interagency policy issues not be allowed to delay promulgation of the final rule.

Sincerely, W.J. Francis
Public Policy Network
703-278-0041

CMS-4068-P-636

Submitter : Mrs. Virginia Florio **Date & Time:** 10/01/2004 04:10:30

Organization : Independent Living, Inc.

Category : Other

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

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

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

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years. Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Thank you for your consideration of my views.

Yours sincerely,
Virgnia M. Florio

Submitter : Mr. Russell Yandon **Date & Time:** 10/01/2004 04:10:43

Organization : University Hospital Syracuse

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The program should include patient assessment by the pharmacist, medication review to identify allergies, drug interactions, preventable adverse drug events, formulating a medication treatment plan, selecting, initiating, modifying medication, evaluating patient response to medication therapy, patient counseling, education, and training, coordination and integration of MTMS in the overall patient treatment plan to achieve the best possible patient outcome. Structure services on chronic diseases where patients would be most likely to benefit from the pharmacist intervention.

CMS-4068-P-638

Submitter : Ms. Cynthia Leonard **Date & Time:** 10/01/2004 05:10:04

Organization : Ms. Cynthia Leonard

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

RE: Comments relating to Medicare Part D proposed regulations - 69 Fed. Reg. 46632 (August 3, 2004).

I support the comments submitted by Voice of the Retarded, and feel strongly that:

1. The definition of "long term care facility" must include Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR).
2. "Institutionalized" should include all individuals eligible for ICF/MR placement, including current residents, home and community-based services (HCBS)waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

The regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives.

Thank you for your consideration.

Sincerely,

Cynthia M. Leonard,
Legal Guardian for Nancy Sue Leonard
3 Camino Costadino
Santa Fe, NM 87508
505-466-3667

CMS-4068-P-639

Submitter : Dr. Daniel Churchill **Date & Time:** 10/01/2004 05:10:31

Organization : Gateway Pharmacy Inc.

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

It is imperative that policy makers understand that Medication Therapy Management is best handled by a patient's primary pharmacist because no other provider has more direct and frequent contact with the patient. The pharmacist has the unique access to the patient's medication usage and compliance history and the expertise to aid in the interpretation and resolution of medication issues. This is extremely important in the Medicare population because of the numerous concerns faced by the elderly with regard to medication issues. Multiple medications and medical conditions, as well as communication and interpretation barriers faced by these patients, add to the complexity of treatment compliance in the elderly population. By allowing a patient's primary pharmacist to deal face-to-face with the patient on medication therapy management issues costly adverse events can be minimized and optimum therapy can be achieved.

Submitter : Mr. Robert Reynolds **Date & Time:** 10/01/2004 05:10:20

Organization : Mr. Robert Reynolds

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

This proposal will lead to the distruction of the trusted community pharmacy as people know it today, especially in the smaller communities across the U.S.. The proposal is pushing the idea of mail order in place of being able to get the guidance of their trusted local pharmacist. People depend upon their local pharmacy not only for the one time prescription, but the ongoing precriptions. People should have a choice in how their prescriptions will be filled. If all Medicare prescriptions become part of a mail order system, it will take away returning business the small community pharmacist depends upon and could jeopardize their ability to stay in business and remains a key player in the community.

Submitter : Mrs. Aileen Martin **Date & Time:** 10/01/2004 05:10:09

Organization : Mrs. Aileen Martin

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Aileen Martin
36788 NYS Route 12E
Clayton, New York 13624

September 30, 2004

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

To Whom It May Concern:

Thank you for this opportunity to comment on the proposed rule ?Medicare Program: Medicare Prescription Drug Benefit?, 69 FR 46632. I am very concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. I am especially concerned about the 7 million people who are dual eligible for Medicare and Medicaid and will lose all Medicaid prescription drug benefits.

I recommend not implementing the Part D program for people who are ?dual eligible?. People who are eligible for both Medicare and Medicaid have more extensive needs and lower incomes than the rest of the Medicare enrollees. Low-income Medicare beneficiaries tend to be sicker and to use more prescription drugs than the average; as a result, they will be disproportionately hurt by a gap in coverage. We rely on prescription drug coverage to maintain basic health needs. I am very concerned that these 7,000,000 people with disabilities on the Part D program will have their present coverage destroyed, resulting in poorer health and will necessitate admission to skilled nursing facilities on a more frequent basis to get necessary medications that will become unaffordable in the community. This regulation therefore will fly in the face of the Supreme Court?s 1999 decision in Olmstead v. E.C. and L.W. as well as the New Freedom Initiative supported by CMS.

I recommend delaying the implementation of the Part D program until its impacts on the Ticket to Work and Work Incentives Improvement Act, Social Security Administration?s Plan for Achieving Self Support and other work incentives is more fully explored. Advocates and the Social Security Administration have worked very hard to remove disincentives to work for beneficiaries. With today?s technology, almost anyone can work. The Americans with Disabilities Act addresses discrimination. So why do so many Americans with disabilities not work? The most common reason people do not return to work once they?ve acquired a disability is the loss of essential health care. As it is proposed, the Part D program will re-introduce disincentives to work and once more, millions of Americans will stay home to stay poor in order to get the medicine they need. This is not a wise course of action in a country that so needs a qualified work force.

My recommendations may need legislation to implement but I?m sure I?m not the only person making similar recommendations. I hope that you will support such legislation in the current congressional session.

Thank you for your time and consideration.

Yours for a barrier free society,

Aileen Martin

Cc: Congressman John McHugh
Senator Hillary Rodham Clinton
Senator Charles Schumer

CMS-4068-P-642

Submitter : Ms. Kathryn Weit **Date & Time:** 10/01/2004 05:10:09

Organization : Oregon Developmental Disabilities Coalition

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-642-Attach-1.doc

Developmental
Disabilities
Coalition 540 24th Place NE, Salem, OR 97301, Ph. 503-945-9941,FAX 503-945-9947, Email coalitions@ocdd.org

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

September 29, 2004

To Whom It May Concern:

Speaking for advocates and providers for people with developmental disabilities throughout Oregon, the Developmental Disabilities Coalition of Oregon welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632.

DD Coalition members represent the entire developmental disability community, including self-advocates, advocates, families, advocacy organizations (e.g. Arc, DD Council), brokerages and providers who deliver residential and vocational supports and services to individuals with developmental and other disabilities, most of whom are Medicare beneficiaries who also have Medicaid coverage.

We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 36 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and

the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Funded collaborative partnerships with organizations representing people with disabilities is critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

- people who are dually eligible for Medicare and Medicaid

- people who live in nursing homes, ICF-MRs and other residential facilities,

- people who have life threatening conditions

- people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

Impose new limits on cost management tools:

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

Require plans to dispense a temporary supply of drugs in emergencies:

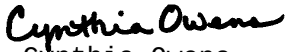
The proposed system does not ensure that beneficiaries' rights are protected and does not guarantee beneficiaries have access to needed medications. For many individuals with disabilities such as epilepsy, mental illness or HIV, treatment interruptions can lead to serious short-term and long-term

problems. For this reasons the final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

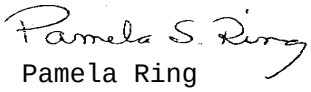
Thank you for your consideration of our views.

Sincerely,

Bill Lynch
OR Council on DD



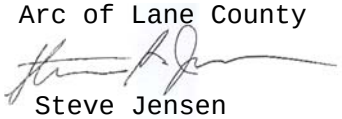
Cynthia Owens
Parent



Pamela Ring
Arc of Lane County

Tim Kral
OR Rehab. Association

Tom Giles
Parent



Steve Jensen
Dungarven Oregon
Community Providers
Association of Oregon

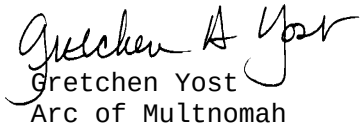
Bob Joondeph
OR Advocacy Center

Francisco Lopez
Integrated Services Network

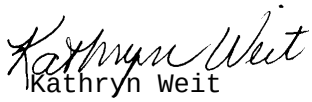
Marcie Ingledue
Arc of Oregon

Margaret Theisen
Full Access Brokerage

Al Sonnecker
Riverside Training Center

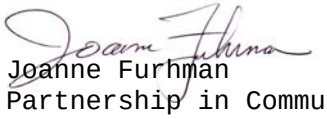


Gretchen Yost
Arc of Multnomah



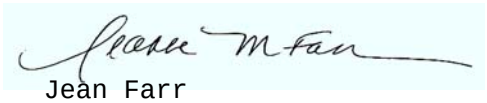
Kathryn Weit
DD Coalition

Vickie Harbough
Sunny Oaks Inc.



Joanne Furhman
Partnership in Community Living

Dan Peccia
Self-Determination Resources, Inc



Jean Farr
Albertina Kerr Center

CMS-4068-P-643

Submitter : Mrs. Maureen Walsh **Date & Time:** 10/01/2004 05:10:58

Organization : Devereux NJ Treatment Network

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-4068-P-643-Attach-1.doc

October 1, 2004

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

To Whom It May Concern:

The Devereux NJ Treatment Network welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Devereux NJ Treatment Network is a not for profit organization that provides services to over 150 individuals with developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate,

and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual

and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Sincerely,

Maureen F. Walsh
Executive Director
Devereux NJ Treatment Network

CMS-4068-P-644

Submitter : Mr. Kevin Siek **Date & Time:** 10/01/2004 05:10:29

Organization : Mr. Kevin Siek

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

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

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

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

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

Submitter : Dr. Arthur Nelson **Date & Time:** 10/01/2004 05:10:21

Organization : Texas Tech University Health Sciences Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The bill is very complex and practicing pharmacists will be at the focal point for Medicare recipients. Program providers should be required to pay pharmacists for the time and efforts that they must give the patients to help them; too often the providers only want to pay a minimum dispensing fee. However, this is a basic administrative cost of the program and should be covered.

Also, the Medication Therapy Management (MTM) program is included as "shall be offered" and "maybe paid" for by program providers. This is really an unacceptable strategy. MTM is clearly and effective and cost containment strategy. It should be mandated for payment at a reasonable leve.

Thanks.

CMS-4068-P-646

Submitter : Mr. Kevin Siek **Date & Time:** 10/01/2004 05:10:20

Organization : Mr. Kevin Siek

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

October 1, 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:

Thank you for the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the proposed rule will adversely affect the 6 million people who are dually eligible for Medicare and Medicaid.

Although the co-pays for these dual eligibles will be small, approximately $1 to $5, they will still be more than what they are currently paying on some medications. Additionally, they will be responsible for the full cost of medications not covered by the formulary in the new plan.

In short, dual eligibles could potentially have increased drug costs under the proposed rule.

I am also concerned that there in an institutional bias built into the proposed rule because dual eligibles in institutions have no co-pay while those receiving their care in the home and community will.

These folks are some of the most needy of Medicare recipients who often have numerous medications that they need to maintain their health and well-being. We must insure that this population does not incur increased health care costs under the proposed rule.

Thank you for your consideration of these comments.

Sincerely,

Kevin Siek
2041 SW Westwood Dr.
Topeka KS 66604

CMS-4068-P-647

Submitter : Miss. Elizabeth Patience **Date & Time:** 10/01/2004 05:10:17

Organization : Elizabeth A. Patience

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

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

The National Council on Disability and many other advocacy groups worked tirelessly in 1994 ? 1996 to develop the Ticket to Work/Work Incentives Improvement Act. The dreams and hard work of so many would be negated. The Part D Program, touted as a benefit. Those ten years of hard work to implement the Ticket to Work program and other incentives could be erased.

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today?s technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.
Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Thank you for your consideration of my views.

Yours sincerely,

Elizabeth A. Patience

Statewide Systems Advocate
Northern Regional Center for Independent Living
165 Mechanic St.
Watertown, N.Y. 13601
(315)785-8703 (V)
(315)785-8794 (TTY)
(315)785-8612 (Fax)
elizabethp@nrcil.org

CMS-4068-P-648

Submitter : Barbara Kennelly **Date & Time:** 10/01/2004 05:10:07

Organization : National Committee to Preserve SS and Medicare

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See the attached.

CMS-4068-P-648-Attach-1.doc

National Committee to Preserve Social Security and Medicare

Barbara B. Kennelly
President &
Chief Executive Officer

October 1, 2004

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

RE: CMS-4068-P

Dear Administrator McClellan:

The National Committee to Preserve Social Security and Medicare—a grassroots advocacy and education organization—has spent years advocating for a comprehensive and affordable prescription drug benefit offered through the Medicare program.

Although we oppose the underlying legislation (P.L. 108-173) because we believe it provides an insufficient benefit and is needlessly complex, we remain committed to bringing senior citizens the best prescription drug benefit possible. Therefore, we are submitting these comments on the proposed regulations on behalf of our 3.2 million members and supporters, who represent current and future Medicare beneficiaries, in a constructive effort to mitigate the negative impact of structural flaws in the statute and to maximize consumer protections and guarantees wherever possible.

Our following comments regarding the employer subsidy and beneficiary protections highlight some of our members' primary concerns about the proposed regulations. In addition, we have outlined additional concerns in letters which we have co-signed with other members of the Leadership Council of Aging Organizations and the Medicare Consumers Working Group.

Employer Subsidy

We remain concerned about the implementation of the employer subsidy in the proposed regulations. We were disappointed that the statute did not include a maintenance-of-effort provision that prohibited employers from lowering their benefits while still receiving $71 billion in federal subsidies. Despite our opposition to components of the employer subsidy, the National Committee agrees with Congress' stated policy goals of maximizing employer-based drug coverage and eliminating undue financial windfalls to employers. Therefore, we strongly urge changes to the statutory and

regulatory definitions of "allowable retiree costs," which determine the amount of subsidies that employers could receive. We believe the definition of allowable retiree costs should only include the employer's financial contribution to employer-sponsored prescription drug coverage. Definitions in both the statute and the regulations include contributions from the employee and employer to prescription drug coverage, which can result in improper cost-shifting.

Considering the uncertainties of legislative changes regarding the definition of allowable retiree costs, it becomes even more important that employer-sponsored plans that engage in improper cost-shifting are prevented from becoming eligible for the subsidy. We firmly oppose the use of a single-prong test in determining whether an employer's plan is at least equivalent to the standard prescription drug benefit offered under Medicare Part D. With the single-prong approach, the proposed regulations acknowledge that "an employer could theoretically impose the full cost of the benefit package on the employee through employer premiums and still be eligible for subsidy payment if the package the employee was buying met the actuarial equivalence test." Eligibility for federal subsidies should not provide a financial incentive to reduce existing coverage. Further, employers should not be eligible for federal subsidies while shifting the burden of costs onto the retiree.

Beneficiary Protections & Appeals

The National Committee believes the proposed regulations should do more to ensure that beneficiaries receive maximum access to drug benefits and sufficient protections from a new and complicated process. We believe four areas are particularly important: (1) late penalties, (2) involuntary disenrollment, (3) communication with beneficiaries, and (4) the appeals process.

First, since beneficiaries in many regions will face an overwhelming number of choices with the new drug benefit, it is important to allow for significant leeway in assigning late penalties. If the drug discount card is any example, seniors will be slow to commit themselves to a plan and should not be financially penalized for confusion caused by the process.

Second, beneficiaries who are involuntarily disenrolled may unfairly face the late penalty without any recourse because the proposed regulations do not contain a late penalty appeals or re-enrollment process.

Third, in order to reduce confusion among beneficiaries, we believe it is important for the Center for Medicare and Medicaid Services (CMS) and drug plans to communicate with beneficiaries through multiple modes of

communication. We have learned from the Medicare prescription drug discount card that even though information on the Internet is useful, few seniors are comfortable using this material. Many seniors respond more positively to written materials and oral communication.

Finally, we are concerned with the complicated and inadequate appeals process. We urge CMS to revise the regulations to ensure that they meet the constitutional due process requirements for adequate notice and timely review when public benefits are being terminated. We believe this section needs major simplification and improvement, at a minimum, to ensure that beneficiaries are protected by Medicare in a manner similar to how beneficiaries are currently protected in the Medicaid program. Priorities for simplification and improvement include: assuring that Medicare beneficiaries receive the drugs their physicians believe are best for them through maximum flexibility in the formulary; informing beneficiaries of their appeal rights when prescription drug plans make unfavorable coverage determinations; and providing a speedy appeals process during which time prescription drugs are available to beneficiaries.

At a time when our nation's seniors are in need of relief from the skyrocketing cost of prescription drugs, it is imperative that CMS makes the needs of beneficiaries the primary concern as implementation of the prescription drug benefit nears. While many seniors' health needs change over time, in general their resources are very limited. Wherever possible within statutory limits, a priority must be placed on stability and affordability of benefits that provide the maximum range of pharmaceutical options that seniors' health needs may require.

Cordially,

Barbara B. Kennelly
President and CEO

Submitter : Chris Lohrman **Date & Time:** 10/01/2004 06:10:50

Organization : Volunteers of America - Ohio River Valley, Inc.

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

GENERAL

GENERAL

"Please see attached"

CMS-4068-P-649-Attach-1.doc

October 1, 2004

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

Re: Medicare Program; Medicare Prescription Drug Benefit
Comments on Proposed Rule
69 Federal Register 46632

The **Volunteers of America/Ohio River Valley** welcomes the opportunity to provide comments on the proposed rule. The **Volunteers of America is a national, spiritually based non-profit providing local human service programs. The Ohio River Valley Chapter began in 1954 and serves both the Cincinnati and Dayton areas.** We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are six critical recommendations:

1. **Delay the implementation of the Part D program for dual eligibles.**

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

CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the high improbability that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we strongly recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

2. **Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process.**

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

3. Designate special populations who will receive affordable access to an alternative, flexible formulary.

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

Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications, and only after much experimentation, find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury, debilitating side effects, hospitalization, or other types of costly medical interventions.

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

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

4. Impose new limits on cost management tools.

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. We strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization.

We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications, which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

5. Strengthen and improve inadequate and unworkable exceptions and appeals processes.

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs.

As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to:

- Establish clear standards by which prescription drug plans must evaluate all exceptions requests;

- Minimize the time and evidence burdens on treating physicians; and
- Ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

6. Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Sincerely,

CMS-4068-P-650

Submitter : **Date & Time:** 10/01/2004 06:10:51

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

To the Centers for Medicare and Medicaid Services,
I believe the MTM program is vital in giving patients the best health care that they can receive. Patients should be educated on their medications, especially if they are a patient with a chronic disease. However, all patients should have the benefit of receiving MTM.
Pharmacists can contribute greatly to a patient's care plan, as they are experts on drug knowledge and can best manage the multiple medications that many patients are on. All pharmacies and pharmacists have the knowledge to participate in such a monumental program that will greatly impact the health care the patients can receive. Patients should continue to be able to choose s pharamacy to provide these services.
As a pharmacy student, I have put much time and effort in to learning how to best care for patients and manage their medications so that my services will be of benefit when I graduate. As a result of better management of patients' medication, I believe that there will be less duplicate therapy and medication errors.
I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by the 11 national pharmacy organizations in July 2004.

Submitter : Ms. LAILA LYNCH **Date & Time:** 10/01/2004 06:10:56

Organization : DEAN HEALTH SYSTEMS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern,

I write today to offer comments regarding the proposed Medicare Part D rules. As a pharmacist, I am deeply concerned with the rules as they are currently proposed.

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

In order for this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all hospital pharmacy providers that perform MTM services.

CMS RULES MUST ALLOW FOR ALL PHARMACIES TO BE INCLUDED NOT PRECLUDED. PLAN SPONSORS SHOULD BE REQUIRED TO ESTABLISH CMS SPECIFIED MTM SERVICES.

CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare receipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation's foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerely,

Laila Lynch, Pharm.D

CMS-4068-P-652

Submitter : Mr. Marc Brandt **Date & Time:** 10/01/2004 06:10:38

Organization : NYSARC, Inc

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-652-Attach-1.pdf

CMS-4068-P-652-Attach-2.doc

Ocbober 1, 2004

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

To Whom It May Concern:

The NYSARC, Inc (formerly The New York State Association for Retarded Children) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. NYSARC, Inc. is the largest non profit agency in the nation serving persons with mental retardation and other developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual

eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically

necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions

process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

CMS-4068-P-653

Submitter : Dr. William Malloy **Date & Time:** 10/01/2004 06:10:50

Organization : Dr. William Malloy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I support the goal of reducing medication errors and increasing cost-effectiveness. Standards deveoped by NCQA should be used as a reference. If PDP's are touse formularies, I support the creation of P&T Committees. The membership should include pharmacists and that they be majority and voting members of the committee.
With respect to medication therapy management I note a potential for regional disconnects with respect to services provided. The regulation should define "chronic medications" and "chronic medical conditions" to reflect standard services that each PDP will have to offer. I support that the primary goal of MTM, proper drug utilization, be available to ANY patient with high drug costs and / or chronic medicaiton conditions who is taking two(w) or more drugs.
Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

CMS-4068-P-654

Submitter : Mrs. Fatima Mendoza **Date & Time:** 10/01/2004 06:10:31

Organization : DaVita Dialysis Centers

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

I would like to comment on the exclusion of prescription vitamins and mineral on (a) Covered Part D Drug (d) (2) (5) . I am a Registered Dietitian and Renal professional who work with dialysis patients. These patients are required to supplement their food intake with water soluble vitamins which are lost during dialysis. These patients become very deficient in these vitamins which are important to prevent severe deficiencies and is important in managing anemia of renal disease. If prenatal vitamins are important to the pregnant woman, it is equally important to include coverage for the renal patients.

CMS-4068-P-655

Submitter : Mr. George Kimes **Date & Time:** 10/01/2004 06:10:18

Organization : Pennsylvania Community Providers Association

Category : Health Care Provider/Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

? 423.120 Access to covered Part D drugs.
Use of formularies by PDPs or Medicare Advantage (MA) organizations must not be so restrictive as to preclude inclusion of branded medications for those who require them. Utilization management processes that restrict access to medications for certain conditions, such as mental illnesses, are detrimental to successful treatment. Therapeutic equivalency is imprecise and does not guarantee that one generic medication has the same effect as another or as the original branded product. Because the likelihood of recovery is diminished if the first course of treatment fails, and physicians must take great care in crafting drug therapies for each individual with mental illnesses, a broad spectrum of medications must be available. This is especially true for older adults who often use multiple medications to treat their health conditions. The use of an open formulary for persons with mental illnesses is strongly encouraged.

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

? 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.
PDPs and MA-PD plans must not use utilization management processes that require prior authorization, fail first and step therapy for persons with mental illnesses. These processes are very harmful and must not be permitted.

ELIGIBILITY, ELECTION, AND ENROLLMENT

? 423.34 Enrollment process.
The impact of the enrollment process for the Medicare prescription drug benefit on dually eligible individuals, those who currently have drug coverage through the Medicaid Program, is of great concern. As Medicaid drug coverage ends for dual eligible individuals on January 1, 2006, disruptions in service are very likely. CMS must ensure that vulnerable beneficiaries, especially those who have mental illnesses, are enrolled in prescription drug plans (PDPs) before their Medicaid benefit ends so that there can be continuity of service. This can be done, either through automatic enrollment in a plan with the ability to switch to another plan of choice, or by extending the deadline for switching coverage from Medicaid to Medicare. The deadline should be extended for at least six months, while outreach efforts are undertaken to educate and enroll vulnerable beneficiaries.

Also, provisions must be included to ensure continuity of psychiatric medications in the transition from Medicaid to Medicare coverage. Changing medications used to treat mental illness is very difficult and harmful to the individual. Provisions are needed to ensure grandfathering of medications used to treat mental illnesses to minimize harm to individuals resulting from changing medications. PDPs open to enrollment by dually eligible beneficiaries are those that offer ?basic prescription drug coverage.? Because these programs will likely have very restrictive formularies, an exception process is needed to ensure that persons with mental illnesses have access to a broad variety of medications that may best meet their needs.

? 423.44 Disenrollment by the PDP.
Allowing PDPs to disenroll individuals for ?disruptive behavior? will effectively deny coverage for those who arguably need it most. This provision could be interpreted to permit exclusion of persons with dementia, mental illnesses, or mental retardation whose disruptiveness and lack of compliance arises from their illness or condition. Further, PDPs can use an expedited disenrollment process for disruptive behavior. Also, PDPs can refuse to reenroll an individual for an unspecified period of time. An individual who is involuntarily disenrolled from a PDP may enroll in another, although subject to a late enrollment penalty. These provisions must be removed.

The language in ?423.44(b)(2)(v) that an ?individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage? is problematic. It is not clear that mistakes or inadvertent omissions would be excluded as criteria for disenrollment.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Subpart M ? Grievances, Coverage Determinations, and Appeals
Requirements in this section are overly complex and inaccessible to this vulnerable population. Many levels of internal appeal are required before an appeal can be made to an administrative law judge. Access to an administrative law judge is not always possible. Persons with mental illnesses and others who have severe impairments will have great difficulty navigating these complex and protracted processes. Simpler and quicker processes that require expedited review for immediate needs must be established.

CMS-4068-P-655-Attach-1.doc

CMS-4068-P-655-Attach-1.doc

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CMS-4068-P-655-Attach-1.doc

PCPA

Pennsylvania
Community
Providers
Association

PCPA promotes a community-based, responsive and viable system of agencies providing quality services for individuals receiving mental health, mental retardation, addictive disease and other related human services.

October 1, 2004

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

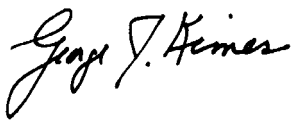
Dear Dr. McClellan:

Attached are comments on the Centers for Medicare and Medicaid Services proposed rule, "Medicare Program; Medicare Prescription Drug Benefit" prepared by the Pennsylvania Community Providers Association (PCPA). PCPA represents more than 150 community mental health, substance abuse and mental retardation service providers in Pennsylvania.

Access to a wide variety of prescription medications is imperative for the populations that our members serve. Indeed, for persons with mental illnesses, continuity in medication use is critical. For such vulnerable persons, sufficient time must be allocated for outreach and education to allow enrollment choice and to ensure that there are no gaps in service. Also, plans must not be permitted to involuntarily disenroll some of the most severely impaired persons, such as those with mental illnesses and dementia, for "disruptive" and "noncompliant behavior," when it is often their illness and condition that causes such behavior. The processes for grievances and appeals are overly complex and take too much time for persons who are so very ill to navigate. They must be simplified, streamlined, and made more independent of the plans.

Thank you for this opportunity to comment.

Sincerely,



George J. Kimes
Executive Director

Attachment

Comments submitted by the Pennsylvania Community Providers Association on Centers for Medicare and Medicaid Services proposed rules "Medicare Programs; Medicare Prescription Drug Benefit" (CMS-4068-P) on October 1, 2004. Comments reference the affected section of the rule.

§ 423.34 Enrollment process.

The impact of the enrollment process for the Medicare prescription drug benefit on dually eligible individuals, those who currently have drug coverage through the Medicaid Program, is of great concern. As Medicaid drug coverage ends for dual eligible individuals on January 1, 2006, disruptions in service are very likely. CMS must ensure that vulnerable beneficiaries, especially those who have mental illnesses, are enrolled in prescription drug plans (PDPs) before their Medicaid benefit ends so that there can be continuity of service. This can be done, either through automatic enrollment in a plan with the ability to switch to another plan of choice, or by extending the deadline for switching coverage from Medicaid to Medicare. The deadline should be extended for at least six months, while outreach efforts are undertaken to educate and enroll vulnerable beneficiaries.

Also, provisions must be included to ensure continuity of psychiatric medications in the transition from Medicaid to Medicare coverage. Changing medications used to treat mental illness is very difficult and harmful to the individual. Provisions are needed to ensure grandfathering of medications used to treat mental illnesses to minimize harm to individuals resulting from changing medications. PDPs open to enrollment by dually eligible beneficiaries are those that offer "basic prescription drug coverage." Because these programs will likely have very restrictive formularies, an exception process is needed to ensure that persons with mental illnesses have access to a broad variety of medications that may best meet their needs.

§ 423.44 Disenrollment by the PDP.

Allowing PDPs to disenroll individuals for "disruptive behavior" will effectively deny coverage for those who arguably need it most. This provision could be interpreted to permit exclusion of persons with dementia, mental illnesses, or mental retardation whose disruptiveness and lack of compliance arises from their illness or condition. Further, PDPs can use an expedited disenrollment process for disruptive behavior. Also, PDPs can refuse to reenroll an individual for an unspecified period of time. An individual who is involuntarily disenrolled from a PDP may enroll in another, although subject to a late enrollment penalty. These provisions must be removed.

The language in §423.44(b)(2)(v) that an "individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage" is problematic. It is not

clear that mistakes or inadvertent omissions would be excluded as criteria for disenrollment.

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Use of formularies by PDPs or Medicare Advantage (MA) organizations must not be so restrictive as to preclude inclusion of branded medications for those who require them. Utilization management processes that restrict access to medications for certain conditions, such as mental illnesses, are detrimental to successful treatment. Therapeutic equivalency is imprecise and does not guarantee that one generic medication has the same effect as another or as the original branded product. Because the likelihood of recovery is diminished if the first course of treatment fails, and physicians must take great care in crafting drug therapies for each individual with mental illnesses, a broad spectrum of medications must be available. This is especially true for older adults who often use multiple medications to treat their health conditions. The use of an open formulary for persons with mental illnesses is strongly encouraged.

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

PDPs and MA-PD plans must not use utilization management processes that require prior authorization, fail first and step therapy for persons with mental illnesses. These processes are very harmful and must not be permitted.

Subpart M – Grievances, Coverage Determinations, and Appeals

Requirements in this section are overly complex and inaccessible to this vulnerable population. Many levels of internal appeal are required before an appeal can be made to an administrative law judge. Access to an administrative law judge is not always possible. Persons with mental illnesses and others who have severe impairments will have great difficulty navigating these complex and protracted processes. Simpler and quicker processes that require expedited review for immediate needs must be established.

No further comments at this time.

CMS-4068-P-656

Submitter : Mr. Mike Bright **Date & Time:** 10/01/2004 06:10:03

Organization : The Arc of Texas

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file from the disability community.

CMS-4068-P-656-Attach-1.doc

October 1, 2004

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

To Whom It May Concern:

The Arc of Texas welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Arc of Texas is a statewide, non-profit volunteer organization that advocates on behalf of Texans with mental retardation and other developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

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Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate,

and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual

and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Respectfully,

Mike Bright – Executive Director
The Arc of Texas

CMS-4068-P-657

Submitter : Mrs. Maria Perez **Date & Time:** 10/01/2004 06:10:38

Organization : Davita Dialysis

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

I'm writing to request that CMS strongly reconsider exclusion of vitamins be changed to allow for the coverage of water-soluble vitamins lost during hemodialysis. Prescription vitamins prevent severe deficiencies and have been found to lower homocysteine levels (which present a cardiovascular risk factor), and are important for erythropoiesis. To receive the recommended dose of 5mg of folic acid to prevent hyperhomocysteinemia would cost $200 per year, which is a substantial sacrifice for a patient population that already acquires a high prescription cost for multiple medications to treat multiple comorbidities including diabetes, hypertension, and hyperlipidemia. Thank you in advance for your concern regarding this matter.
Sincerely,
Maria Perez,RD

Submitter : Mr. Walter K. Moore **Date & Time:** 10/01/2004 06:10:46

Organization : Genentech, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Genentech, Inc. appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services? (CMS) proposed rule regarding the Medicare Prescription Drug Benefit. As you are aware, Genentech is a leading biotechnology company headquartered in South San Francisco, California. Our primary mission is to develop, manufacture, and market breakthrough biologics that address significant unmet medical needs, including cancer, heart disease, and immunological diseases. Several of our therapies will be eligible for coverage under Medicare Part D, and we expect Part D plans to allow access to these therapies for Medicare beneficiaries.

While Genentech is supportive of CMS in implementing the Medicare Prescription Drug Benefit and of Prescription Drug Providers (PDP) by participating in Part D, we have concerns related to Medicare beneficiary access to needed Medicare Part D drugs and biologics. These concerns are as follows: (i) United States Pharmacopoeia (USP) Model Guidelines do not adequately provide coverage for many products; (ii) periodic review of plan formularies is necessary to reflect availability of new therapies and new uses for existing therapies, but is not specified by the NPRM; and (iii) beneficiary assess to necessary therapies during coverage determinations and exceptions process should be guaranteed.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Genentech appreciates the hard work that the USP Committee has put into the difficult task of creating the draft Model Guidelines. We understand the complexity of evaluating the vast clinical information available on prescription drugs and biologics and creating the draft therapeutic categories and classes. If done well, Genentech believes the final Model Guidelines will be a significant, positive influence on patient access to therapy within the Medicare prescription drug program.

However, Genentech is concerned that the broad therapeutic categories and pharmacologic classes in the draft guidelines will negatively impact beneficiaries by excluding from coverage a large number drugs and biologics. Without further development of subcategories, many innovative and life-saving therapies will not be covered as the result of the lack of available category or class to appropriately describe the drug or biologic. In addition, the required inclusion of at least, but not necessarily more than, two covered drugs within each category or class may discriminate against certain groups of Medicare beneficiaries. For example, beneficiaries with certain types of cancer may not have access to needed life-saving therapies if a plan only includes two drugs in the antineoplastic category. Cancer care regimes are frequently comprised of multiple drugs and biologics and may vary greatly between types of cancer as well as stage of disease. Genentech strongly urges CMS to require subcategories be created within the antineplastic agents category so as to specifically address various tumor types, as well as proactively monitor plan formularies. These steps will greatly aid beneficiary access to life-saving and life prolonging therapies.

In addition to the creation of subcategories and classes, Genentech urges CMS to adopt provisions in the Proposed Rule that would require prescription drug plans to update covered drugs and biologics within categories and classes during the plan year, as new therapies or new uses for existing therapies become available. It is important that plans add new therapies to their formularies in a timely manner. We urge CMS to work with PDP to ensure that pharmaceutical and therapeutics (P&T) committees review plan formularies at least on a quarterly basis. Regular review of formularies is vital to ensuring the access of Medicare beneficiaries to the latest drugs and biologics.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Genentech is concerned that the coverage determination, appeals, and exceptions process as defined in the Proposed Rule does not adequately ensure Medicare beneficiary access to necessary therapies. The Proposed Rule allows much discretion by PDPs in developing and implementing these

processes. Without clearly defined and consistent criteria, Genentech is concerned that an overly complex and burdensome process may be created, which could unintentionally impose a clear and direct barrier to access to medicines for beneficiaries.

Genentech urges CMS to work with individual PDPs to review grievance coverage determination, and the exception policies. It was the intent of the MMA to allow Medicare beneficiaries access to all necessary drug and biologics in a timely manner. CMS and PDPs should work to ensure that processes are simple and easy to follow. Processes that are complicated or difficult to navigate will be a significant barrier to access for the elderly Medicare population.

In addition, Genentech urges CMS to ensure uninterrupted access to drugs and biologicals during the appeals and coverage determination process. Any delay in processing an appeal or coverage determination request may result in a significant financial burden for Medicare beneficiaries. We encourage CMS and PDPs to continue providing coverage during appeals and coverage determinations so that necessary therapies are not interrupted or discontinued.

CMS-4068-P-658-Attach-1.pdf

CMS-4068-P-658-Attach-1.pdf

CMS-4068-P-658-Attach-1.pdf

Genentech
IN BUSINESS FOR LIFE

1399 New York Ave, NW Suite 300
Washington, DC 20005
Phone: (202) 296-7272
Fax: (202) 296-7290

October 1, 2004

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. – Room 445-G
Washington, D.C. 20201

Re: Comments on CMS-4068-P (Medicare Program; Medicare Prescription Drug Benefit)

Dear Administrator McClellan:

Genentech, Inc. appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the Medicare Prescription Drug Benefit. As you are aware, Genentech is a leading biotechnology company headquartered in South San Francisco, California. Our primary mission is to develop, manufacture, and market breakthrough biologics that address significant unmet medical needs, including cancer, heart disease, and immunological diseases. Several of our therapies will be eligible for coverage under Medicare Part D, and we expect Part D plans to allow access to these therapies for Medicare beneficiaries.

While Genentech is supportive of CMS in implementing the Medicare Prescription Drug Benefit and of Prescription Drug Providers (PDP) by participating in Part D, we have concerns related to Medicare beneficiary access to needed Medicare Part D drugs and biologics. These concerns are as follows: (i) United States Pharmacopoeia (USP) Model Guidelines do not adequately provide coverage for many products; (ii) periodic review of plan formularies is necessary to reflect availability of new therapies and new uses for existing therapies, but is not specified by the NPRM; and (iii) beneficiary assess to necessary therapies during coverage determinations and exceptions process should be guaranteed.

Subpart C – Benefits and Beneficiary Protections

Formularies – Two Drugs or Biologics Per Category or Class

Genentech appreciates the hard work that the USP Committee has put into the difficult task of creating the draft Model Guidelines. We understand the complexity of evaluating the vast clinical information available on prescription drugs and biologics and creating the draft therapeutic categories and classes. If done well, Genentech believes the final Model Guidelines will be a significant, positive influence on patient access to therapy within the Medicare prescription drug program.

However, Genentech is concerned that the broad therapeutic categories and pharmacologic classes in the draft guidelines will negatively impact beneficiaries by excluding from coverage a large number drugs and biologics. Without further development of subcategories, many innovative and life-saving therapies will not be covered as the result of the lack of available category or class to appropriately describe the drug or biologic. In addition, the required inclusion of at least, but not necessarily more than, two covered drugs within each category or class may discriminate against certain groups of Medicare beneficiaries. For example, beneficiaries with certain types of cancer may not have access to needed life-saving therapies if a plan only includes two drugs in the antineoplastic category. Cancer care regimes are frequently comprised of multiple drugs and biologics and may vary greatly between types of cancer as well as stage of disease. Genentech strongly urges CMS to require subcategories be created within the antineplastic agents category so as to specifically address various tumor types, as well as proactively monitor plan formularies. These steps will greatly aid beneficiary access to life-saving and life prolonging therapies.

Formularies – New Drugs and New Uses for Existing Drugs

In addition to the creation of subcategories and classes, Genentech urges CMS to adopt provisions in the Proposed Rule that would require prescription drug plans to update covered drugs and biologics within categories and classes during the plan year, as new therapies or new uses for existing therapies become available. It is important that plans add new therapies to their formularies in a timely manner. We urge CMS to work with PDP to ensure that pharmaceutical and therapeutics (P&T) committees review plan formularies at least on a quarterly basis. Regular review of formularies is vital to ensuring the access of Medicare beneficiaries to the latest drugs and biologics.

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

Genentech is concerned that the coverage determination, appeals, and exceptions process as defined in the Proposed Rule does not adequately ensure Medicare beneficiary access to necessary therapies. The Proposed Rule allows much discretion by PDPs in developing and implementing these processes. Without clearly defined and consistent criteria, Genentech is concerned that an overly complex and burdensome process may be created, which could unintentionally impose a clear and direct barrier to access to medicines for beneficiaries.

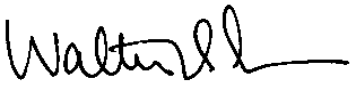
Genentech urges CMS to work with individual PDPs to review grievance coverage determination, and the exception policies. It was the intent of the MMA to allow Medicare beneficiaries access to all necessary drug and biologics in a timely manner. CMS and PDPs should work to ensure that processes are simple and easy to follow. Processes that are complicated or difficult to navigate will be a significant barrier to access for the elderly Medicare population.

In addition, Genentech urges CMS to ensure uninterrupted access to drugs and biologicals during the appeals and coverage determination process. Any delay in processing an appeal or coverage determination request may result in a significant financial burden for Medicare beneficiaries. We encourage CMS and PDPs to continue providing coverage during appeals and coverage determinations so that necessary therapies are not interrupted or discontinued.

Conclusion

Genentech appreciates the efforts of CMS in implementing Medicare Part D. We encourage CMS to work with PDPs to develop formularies and coverage processes that will ensure Medicare beneficiary access to Part D drugs and biologicals. Again, Genentech appreciates this opportunity to comment.

Sincerely,



Walter K. Moore, Vice President
Government Affairs

Submitter : Ms. Susan Cohen **Date & Time:** 10/01/2004 06:10:16

Organization : Capital District Center For Independence

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-659-Attach-1.doc

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

To Whom It May Concern:

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

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

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

I am an individual with Epilepsy who is receiving both Medicaid and Medicare for several years. I cannot afford to loose either on the insurances. Just one of my medications cost over $600.00 per month there is no way I can afford to this prescription out of my pocket-nor will I be able to cover the expensive co-pays if I loose Medicaid. I am also hoping to have employment in the community. I do not want to stay at home and waste my life in order to get the medications I need to live a healthy life. I am appalled that I even have to make such terrible choices.

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.
Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of
Congress.

Thank you for your consideration of my views.

Yours sincerely,

Tony DiGiovannantonio
518-377-2039
1011 Union St.
Schenectady, N.Y. 12308

CMS-4068-P-660

Submitter : Ms. Sarah James **Date & Time:** 10/01/2004 06:10:07

Organization : Devereux Foundation

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

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

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

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

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

CMS-4068-P-661

Submitter : Ms. Sarah James **Date & Time:** 10/01/2004 06:10:38

Organization : Devereux Foundation

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-661-Attach-1.doc

October 1, 2004

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

To Whom It May Concern:

The Devereux Foundation welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Devereux Foundation is a non profit agency serving individuals with developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate,

and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual

and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

CMS-4068-P-662

Submitter : Mr. Bill Lynch **Date & Time:** 10/01/2004 06:10:28

Organization : Oregon Council on Developmental Disabilities

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file

CMS-4068-P-662-Attach-1.doc

Oregon
Theodore R. Kulongoski, Governor

Oregon Council on Developmental Disabilities
540 24th Place, NE
Salem, OR 97301-4517
(503) 945-9941
FAX 945-9947
1-800-292-4154

September 30, 2004

Center 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:

Please accept our comments on the proposed rule "Medicare Program: Medicare Prescription Drug Benefit," 69 FR 46632.

We have attached comments that address specific areas of the proposed rule we believe will have the greatest impact on people with developmental disabilities in Oregon.

We urge you to exercise any flexibility in the rule making process to address our concerns and the concerns expressed by advocates and people with disabilities.

We believe that the proposed changes will have serious financial implications to the State of Oregon and threaten the health and safety of Oregonians with developmental disabilities.

Sincerely,

Bill Lynch
Executive Director

CMS-4068-P-663

Submitter : Ms. Susan Cohen **Date & Time:** 10/01/2004 06:10:59

Organization : Capital District Center For Independence

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-663-Attach-1.doc

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

To Whom It May Concern:

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

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

As a Systems Advocate for the Capital District Center for Independence I work with many individuals who will be badly impacted by Part D of the program. These individuals do not have 6,000.00 to put into their prescription drugs. Many of these people are working or want to work. They do not want to stay home in order to be poor enough to get the medications the desperately need. Part D will be a tragedy for so many people who want to live a free life in the community.

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work.

The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.
Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of
Congress.

Thank you for your consideration of my views.

Yours sincerely,

Susan H. Cohen
Capital District Center For Independence
518-459-6422

855 Central Ave.
Albany, N.Y. 12206

Submitter : Mr. Thomas Peifer **Date & Time:** 10/01/2004 06:10:48

Organization : The Hospital & Healthsystem Association of PA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

October 1, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of our members in the state of Pennsylvania?approximately 250 hospitals and health systems? would like to submit the following general comments regarding the Medicare Part D proposed rule.

We have several areas of concern beginning with the confusion that this proposed rule will cause for providers and more importantly with beneficiaries. The following are five issues that will cause this confusion:

? No fixed benefit package

? Not all drug types are covered and even if a drug type is covered, not all drugs within a particular type are covered

? Coverage will vary from plan to plan

? Plans will utilize formularies ? prior authorization will be required.

? Plans can offer alternative prescription drug coverage which can include tiered co-payments and other cost savings.

The lack of standard benefit package will create confusion for consumers and providers. It will be hard for consumers to know what plan to choose and it will be a challenge for providers to know how to prescribe medications based on the different plan coverage.

The second issue is the access to prescriptions for mental health disorders. Overall, the proposed classification of mental health drugs is badly flawed in grouping older medication?that are far inferior in terms of their efficacy and dangerous properties?with newer therapies that are more effective and have much more manageable side effects. Because these newer drugs are more expensive, grouping them together with the older medications will encourage health plans offering the Medicare drug benefit to cover only the older, less expensive drugs. Such an outcome is fundamentally inconsistent with Congress? core goal of assuring beneficiaries access to the drugs they need. Yet, in proposing so few categories and classes, and creating groupings that include highly diverse agents, the draft guidelines would give health plans economic incentives to override consumer needs and standards of care.

The third issue is the appeals process. The following are our concerns:

? Appeals process mirrors what has been in place for Medicare+Choice which has far longer time frames than a Medicaid appeal process and there are fewer beneficiary protections

? The continuity of drug benefits during an appeal is only extended if an appeal is based on a drug being removed from a formulary. The continuity of care/continuation of coverage should be expanded as follows: to include situations such as when a plan decides that it will no longer cover a medication from a particular date forward; to include coverage for Medicaid recipients whose care will be interrupted on January 1, 2006

? There is no clearly defined definition of medical necessity.

Lastly, pharmacy access is based on mileage not on the amount of time it takes to travel to the pharmacy. This is a problem in urban areas as a two-mile distance can be a long period of time to travel in a city. When Pennsylvania was designing the requirements for HealthChoices, the mandatory managed care program for Medical Assistance recipients, they determined that a travel time standard was more appropriate than a mileage one for pharmacy access.

HAP appreciates the opportunity to comment on the Medicare Part D proposed rule. If you have any questions with regard to these comments, or would like to discuss these in more detail, please feel free to contact me at phone (717) 561-5316 or via email at tpeifer@haponline.org.

Sincerely,

THOMAS A. PEIFER
Director, Billing and Claims Management

CMS-4068-P-664-Attach-1.doc

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

October 1, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-4068-P
PO Box 8014
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- Coverage will vary from plan to plan
- Plans will utilize formularies – prior authorization will be required.
- Plans can offer alternative prescription drug coverage which can include tiered co-payments and other cost savings.

The lack of standard benefit package will create confusion for consumers and providers. It will be hard for consumers to know what plan to choose and it will be a challenge for providers to know how to prescribe medications based on the different plan coverage.

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Sincerely,

THOMAS A. PEIFER
Director, Billing and Claims Management

Submitter : Mr. Kenneth Robinson, R.Ph **Date & Time:** 10/01/2004 07:10:26

Organization : Eckerd

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

Eckerd & Brooks have analyzed the proposed regulations from the Centers for Medicare and Medicaid Services (CMS) that would implement Title I of the Medicare Modernization Act (MMA) relating to the new Part D prescription drug benefit program. Provided below are our comments to the proposed regulation "CMS-4068-P". In these comments, references made to Part D plans refer to Prescription Drug Plans (PDP) and Medicare Advantage - Prescription Drug Plans (MA-PD).
Information about Generic Drug Costs

We do not support the proposed requirement that pharmacies have to disclose at the point of sale the difference in price of the drug being dispensed and the lowest cost generic available at that pharmacy, unless the product being dispensed is the lowest cost generic available at the pharmacy. The pharmacy can only respond to the customer with an estimated savings. Actual savings would have to be passed back in the adjudicated response from the processor (which may not be possible).

Standard Benefit Card

We support the proposed requirement that plans use by January 2006 a standard benefit card using the NCPDP-approved format. The regulation requires that a number other than a Medicare beneficiary's Social Security number be used for identification purposes.

BENEFITS AND BENEFICIARY PROTECTIONS

Proposed Regulation Fails to Define Traveling Distances: The proposed regulation also fails to indicate that, in determining distances to pharmacies required under the TriCare standards (i.e. "within 2 miles", "within 5 miles"), plans must apply the standards using "commercially traveled routes". These are the actual travel distances for beneficiaries to pharmacies, not just the geographic distances between the beneficiary and the pharmacy. For example, a beneficiary may only be geographically two miles from a pharmacy, but because of the way that the road system is structured, the beneficiary has to travel or drive 5 miles to reach that pharmacy. The actual driving distance should be used to determine whether the TriCare access standards are being met.

Equal Access to Retail and Mail Order Pharmacies for Medicare Beneficiaries

It was the intent of Congress to assure that Medicare beneficiaries are able to obtain covered prescription drugs and medication therapy management services from their pharmacy provider of choice. As such, PDP or MA-PD plans have to permit Medicare beneficiaries to obtain the same amount, scope, and duration of covered outpatient drugs and medication therapy management services at any community retail pharmacy that is in the plan's pharmacy network (which include those that are in the preferred network and non preferred network) as the plans offer through mail order pharmacies.

Regulation Does Not Prohibit Differential Cost Sharing: Based on legislative history and Congressional intent, plans cannot create differential cost sharing requirements to shift beneficiaries to mail order. This point, however, is not explicit in the proposed regulation. The only difference that a beneficiary would have to pay between a retail and mail order prescription is, according to the law, the difference in "charge" to obtain that prescription from retail pharmacy rather than mail order. The proposed regulation has interpreted this difference in "charge" as the net cost, if any, between the retail and mail "negotiated prices" as explained below.

Definition of "Negotiated Price" Unclear: Consistent with this definition, the "negotiated price" should reflect the net direct cost to the PDP or

MA-PD plan, and take into account rebates, discounts or other price concessions, for the same quantity of medication dispensed to the patient. That means, the cost difference to the Medicare beneficiary should only reflect the net cost of the plan of paying for the prescription through retail versus mail, net of any manufacturer rebates, discounts, or price concessions paid to the plan for a similar quantity of the drug dispensed through retail versus mail order, with those various price concessions applied directly to reducing the cost of the retail or mail order prescription.

Plans should not be allowed to use rebates that are provided to them for prescription drugs that are dispensed through retail pharmacies to artificially lower the cost of mail order prescriptions. This makes it falsely appear that mail order is less expensive.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Out of Network Pharmacies

We are concerned that the requirements in the regulation regarding "out of network" pharmacies are impractical and inconsistent with current industry practice. They may also create unrealistic expectations for beneficiaries regarding the use of these out of network pharmacies. Under the proposed regulations, if a pharmacy is not in the plan's network, whether as a preferred or non-preferred pharmacy, then it is an "out of network pharmacy." Plan enrollees may use out of network pharmacies under certain limited conditions.

However, the regulation seems to imply that these out of network pharmacies, which would not have contract with the plan or access to necessary beneficiary information, may in fact have to know certain patient and plan-specific information to fill the prescription. This includes whether a particular drug is on the beneficiary's plan formulary, whether the beneficiary is in the "donut hole" or has met their out of pocket maximum; what their copays might be under the plan; and whether they are even eligible for the plan.

If a beneficiary has to use an out of network pharmacy to obtain covered outpatient drugs, then all the out of network pharmacy can do is fill the prescription for the beneficiary and charge the beneficiary the pharmacy?s full ?usual and customary price? for the medication. The pharmacy can provide the beneficiary with a receipt for the prescription, and the beneficiary will then have to reconcile with the plan any cost sharing, plan allowances, formulary status issues and application of the amount paid to the out of pocket maximums, after the prescription is filled. The very fact that the pharmacy is not in the plan?s network means that the pharmacy cannot determine many important plan components that are necessary to fill the prescription if the beneficiary was enrolled in the plan

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

Medication Therapy Management (MTM)

The regulation requires that each PDP and MA-PD plan include a program of medication therapy management (MTM) for Medicare beneficiaries with high drug spending, multiple chronic medical conditions, and taking multiple chronic medications. The goal of these programs is to improve the quality of care provided to Medicare beneficiaries and reduce the potential for adverse events from medication use.

No Standard MTM Benefit Level Defined: The proposed regulations recognize that some beneficiaries may require more intensive MTM services, and gives plans significant discretion in designing their MTM programs. For example, the regulation indicates that, in addition to services such as beneficiary counseling and activities designed to promote adherence to prescription medications, MTM services could include formulating prescription drug treatment plans, and evaluating and monitoring patient response to drug therapy. However, unlike the prescription drug coverage portion of the program, there is no standard package of MTM services that a plan has to offer and that a beneficiary should expect to receive. This means there could be wide variability in the types of MTM services that will be offered, even within plans within the same region.

No Minimum Eligibility Criteria Defined: In addition, the regulations are not more specific on eligibility for MTM services, other than to restate the law, which indicates that beneficiaries eligible for MTM services have to use multiple medications, have multiple chronic conditions, and have high drug spending. However, each plan can define this differently, meaning that beneficiaries will have unequal access to MTM services. In one region, a beneficiary with two chronic conditions taking two medications may be eligible for MTM services, while in another region, the threshold may be four chronic conditions and four medications.

No Minimum Payment Levels Defined: The regulation acknowledges that pharmacists will be the primary provider of these services, but that other providers might also provide these services. The regulations also specify that plans have to pay pharmacies for these services, although it doesn't specify a minimum payment amount that must be made. As a result, plans can make payments for MTM services so low that pharmacists would not be able to afford to provide these services, meaning that beneficiaries may have no choice but to obtain their MTM services through telephone

services, rather than more important face to face counseling.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Proposed Regulation Creates Networks Smaller than TriCare: The proposed regulation also allows plans to circumvent the TriCare standards by creating "preferred pharmacies" and "non-preferred" pharmacies within the TriCare network. Thus, a plan can include the minimum number of pharmacies in its overall network to meet the TriCare access standards, and then create a smaller network by allowing some of the pharmacies in the general TriCare network to offer lower cost sharing to beneficiaries than the non-preferred pharmacies. This approach has the net effect of increasing cost sharing to a larger number of Medicare beneficiaries who would otherwise had paid lower cost sharing had all pharmacies in the TriCare network been required to charge the same cost sharing across the board.

In contrast, the DOD in network of pharmacies meets (and exceeds) the TriCare access standards, and has uniform cost sharing for all these in network pharmacies. All pharmacies not in the DOD network have a different, higher uniform cost sharing than in network pharmacies. Thus, CMS application of the TriCare pharmacy access standards is inconsistent with DOD's application of the standards.

While such reduction in cost sharing for in network pharmacies under the proposed CMS regulation might be helpful to a small number of Medicare beneficiaries, CMS is allowing plans to create a smaller network than TriCare that was simply not envisioned by the statute. The report language accompanying the statute makes it clear that plans cannot create "smaller networks" than the TriCare access standards. It indicates that the "..minimum in network pharmacy for each plan offered by a PDP or MA in a geographic area must provide access to pharmacies that is not less restrictive than the TriCare access standards." The report language further states that "plan sponsors cannot create any pharmacy networks that are more restrictive than the TRICARE access standards."

GENERAL PROVISIONS

Beneficiary Access to Community Retail Pharmacies

The standards for Medicare beneficiary access to pharmacies are being implemented in a manner that is inconsistent with Congressional intent, and will significantly reduce Medicare beneficiaries' access to retail pharmacies. These standards, known as the Department of Defense's (DOD) TriCare pharmacy access standards, require that 90 percent of Medicare beneficiaries in urban areas have access to a pharmacy within 2 miles; 90 percent of Medicare beneficiaries in suburban areas have access to a pharmacy within 5 miles; and 70 percent of Medicare beneficiaries in rural areas have access to a pharmacy within 15 miles.

Also, the network status of pharmacies can be very confusing to beneficiaries under the scheme that CMS has constructed. Pharmacies can be considered preferred, non-preferred or out of network. Plans must specify the status of specific pharmacy locations, not just note whether a particular chain is in the network. In addition, beneficiaries should know the exact cost sharing amounts involved with using particular pharmacies in the network. Material should be carefully reviewed by CMS to assure that plan designs do not steer beneficiaries to mail order pharmacies.

Proposed Regulation "Averages" TriCare Access Standards: Under the proposed regulation, each PDP and MA-PD plan is required to apply these standards, on average, for each plan that they are offering in each region, even if they are offering the plan in more than one region. (CMS has yet to determine or define the number of PDP regions that will exist, but the statute allows for anywhere from 10-50 regions.)

We agree that a plan should have to meet the standards in each region in which it operates, even if it operates in multiple regions. However, the proposed regulation does not specify that a plan has to meet the TriCare access standards in each state in each region that the plan serves. For example, beneficiaries in urban areas in one state in the region may have much greater access than beneficiaries in urban areas in another state in the region. The same is true for the suburban and rural areas of the region. Since PDP and MA-PD plans are permitted to average the access standards across all the urban, suburban, and rural areas in the region, they can be considered to be in compliance with these standards, even though the result will be unequal access to retail pharmacies for many Medicare beneficiaries.

CMS-4068-P-665-Attach-1.pdf

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CMS-4068-P-665-Attach-1.pdf

GROWING *together*
Joining Forces for a Stronger Tomorrow
A Pharmacy First

October 4, 2004

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

SUBJECT: Medicare Program; Medicare Prescription Drug Benefit, CMS 4068-P, RIN 0938-AN08

To Whom It May Concern:

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Standard Benefit Card

We support the proposed requirement that plans use by January 2006 a standard benefit card using the NCPDP-approved format. The regulation requires that a number other than a Medicare beneficiary's Social Security number be used for identification purposes.

We appreciate the opportunity to submit these comments and look forward to continued dialogue with CMS to assure that the Part D prescription drug program is implemented consistent with Congressional intent.

Sincerely,

Kenneth Robinson R.Ph
VP Managed Care
Eckerd & Brooks Pharmacy
50 Service Ave.
Warwick, RI 02886

Ph. 401-825-3916
ken.robinson@brooksrx.com

CMS-4068-P-666

Submitter : **Date & Time:** **10/01/2004 07:10:29**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-4068-P-666-Attach-1.doc

October 1, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

Dear Sir or Madam:

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

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

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

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

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

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

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

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

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

Thank you for considering my comments.

Sincerely,

Clara P. Linz

CMS-4068-P-667

Submitter : Ms. Heidi Margulis **Date & Time:** 10/01/2004 07:10:33

Organization : Humana Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find comments from Humana Inc. regarding CMS' proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program.

Thank you for your consideration.

Heidi Margulis
Senior Vice President, Government Relations
Humana Inc.

CMS-4068-P-668

Submitter : Ms. Heidi Margulis **Date & Time:** 10/01/2004 07:10:49

Organization : Humana Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find comments from Humana Inc. regarding CMS' proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program. Thank you for your consideration. Heidi Margulis Senior Vice President, Government Relations Humana Inc.

CMS-4068-P-668-Attach-1.doc

Humana Inc.
500 West Main Street
Louisville, KY 40202

October 1, 2004

The Honorable Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

Attn: CMS 4068-P and CMS-4069-P

Dear Dr. McClellan:

The purpose of this letter is to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program enacted in Title I and Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We have also attached a recent letter Humana submitted to you regarding the regional PPO program.

Humana Inc., headquartered in Louisville, Kentucky, is one of the nation's largest publicly traded health benefits companies, with approximately 5.8 million medical members located primarily in 15 states and Puerto Rico. We offer coordinated health insurance coverage and related services - through traditional and Internet-based plans - to employer groups, government-sponsored plans, and individuals. As of January 2004, Humana serves over 350,000 Medicare beneficiaries in markets across the nation.

Humana is also a member of America's Health Insurance Plans (AHIP), the principal national trade association representing companies that provide health benefits to consumers and employers throughout the United States. We provided technical input into the AHIP's comments regarding the proposed rules for the Medicare Prescription Drug Benefit and the MA Program, and want to express our support for and agreement with the comments and recommendations submitted to CMS by this organization. Additionally, we are appending a copy of our recent letter to you reiterating our support for considering participation in the regional PPO program should there be fewer than 50 regions and our belief that the Secretary must use his authority to ensure that seniors, no matter where they live, have access to coverage choices with adequate provider networks.

As a strong supporter of the MMA, we commend the CMS' efforts to expeditiously issue proposed rules for both these programs as well as your outreach efforts to explain the provisions and seek guidance. Given the short timeframe for many of the Act's program effective dates, we urge CMS to promulgate the final regulations as quickly as possible to ensure that interested entities can make the kinds of decisions necessary for operational implementation. We believe the law and subsequent final regulations should strengthen the Medicare program and should protect and provide seniors with meaningful choices of affordable, quality health care coverage.

We appreciate the opportunity to provide these comments. Humana has enjoyed a long partnership with the federal Medicare program, and we look forward to working with you to strengthen the Medicare program for today's seniors and future generations. If you have any questions, please do not hesitate to contact me.

Sincerely,

Heidi Margulis

Heidi Margulis
Senior Vice President, Government Relations
Humana Inc.

CMS-4068-P-669

Submitter : Anne Smith **Date & Time:** 10/01/2004 07:10:50

Organization : Anne Smith

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I write today to offer comments regarding the proposed Medicare Part D rules. I am deeply concerned with the rules as they are currently proposed.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns expressed by pharmacists and their patients around the nation are being considered. Private sector health plans have far too often targeted pharmacies and pharmacy reimbursement in cost containment measures rather than working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow this same path.

I am primarily concerned with three aspects of the Medicare part D proposed rules and recommend that CMS enable the following three policies:

?< Medicare recipients must be able to choose their own pharmacies
It is critical that plan sponsors make every effort to include as many pharmacy providers as possible in the Part D benefit. The access standards should be applied at a level no broader than a county to ensure that recipients have ready access to the pharmacies in their community. Furthermore, plan sponsors should be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. Private health plans have often used their market force to drive down pharmacy reimbursement below a pharmacy!|s operational costs, thereby forcing the pharmacy providers to cost shift to other business sectors. Medicare must not allow this business practice to continue.

?< Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Recipients should not be economically coerced into using one pharmacy over another unless the plan sponsor for defined quality reasons prefers the preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.

?< Plan sponsors should be required to establish specified MTM services.
CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation!|s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacies must be allowed to participate equally.

CMS-4068-P-670

Submitter : Mr. Daniel Griesau **Date & Time:** 10/01/2004 07:10:15

Organization : Mr. Daniel Griesau

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Pleased see attached file from the disability community

CMS-4068-P-670-Attach-1.doc

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

To Whom It May Concern:

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

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

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

As an individual with a closed brain injury I am on a very low income and will be very badly impacted by loosing my Medicaid. I do not have my own money to pay for my prescription drugs and therefore I could be in danger as a young man to be placed in a nursing home or other institution to be able to receive my prescriptions. This will be absolutely horrible for me. Please don't put me in this position.

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many

Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.
Once more, millions of our citizens will stay home to stay poor in order to get the medicine they need.

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of
Congress.

Thank you for your consideration of my views.

Yours sincerely,

Daniel T. Griesau

216 Woodlawn Ave.
Albany, N.Y. 12208

CMS-4068-P-671

Submitter : **Date & Time:** **10/01/2004 07:10:23**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Specific to HIV/AIDS, due to required treatment with 3 antiretrovirals and due to vast differences within classes and necessity of treatment with 1-4 drugs from any particular class, we beg for our patients and their lives that you require all Antiretroviral medications to be available on all medicaid drug programs w/o copay restrictions or penalties.
Many 3rd party companies competing for this benefit will take advantage of the system by being the only bidder in an area or underminig bidding via restrictions. We see this with NC State Employees programs and the BCBS of NC Federal Employees program. Thus there is no competition and copays continually rise. It is worse with smaller programs/managed care companies in our area.
Again, please put all antiretrovirals on all programs for the medicare drug benefit for patients. Especially since medicaid will no longer be available to the population who have medicaid and medicare and thus will loose that option.
Please consider this carefully as with estimated 40,000 new infections per year and no increase in federal funding for indigent/underserved patients, patients with medicare can hopefully get treatment and live a more productive life if you (as the govt) will take notice and provide access to these lifesaving meds.
Thank you,
Marnie Jones

CMS-4068-P-672

Submitter : Mr. Peter Vogel **Date & Time:** 10/01/2004 07:10:35

Organization : Devereux

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file!

CMS-4068-P-672-Attach-1.doc

October 1, 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:

Devereux welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. Devereux is a community-based agency working with a variety of developmentally disabled individuals throughout the state of New Jersey. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

Delay the implementation of the Part D program for dual eligibles:

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries.

We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate,

and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process:

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

Designate special populations who will receive affordable access to an alternative, flexible formulary:

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

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

must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual

and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Sincerely,

Peter E. Vogel
Director of Behavioral Health
Devereux, New Jersey

CMS-4068-P-673

Submitter : Mr. John Keegan **Date & Time:** 10/01/2004 07:10:52

Organization : Heights Terrace Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Attached are my comments on proposed rule on Section 423.120 (CMS-4068-P). I ask that you repeal your proposed rule Section 423.120(a)(5) so that the plan sponsor would not have the authority to create "preferred pharmacies" within the network. This system would absolutely negate the participation guarantee provided an individual pharmacy under the "any willing provider" provision written into the law and extended in your rule under Section 423.12(a)(4)(i). I ask that my comments become part of the official record. Thank you.

CMS-4068-P-674

Submitter : Mr. James Proulx **Date & Time:** 10/01/2004 07:10:36

Organization : Fairview Families

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

October 1, 2004

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

RE: Comments relating to Medicare Part D proposed regulations -
69 Fed. Reg. 46632 (Aug. 3, 2004).

My wife and I support the comments submitted by Voice of the Retarded (VOR). We feel strongly that:

* The definition of "long term care facility" must include Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR).

* "Institutionalized" should include all individuals eligible for ICF/MR placement, including current residents, home and community-based services(HCBS) waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

The regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives.

Thank you for your consideration.

Sincerely,

James E. & Mary J. Proulx
8505 Gulana Avenue, Unit 4209
Playa del Rey, CA 90293
(310) 306-2734 FAX: (310) 821-5764

Submitter : **Date & Time:** 10/01/2004 07:10:07

Organization : Ocean State Center for Independent Living

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:
Thank you for this opportunity to comment on the proposed rule
"Medicare Program: Medicare Prescription Drug Benefit" 69FR46632.
As a Center serving persons having disability we are concerned about
its impact on persons who are dual-eligible.

At a time when Social Security has spent millions to launch the Ticket to Work program in order to encourage individuals with disabilities to return to work, it is inconceivable that individuals who are dually-eligible may lose their Medicaid protection when the new Medicare Prescription Drug "Benefit" takes effect on January 1, 2006.

This is a giant step backward! It will certainly dissuade many SSI recipients from attempting to return to work. They will quickly come to understand that once they earn enough credits to become eligible for even a small SSDI check, they will lose their Medicaid protection. Many will not be willing to take this risk, and those who have done so in the belief that they will have continuing Medicaid protection will feel that they have been betrayed.

Other dual-eligibles will also suffer. A 25% co-payment for prescription drugs up to $2,400 may seem reasonable, but when one is living on $641.35/month (as are many individuals in RI who are dually eligible), $600/year in co-payments is a hardship. Those who have higher medication costs will really suffer.

We ask that you delay the passage of the Part D program until its impact on the Social Security work incentives is fully understood.

Submitter : Mr. Stephen Suroviec **Date & Time:** 10/01/2004 07:10:29

Organization : The Arc of Pennsylvania

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community.

CMS-4068-P-676-Attach-1.doc

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

To Whom It May Concern:

The name of organization welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The name of organization is standard description of your organization. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Mental retardation is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. For example, the prevalence of epilepsy may be as high as 40% in those with profound mental retardation. Psychiatric and behavioral problems occur in individuals with mental retardation at 3–6 times the rate in the general population. As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

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We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), we recommend that transfer of drug

coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

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

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

of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

- people who are dually eligible for Medicare and Medicaid
- people who live in nursing homes, ICF-MRs and other residential facilities
- people who have life threatening conditions
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Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and

appeals process. We recommend that CMS revamp the exceptions process to: establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies:

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

Thank you for your consideration of our views.

Submitter : Mr. Charles Dauerty **Date & Time:** 10/01/2004 07:10:01

Organization : Haven House

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Based on my examination of CMS-4068-P, Haven House submits the following concerns and comments on the proposed rule, ?Medicare Program; Medicare Prescription Drug Benefit,? published August 4, 2004 in the Federal Register.
As a member of the provider community who is professionally and personally committed to maintaining mental health services of the highest possible quality, I appreciate the opportunity to give comments and voice concerns regarding these proposed regulations.

Sincerely,
Charles Dauerty
President & CEO
Haven House Psychiatric Services

Issues 1-10

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

Concern
? 423.120 Access to covered Part D drugs.
Use of formularies by PDPs or Medicare Advantage (MA) organizations must not be so restrictive as to preclude inclusion of branded medications for those who require them.
PDP utilization reviews/management processes that place significant restrictions on access to medications for certain conditions, such as mental illnesses, definitely hinder successful treatment for many individuals. Therapeutic equivalency is often imprecise and there are studies which indicate that bio-equivalency is not always obtained from generic versions of medications. There needs to be some provision for persons with mental illnesses to have either more open formularies or a streamlined non-formulary request process.

ELIGIBILITY, ELECTION, AND ENROLLMENT

Concern:
? 423.34 Enrollment process.
The impact of this Medicare prescription drug benefit on dually eligible individuals, Medicare/Medicaid) is of great concern. As Medicaid drug coverage terminates for dually eligible individuals on January 1, 2006, I envision disruptions in continuity of prescription medications for many. In Pennsylvania, the provider community has experienced problems in the transition of individuals between Medicare, Medicaid, public sector managed care, and county-funded coverage for people with psychiatric disorders. ? 423.34 has the potential to further confuse these people and to complicate things for providers. CMS needs to ensure that its beneficiaries/customers, especially those who have mental illnesses, are enrolled in prescription drug plans before their Medicaid benefit ends. I believe this could be accomplished through beneficiaries? automatic enrollment in/assignment to a plan with the ability to (later) switch to another plan of choice. This method was used in Pennsylvania when public sector managed care was initiated, and overall worked out fairly well. An alternative method could be to extend the deadline for switching coverage from Medicaid to Medicare. A deadline extension of six months (minimum), along with a high-visibility campaign to educate and enroll vulnerable beneficiaries would be essential in using this option. Either way, provisions must be included to ensure continuity of psychiatric medications in the transition from Medicaid to Medicare coverage. Changing medications used to treat mental illness, (especially with comorbid conditions) is always complex and difficult, with significant (and well documented) levels of patient decompensation and higher system costs when this occurs. Provisions are needed in the enrollment process assuring extended access to medications used to treat mental illnesses in order to minimize harm to individuals.

Concern
? 423.44 Disenrollment by the Prescription Drug Plan (PDP).
I have a grave concern about allowing PDPs to disenroll individuals for ?disruptive behavior?. Depending on the definition of disruptive behavior, this will effectively deny coverage for
those who arguably would need it most. ? 423.44 could be interpreted to permit the disenrolling of persons with dementia, mental illnesses, or mental retardation whose disruptiveness and lack of compliance is a result of their illness or condition. The section also allows PDPs to use an expedited disenrollment process for disruptive behavior. Where will these individuals then obtain these resources to stay out of the hospital, or is inpatient treatment the only alternative for these people? I am well aware (and supportive) of the need to have limits on an individual?s ability to disrupt care, I feel that the individual?s effect on the PDP is far outweighed by the effect of the PDP?s disenrollment on the person?s health. I am also troubled that the PDPs can refuse to reenroll an individual for an unspecified period of time. I understand that an individual who is disenrolled from a PDP may enroll in another, but is subject to a late enrollment penalty. These provisions do not seem to have taken into account much of the characteristics of the population the mental health provider community serves. I strongly recommend revision of this section.
Also, this section?s language - ?materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage? - is vague. Again, what are the criteria for this determination? It is not clear to me that unintentional mistakes or inadvertent omissions would not be treated as criteria for disenrollment.

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Comment
Subpart M ? Grievances, Coverage Determinations, and Appeals
Requirements in this section are overly complex and may be inaccessible to many (if not most) people with mental illness, mental retardation and/or dementia. Several levels of internal appeal are required according to this subpart before an appeal can be made to an administrative law judge. In the real world, access to an administrative law judge is not always possible, especially within a reasonable time frame. Additionally, persons with mental illnesses will certainly have great difficulty navigating these complex and protracted processes. Simpler and quicker processes that require expedited review, especially for immediate needs, must be established.

CMS-4068-P-678

Submitter : Mr. Tom Anzalone **Date & Time:** 10/01/2004 07:10:19

Organization : osora

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

This is a test.....

CMS-4068-P-679

Submitter : Mr. Steven Turney **Date & Time:** 10/01/2004 07:10:04

Organization : Mr. Steven Turney

Category : Other

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,

Steven S. Turney
1948 East Sunrise Blvd. Suite #6
Fort Lauderdale, Florida
33334

CMS-4068-P-680

Submitter : Dr. R.W. Soller **Date & Time:** 10/01/2004 07:10:58

Organization : UCSF Center for Consumer Self Care

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

See attachment for full comments from the UCSF Center for Consumer Self Care, UCSF School of Pharmacy.
R. Williams Soller, Ph.D.

CMS-4068-P-680-Attach-1.doc

UCSF Center for Consumer Self Care

Department of Clinical Pharmacy
School of Pharmacy
University of California, San Francisco

3333 California Street
Suite 420K
San Francisco, CA 94143-0163
(415) 502-7633

October 1, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21224-8014

RE: Proposed Rules, Medicare Program; Medicare Prescription Drug Benefit; 42 CFR Parts 403, 411, 417, and 423 [CMS–4068–P] *Federal Register 2004:* 69(148);46632-46863.

CMS-4068-P

VIA: Electronic Submission:
http://www.cms.hhs.gov/regulations/ecomments

To Whom It May Concern:

The UCSF Consumer Self Care submits these comments in response to the August 3, 2004 publication by Centers for Medicare & Medicaid Services (CMS) of proposed rules relating to the implementation of the new Medicare prescription drug benefit. Specifically, our comments pertain to the new Medication Therapy Management Program (MTMP) provisions that were established by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).

The UCSF Center for Consumer Self Care (CCSC) is a faculty collaboration within the Department of Clinical Pharmacy of the UCSF School of Pharmacy. The Center's mission is to help people take a central role in their own health care. In fulfilling this mission, we view the patient as a consumer of health care, and the central element in a team-managed approach to disease and drug therapy management. UCSF pharmacy faculty has had extensive experience in collaborative care approaches in a variety of clinics within the medical center and in the community setting. This is a result of the California state provisions for pharmacist-furnished medication management services now in place, as well as our faculty's strong support of the now expanded role of the

pharmacist in this area of clinical practice. It is from this experience that we offer our comments.

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Detailed Comments

I. Overarching Perspective: Support for Flexibility in the Development of Regulation and Guidances

[Re: Preamble to Proposed §423.153(d)(1)(iii)]

As part of the preamble to the discussion of MTMPs (see proposed rule at page 46668), CMS states, "We are mindful of the importance of stimulating the evolution of the most appropriate and efficient form of MTMPs, without stifling innovation or prematurely locking-in specific attributes."

The Center agrees with this overarching perspective of flexibility in developing regulation and guidances that would be helpful to the development of this important area of pharmaceutical care service. We support: (a) CMS' approach to seeking public comments on this matter; (b) CMS' intention to undertake additional research and public comment as this public rulemaking proceeds; and (c) CMS' current framing of the proposed rule as a narrow reading of the statute.

As this field develops, experience may identify areas where additional direction from CMS would be helpful through formation of guidances. Hence, a mechanism (e.g., open docket) should be created for use in the early stages of implementation of MTMP-relevant sections of the MMA that would capture recommendations for specific guidances, which would then be evaluated in relation to their need and applicability through public commentary. We believe that this would have the added value of stimulating interest and collaborative development of this area of pharmacist-mediated medication therapy management practice. It would certainly facilitate early resolution of potential conflicts between state and CMS-proposed guidances and regulations.

Furthermore, as this process proceeds, we anticipate that CMS will seek specific evidence necessary to evaluate the need and/or actual usefulness of future regulations and guidances. This should be an open process, and one that CMS actively develops through specific requests for information from interested parties.

Recommendations:

We recommend that CMS should:

- Maintain its current flexible perspective during the development of regulations and guidances for MTMPs;
- Create a mechanism (e.g., open docket) for receipt and public commentary on recommendations for MTMP-related guidances;

- Open all proposed guidance topics and guidances for public comment;

- Develop a process for identifying specific areas for additional research or evidence development that would specify in detail, for example, the scope and nature of information needed, so that there can be feedback on the value of required and other innovative practices.

II. Definition, Providers and Levels of Medication Therapy Management Programs (MTMPs)

[Re: Proposed §423.153(d)(1)(iii)]

A. Proposed Regulatory Definition of MTMPs Appropriately Closely Follows the Statutory Definition in the MMA But Should Be Amended to Qualify Pharmacists as Licensed

The MMA defines a Medication Therapy Management Program as:

> "A medication therapy management program described in this paragraph is a 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." [See 1860D-(4)(c)(2)(A)(i)]

CMS proposes a regulatory definition (see page 46821 of the proposed rule) that closely follows the legal definition.

> "A medication therapy management program – (i) must assure that drugs prescribed in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use; (ii) must, for targeted beneficiaries described in paragraph 9d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions; (iii) may be furnished by a pharmacist; and (iv) may distinguish between services in ambulatory and institutional settings." [See Proposed §423.153(d)(1)(iii)]

In general, we concur that CMS' narrow reading of the act is appropriate in defining the regulatory definition.

Recommendation:

We recommend that CMS:

- Retain the definition for MTMP as the proposed regulation, as it accurately reflects the statutory definition of the MMA.

B. MTMPs Should Be Furnished by Licensed Pharmacists

We believe that the regulation should add a clarification to the statutory intent that MTMPs may be furnished by a pharmacist by adding "licensed" before the word, " pharmacist" at proposed §423.153(d)(1)(iii), The clear intent of MMA is to optimize therapeutic outcomes through clinical practice, which can only be undertaken with a license to practice. While this may seem obvious, specific clarification in the regulation would avoid potential ambiguity that might arise by the final regulation not being specific in this regard. It would also help to specify the scope and nature of professional competency necessary to furnish MTMPs.

In the preamble to the proposed regulation, CMS provided the following interpretation:

> "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 reimbursable when adopted by a plan and only when provided to targeted beneficiaries as defined in 423.153(2) of our proposed rule[1]." (See page 46668 left column, last paragraph, emphasis added)

Potential MTMP services are intended by statute to focus on optimizing therapeutic outcomes and minimizing risks of adverse events, and are viewed by CMS as distinct from those required for dispensing medication. In California, both of these functions are within the scope of the professional practice of a licensed pharmacist.

As a result, we believe that individuals who furnish (i.e., deliver) services under MTMPs that involve patient interactions, such as counseling, preventing adverse experience, and/or optimizing therapeutic outcomes through improved medication use, should be licensed pharmacists.

[1] See page 46821 of the proposed rules. §423.153 (d)(2)"Targeted beneficiaries for the MTMP … 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."

First, it has been our experience in collaborative care clinics in California that licensed pharmacists add a unique expertise to the health care team, based on their educational and clinical practice experience. This experience is specialized in pharmacy school curricula to provide pharmacy students with an understanding of disease processes, disease risk factors, health promotion, the pharmacological basis of drug action, drug safety including drug-drug and drug-food interactions, therapeutic assessments, drug utilization, counseling, pharmacoeconmics, medical product use, and clinical practice, among other areas of study.

Furthermore, pharmacists who maintain their license maintain an up-to-date understanding of evolving health practice through their ongoing clinical experience and certain other requirements relating to continuing professional education and credentialing (addressed below). The ongoing quality assurance of pharmacist competency is enforced by the State Boards of Pharmacy.

Thus importantly, the pharmacy curriculum and State-enforced requirements of pharmacy practice ensure a broad scope of knowledge and expertise pertaining to medical products, especially pharmaceuticals, thereby uniquely qualifying licensed pharmacists as providers of MTMPs.

Second, while individuals providing MTMP services should be licensed pharmacists, they should also engage in on-going competency assessments that are defined by the individual institutions, and organizations[2] through locally-developed and applied quality assurance programs (see comments relating to quality assurance, and pharmacy practice protocols). We believe that, by (a) specifying "licensed" in the proposed regulation at §423.153(d)(1)(iii)] and (b) addressing broad objectives of competency through guidances relating to quality assurance provisions of MTMPs (see below), the necessary standard of care of Part D beneficiaries will be ensured as the State and local level for MTMP services furnished by pharmacists.

In summary, the MMA and appropriately the proposed regulation have identified the pharmacist as a unique provider of services under MTMPs. As noted above, for the benefit and safety of patients enrolled in an MTMP, the regulation should specify that pharmacists furnishing such a program be licensed, to omit any ambiguity about the scope of expertise expected by statute for individuals furnishing MTMPs. Further, CMS

[2] Individual institutions and organizations are defined here to mean any group with administrative responsibilities for assuring the quality of Medication Therapy Management Programs within a facility, including for example hospitals, medical centers, ambulatory clinics, pharmacy organizations, provider organizations, or other facilities providing MTMPs under the MMA.

should rely on the states and on individual institutions and organizations for determining necessary qualifications for pharmacists furnishing MTMPs in their organizations.

Recommendation:

We recommend that CMS:

- Revise the proposed rule to incorporate the terms, "licensed," prior to the word, "pharmacist," at §423.153(d)(1)(iii), as follows:
  "(iii) may be furnished by a licensed pharmacist."

- Rely on the states and local institutions and provide organizations for credentialing and competency of pharmacists providing MTMPs and on local institutions and provide organizations for determining necessary institution-specific qualifications for pharmacists providing MTMP in those organizations.

C. Levels of Care under MTMPs

In the proposed regulation[3] that Section 1860D-(4)(c)(2)(B) of the Act CMS states that MTMPs may include elements to promote: (a) enhanced enrollee understanding (via education, counseling, etc.) that promote the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications; (b) increased enrollee adherence to Rx medication regimens (e.g., via medication refill reminders, special packaging, and other compliance programs and appropriate means); (c) detection of adverse drug events and patterns of overuse and underuse of Rx drugs.

To do this, we understand from the proposed rule that CMS possibly envisions MTMPs may offer a range (i.e., levels) of services from simple to complex including the following services – in addition to those mentioned in the Act and stated by CMS (i.e., as summarized in the above paragraph):

- Performing patient health 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
- Participating in State-approved collaborative drug therapy management

[3] See proposed regulation at page 46668 top, middle column.

- Potentially offered as part of a more comprehensive disease management program

Under certain circumstances, we concur that some MTMPs might offer services that others do not. For example, as a result of specific State-approved collaborative care management services, MTMPs in some states might provide some services that other states might not be permitted to. However, the overall scope of services for each MTMP would need to be basically the same, because the MMA is very specific as to what a medication therapy management program is, as follows:

> "…a 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." [MMA, Section 1860D–4(c)]

Certainly, Congress' intent in passing MMA is to help *every* qualifying beneficiary to improve therapeutic outcomes by improving medication use and reducing the risk of adverse events for every qualifying beneficiary.

Thus, each qualifying beneficiary for MTMP services has a right to expect that the program will deliver on all of the statutory objectives, including its delivery by an individual with his/her scope of practice defined by being qualified as a licensed pharmacist. This is true irrespective of the nature of the clinically related communications between a pharmacist and beneficiary (e.g., face-to-face, telephone, e-mail etc.) that address optimizing therapy and minimizing risks of adverse effects.

As a result, we can only conclude that the providers of MTMPs serving patients at whatever clinically-related communication level must be a licensed pharmacist in order for the MTMP-related clinical communications to meet their statutorily mandated objectives. This does not mean, however, that the pharmacist would not have assistants to aid in administrative matters relating to furnishing MTMP services.

<u>Recommendation</u>:

We recommend that CMS:

- Support a requirement that the individual furnishing a level of service of an MTMP (irrespective of, for example, level of clinically-related communication) that will have an impact on the statutory objectives of optimizing therapeutic outcomes and reducing risk of adverse effects through direct patient interactions be a licensed pharmacist.

III. Best Practices of Medication Therapy Management Services [Re: Response to CMS' Call for Information in the Preamble to §423.153]

A. Introduction

The collaborative care clinics in California represent clinical practice settings that are similar to those that might be envisioned for MTMPs, and therefore are useful models to consider the best practices for MTMPs.

Pharmacists at the University of California San Francisco participate in conducting expanded scope of practice activities in accordance with the California State Board of Pharmacy regulations. General elements of this expanded scope of practice include:

- Protocols describing the specific site are developed and approved by the pharmacists and physician director of the specific service.
- The protocol is approved by the Pharmacy and Therapeutics Committee, the Committee on Interdisciplinary Practice (CIDP) and the Executive Medical Board.
- Protocols follow a prescribed template.
- Competence is established through examination, direct observation and ongoing quality assurance and improvement. Currently protocols exist for the following UCSF clinics: epilepsy, adult hematology-oncology, women's depression clinic, anticoagulation, thyroid, neurosurgery, orthopedic surgery, renal transplant, women's health and comprehensive cancer services.

B. Example of the Value of Pharmacists in Providing Cost-Efficient Medication Therapy Management Services in a Seniors Clinic Affiliated with the University of California

This section provides an example of the types of benefits seniors receive from medication therapy management services, and provides a background for the following section that describes a number of the best practices of such services. The example provided is the current experience of pharmacists on the faculty of UCSF School of Pharmacy at a Seniors Clinic in Sacramento, California.

Overview of the PRICE Clinic[4]: The Pharmacist Review to Increase Cost Effectiveness (PRICE) Clinic in Sacramento, California, represents an innovative model of providing MTMP services as required by the MMA. Operating since 2001, PRICE Clinic pharmacists, staff, and volunteers serve a three-fold mission:

[4] Stebbins, M. PRICE Clinic. (Submitted for publication and under current editorial review.)

1. Help elderly patients decrease out-of-pocket (OOP) drug expenses;

2. Assure that patients receive clinically appropriate, cost-effective drug regimens;

3. Improve access to, and compliance with, needed medications.

These goals are consistent with the statutorily defined objectives of MTMPs to encourage safe, appropriate, and cost-effective medication use among elderly patients with multiple chronic diseases on multiple medications with high costs.

Objectives of the PRICE Clinic Study: Researchers examined the following outcomes of PRICE Clinic interventions: (1) change in generic drug use; (2) savings in OOP drug costs, and; (3) patient access to drugs that had been or would have been discontinued due to cost.

PRICE Clinic Study Methods: In brief, a retrospective review of the PRICE Clinic database was conducted for the 520 patients seen in the PRICE Clinic in 2002. Study participants were low-income elderly with multiple chronic diseases, multiple medications and high drug costs; thus, this cohort reflects the population targeted by the proposed MTMP regulations. Changes in generic drug use and OOP costs were assessed by a pre/post analysis of selected outcome variables. Self-report was used to determine if patients had or would have discontinued medications due to cost, and Price Clinic database analysis determined whether PRICE Clinic interventions enabled patients to continue the medication in question. For each patient, researchers documented the number and type of interventions performed and the drug class involved in each intervention.

PRICE Clinic Study Results: A total of 1297 cost-reducing interventions were conducted among the 520 patients who visited the PRICE Clinic in 2002, an average of 2.5 interventions per patient.

Generic drug use increased from 51% before PRICE Clinic interventions to 56% afterward. OOP medication expenditures decreased from $185 per member per month (PMPM) to $60 PMPM, a 69% percent reduction. On average, PRICE Clinic patients reduced their annual drug costs by $1,500. A total of 215 (41%) patients reported that they had or would soon discontinue drugs due to cost, and 186 (87%) of these patients were able to continue the drug due to PRICE Clinic interventions.

The most common interventions were: pharmaceutical industry-sponsored patient assistance programs (PAP); generic substitution; and therapeutic interchange. The most common drug classes intervened upon were lipid-lowering drugs, ACE inhibitors, and asthma/allergy drugs.

PRICE Clinic Study Conclusions: The PRICE Clinic demonstrates the benefit of expanding medication therapy management services by licensed pharmacists to low-income Medicare beneficiaries with multiple drugs and multiple chronic diseases. By providing pharmacist consultation at the point-of-care to ensure appropriate drug use, decreasing OOP expenditures, and improving access to needed drugs, PRICE Clinic serves as a model for further development and implementation of MTMPs that are furnished by licensed pharmacists under the MMA.

In summary, the elements of pharmacist-furnished medication therapy management services that achieved success in reducing unneeded medications and reducing cost for seniors and for the service included:

- Perform patient health assessments
- Formulate prescription drug treatment plans
- Manage high cost "specialty" medications
- Evaluate and monitor patient response to drug therapy, providing education and training
- Coordinate medication therapy with other care management services

The value of the PRICE clinic approach to medication therapy management is of particular note in light of recent findings published in the *Archives of Internal Medicine*[5], relating to experience at the University of Michigan and Stanford University. The study found that two-thirds of 660 chronically ill patients cut back on their prescription drugs because of trouble paying for them, but did not tell their doctors before they did it. Even after cutting back, 35 percent never told their doctors. Together, this study and the PRICE clinic study show that a pharmacist-managed clinic that proactively seeks ways to help patients improve outcomes and manage costs will meet a current and urgent need, and that the MTMP provision under the MMA as furnished by a licensed pharmacist will help facilitate a collaborative interaction between physicians and pharmacists for the benefit of Part D beneficiaries qualifying for MTMP services.

C. Best Practices in UCSF Collaborative Care Clinics

CMS has requested comments on what constitutes best practices for MTMPs. As stated above, the collaborative care experience of UCSF pharmacists provides a basis for commentary on CMS's request for information in this area.

[5] Federman, AD. Don't ask, don't tell: the status of doctor-patient communication about health care. *Archives of Internal Medicine*. 2004;164:1723-4.

Best practices in UCSF collaborative care clinics are based on the integration of national, state, local and clinic-specific requirements for ensuring provision of quality services that protect and benefit the patient. The delegation of authority to the individual institutions and organizations down to clinic levels is vital to ensure the tailoring of high quality services. Best practices include:

- Provision of medication therapy management services by licensed pharmacists, qualified at the state board and individual institutions and organizations down to clinic levels and under the collaborative practice agreements with prescribers consistent with California law[6];

- Provision of the following core pharmacist-mediated functions necessary for comprehensive medication therapy management services, which are tailored to the type of clinic, and include but are not necessarily limited to:
  - Reviewing patient charts
  - Interviewing patients
  - Performing basic physical assessment
  - Ordering laboratory values
  - Determining and implementing appropriate drug therapy
  - Clinical monitoring of the patient in relation to drug therapy, including specifically performing point-of-care (POCT) testing as a part of appropriate monitoring services (e.g., prothrombin times/INR)
  - Assessment of patient adherence
  - Altering dosage regimens and providing patient instruction in the use of oral and parenteral medications
  - Performing various health screening and health education programs.
  - Managing a medication refill clinic, including medication refill authorization
  - Case management (i.e., coordination of medical and social services)
  - Patient counseling (e.g., alcoholism treatment, nutrition, physical activity)

[6] California, like 31 other states, permits pharmacists to administer drug therapy under collaborative protocols (also known as collaborative practice agreements) with prescribers. However, prior to 2002 when new legislation took effect, California's collaborative protocols had limited utility in terms of significantly increasing consumer access to prescriptive contraception including emergency contraception. Most pharmacy laws in the United States governing collaborative protocols are intended to be patient specific, and often further specify that the physician first see the patient for the condition being treated by the pharmacist. This provision alone in California prohibited pharmacists operating under collaborative protocols from serving the broader community. From: Pharmacy Access Partnership. See Hhttp://www.pharmacyaccess.org/ECStoryInCA.htm#Collaborative_ProtocolsH. Accessed September 19, 2004.

- Home visits
- Drug therapy consultation to collaborating clinic nurses and physicians
- Review of patient income and prescription drug coverage to determine ability to pay for medications

- Provision of a quality assurance program, including: State-related and credentialing by the individual institution or organization; initial and periodic competence reviews by the individual institution or organization; and general institutional/organizational guidance and clinic-specific practice protocols, which are addressed in the next section.

D. Quality Assurance Requirements in UCSF Collaborative Care Clinics

1. The Overarching Perspective for Quality Assurance Requirements for MTMPs Should Be One that Uses a Guidance Approach and Allows for Flexibility and Innovations.

As noted above, UCSF collaborative care clinics have successfully provided a scope of practice by licensed pharmacists that includes many, if not all, of the possible services that might be encompassed under a final rule relating to MTMPs.

The approach taken by our clinics is to provide general guidance for assuring quality in the provision of care for each clinic and require that each clinic develop its own specific standard operating procedures for assuring quality of service. We believe that this type of approach should be used by CMS – i.e., development of guidance on quality assurance for MTMPs that is flexible and allows for innovations.

First, given that this specific area of government oversight is new to CMS and the regulated industry, creation of detailed regulatory requirements would be presumptive. A guidance approach is less burdensome and more responsive to potential innovations.

Second, the physical layout, technological support, the clinical services and support personnel provided by different UCSF collaborative clinics differ from site to site. When it comes to detailed standard operating procedures, our experience is that one size does not fit all. For example, services provided to an acute care (hospitalized) population of patients will differ from an ambulatory care group of patients.

Hence, any guidance in this area should be flexible, allowing for local tailoring of QA programs to meet the broader goals and objectives stated in the guidance.

In sum, CMS should specify the broader goals and objectives that a quality assurance program associated with a MTMP should achieve, but not get mired in the details of all the specifics that each QA program might explain to be site-specific.

Recommendation:

We recommend that CMS:

- Use a flexible guidance approach to addressing quality assurance for MTMPs that favors innovation and site-specific applications;

- In using a guidance approach, identify broader goals and objectives in a general guidance, thereby allowing individual MTMP programs to create clinic-specific protocols and standard operating procedures for quality assurance.

2. Specific Elements of Quality Assurance Guidance for MTMPs

MTMPs should be flexible to permit inclusion of state provisions for pharmacy practice, such as those relating to expanded scope of practice in California. In this context, therefore, we believe that it would be useful for CMS to consider the value of Pharmacy Practice Protocols in the development of quality assurance components of MTMPs.

Specifically at UCSF's expanded scope of practice clinics, licensed pharmacists may furnish all of the services outlined in Section III.C. above, although specific services are tailored to the specific clinical site. In participating in these services, UCSF pharmacists must comply with the provisions of the quality assurance and peer review provisions of the Pharmacy Practice Protocol found in Appendix A.

Briefly, consistent with the MMA and proposed regulation, pharmacists and the physician director of the clinic collaborate in developing and approving each clinic-specific practice protocol. In turn, each protocol must be approved by the Pharmacy and Therapeutics (P&T) Committee, the Committee on Interdisciplinary Practice (CIDIP) and the Executive Medical

Board – thereby ensuring peer review. Each protocol must follow a standard template (attached in Appendix A).

Furthermore, assessments of hospital credentialing and competence are incorporated as a matter of quality assurance in the Pharmacy Practice Protocols. Specific documentation is required, and it is the responsibility of the pharmacist practicing under the protocol to ensure his/her files are complete and updated. This documentation includes:

As required to be maintained in the files of the appropriate Human Resource Department(s)

- Xeroxed copy of current Pharmacy license
- Xeroxed copy of residency certificate(s)
- Xeroxed copy of specialty board of certification (if applicable)
- Current curriculum vitae, with a special effort to include a listing of all publications and lectures given that demonstrate recognized expertise in the field of practice
- Listing of all continuing education seminars/sessions attended for the current year and two complete calendar years prior to the current year, with special efforts made to attend professional meetings and obtain continuing education credits within the pharmacist's field of expertise
- Initial Peer Review performance Evaluation form (see Appendix A)
- Annual Performance Evaluations, including the Peer Review Performance Evaluation Form from physicians and nurses
- Current CPR certification

As required to be maintained in the office of each clinical pharmacist practicing under protocol

- A copy of the current practice protocol
- A copy of the semi-annual quality improvement reports for the clinic (for the last two years)

In addition, pharmacists practicing under protocol must complete UCSF-required (i.e., local to the individual institution or organization) pharmacy competency examinations or assessments (e.g., CPR certification).

Credentialing of clinical pharmacists practicing under protocol is performed by the Committee on Interdisciplinary Practice every 2 years. It is the responsibility of each pharmacist practicing under protocol to ensure his or her files are complete and updated

annually. An example of the peer review form used appears in Appendix A.

Notably, it is our experience that the policies and procedures do not need to be complicated to be effective. Based on our experience, we strongly recommend that CMS outline the main goals and objectives to ensure credentialing and competence as well as protocol development, use and maintenance, and to allow the individual institutions or organizations and ambulatory settings determine the details (i.e., general guidance for operations within the individual institution or organization, and clinic-specific standard operating procedures and protocols).

Recommendation:

In sum, we believe that CMS:

- Should consider the elements of "pharmacist practice under protocol" as a reference model in developing a guidance to individual institutions and organizations in developing quality assurance systems and documentation systems associated with MTMPs. We do not believe that CMS should specifically create forms and detailed procedures, but we do think that a broader level of guidance would be helpful in creating a basic framework of consistency across programs.

IV. Evaluation of PDPs and MA-PDs Based on Medication Errors

CMS asks how should PDPs (Prescription Drug Programs) and MA-PDs (Medicare-Advantage Prescription Drug Programs) be evaluated based on the types of quality assurance they have in place, including the use of error rates to compare and evaluate plans. Specifically, CMS asks whether the definition of medication error (ME) used in FDA's bar code rule and adopted by the National Coordinating Council for Medication Error Reporting (NCCMER) be used as a criterion for assessing quality. This definition of medication error used by FDA and NCCMER is:

> "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (See 68 FR 12500 (March 14, 2003))."

While the proposed definition is appropriate in a general sense to frame the scope of potential MEs, it has practical limitations requiring clarification and refinement.

We believe that, for purposes of evaluating PDPs and MA-PDs, the following interpretative language should be used to refine the application of the proposed definition:

> "A ME should be considered source data for evaluating quality if: (a) it is documented to have occurred; and (b) determined to have resulted in the application, delivery or use of an incorrect product, incorrect dose, incorrect timing of dose, and (c) not corrected prior to the patient receiving treatment or product."

Our reasoning is as follows. The proposed definition neither requires documentation of the ME, nor allows for correction of the ME by a quality assurance system, which would include investigation and correction of the root source of the error.

A medication error is relevant if it results in harm to the patient due to failure of quality assurance systems. If the error is corrected because an MTMP has an effective quality assurance system, then the MTMP should not be given a poor evaluation, or be assessed in a way that could be misinterpreted to mean it should have a poor evaluation. The fact that the QA system in the MTMP caught the error means it is an effective system. Therefore, the proposed definition is limited in its application.

Systems evaluations should be evidence based, and that evidence should stand the test of documentation and review by internal quality assurance systems. Hence, there needs to be an interpretative phrase relating to documentation and review, as suggested above.

Recommendation:

We recommend CMS should:

- Refine its proposed application of the definition of medication errors (MEs), as follows:

  > "For purposes of evaluating PDPs and MA-PDs, a ME should be considered source data for evaluating quality if: (a) it is documented to have occurred and (b) determined to have resulted in the application, delivery or use of an incorrect product, incorrect dose, incorrect timing of dose, and (c) not corrected prior to the patient receiving treatment or product."

V. Summary of Recommendations

We recommend that CMS should:

- Maintain its current flexible perspective during the development of regulations and guidances for MTMPs;

- Create a mechanism (e.g., open docket) for receipt and public commentary on recommendations for MTMP-related guidances;

- Open all proposed guidance topics and guidances for public comment;

- Develop a process for identifying specific areas for additional research or evidence development that would specify in detail, for example, the scope and nature of information needed, so that there can be feedback on the value of required and other innovative practices.

- Retain the definition for MTMP as the proposed regulation, as it accurately reflects the statutory definition of the MMA.

- Revise the proposed rule to incorporate the terms, "licensed," prior to the word, "pharmacist," at §423.153(d)(1)(iii), as follows:

  "(iii) may be furnished by a licensed pharmacist."

- Rely on the states and local institutions and provide organizations for credentialing and competency of pharmacists providing MTMPs and on local institutions and provide organizations for determining necessary institution-specific qualifications for pharmacists providing MTMP in those organizations.

- Support a requirement that the individual furnishing a level of service of an MTMP (irrespective of, for example, level of clinically-related communication) that will have an impact on the statutory objectives of optimizing therapeutic outcomes and reducing risk of adverse effects through direct patient interactions be a licensed pharmacist.

- Use a flexible guidance approach to addressing quality assurance for MTMPs that favors innovation and site-specific applications;

- In using a guidance approach, identify broader goals and objectives in the guidance, thereby allowing individual MTMP programs to create tailored standard operating procedures for quality assurance.

- Should consider the elements of "pharmacist practice under protocol" as a reference model in developing a guidance to individual institutions and

organizations in developing quality assurance systems and documentation systems associated with MTMPs. We do not believe that CMS should specifically create forms and detailed procedures, but we do think that a broader level of guidance would be helpful in creating a basic framework of consistency across programs.

- Refine its proposed definition of medication errors, as follows:

  For purposes of evaluating PDPs and MA-PDs, a ME should be considered source data for evaluating quality if: (a) it is documented to have occurred and (b) determined to have resulted in the application, delivery or use of an incorrect product, incorrect dose, incorrect timing of dose, and (c) not corrected prior to the patient receiving treatment or product.

In closing, we would be pleased to provide any additional follow-up information or clarification pertaining to these comments.

Sincerely,

R. William Soller, Ph.D. *Steven R. Kayser, Pharm.D.*

R. William Soller, Ph.D.
Executive Director
Center for Consumer Self Care
Clinical Professor of Pharmacy
Department of Clinical Pharmacy
UCSF School of Pharmacy
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Steven R. Kayser, Pharm.D.
Professor of Clinical Pharmacy
Vice Chair
Department of Clinical Pharmacy
UCSF School of Pharmacy
Chair, CCSC Discussion Group on
Medication Therapy Management

Appendix: Pharmacy Practice Protocol: Policy and Procedures

(See next page for appendix.)

Appendix

Implemented YEAR
Revised MONTH/year, MONTH/YEAR

Pharmacy Practice Protocol

Policy:

The Department of Pharmaceutical Services, with the Department of Clinical Pharmacy, requires pharmacists conducting expanded scope of practice activities to function under a ten protocol, approved by the Pharmacy and Therapeutics Committee, the Committee on Interdisciplinary Practice, and the Executive Medical Board. Annual certification of competency is required. Record-keeping requirements must be adhered to.

Procedure:

1. Practice Protocol Development and Approval

a. Each protocol must be developed and approved by the pharmacists and the physician director of the service with which he/she is working.
b. Each protocol must be approved by the Pharmacy and Therapeutics Committee, the Committee on Interdisciplinary Practice (CIDP), and the Executive Medical Board (EMB).

2. Practice Protocol Template

a. Each protocol must follow a prescribed template, as directed by the CDIP.

3. Credentialing and Competence

Competence is established through this mechanism:

a. Pharmacy competency examinations in the following areas: pediatrics, geriatrics, antibiotics and drug information.
b. Initial and annual Peer Review Evaluation Form. (attached)
c. A semi-annual quality improvement report must be completed and forwarded to the physician director of the service with whom the pharmacist is working.

4. Documentation of Credentialing and Competence

a. Documentation is required and is the responsibility of each pharmacist practicing under the protocol to ensure his/her files are complete and updated. (see attached)

Implemented YEAR
Revised MONTH/year, MONTH/YEAR

Pharmacy Practice Protocol

Documentation for Pharmacy Practice Protocol

1. Documenting of Credentialing and Competence

A. Intradepartmental

The following documentation will be kept on file in the office of Human resources in the Department of Pharmaceutical services (for Medical Center employees) of the Department of Clinical Pharmacy (for School of Pharmacy employees)

a. Xeroxed copy of the current California Pharmacy License
b. Xeroxed copy of the Pharmacy Residency Certificate(s)
c. Current Curriculum Vitae (making special effort to include a listing of all publications and lectures given that demonstrate recognized expertise in the field of practice)
d. Listing of Continuing Education seminars/sessions attended for the current year and complete calendar years prior to the current year. Special efforts should be made to attend professional meetings and obtain continuing education credits within the pharmacist's field of expertise.
e. Initial Peer Review: performance Review Evaluation form
f. Annual peer review: Performance Review evaluation Form
g. Periodic Competency Assessment documents for merit and promotion (for School of pharmacy Employees)
h. Current CPR Certification

The following will be kept in the office of each clinical pharmacist practicing under protocol

B. The Credentialing Files at the Medical Staff Office (Box xxxx)

The Pharmacy administration Office (xxx-xxxx) will make available all appropriate Pharmacy Practice Protocol documentation upon request from the Medical staff Office.

The Committee on Interdisciplinary Practice will review the pharmacist's credentialing file every 2 years.

C. Responsibility for Upkeep

It is the responsibility of each pharmacist practicing under the protocol to ensure his or her files are complete and updated annually. It is the responsibility of the pharmacist representing the Department of Pharmaceutical Sciences on the Committee on Interdisciplinary practice to maintain a file of all current and past versions of pharmacy practice protocols.

Implemented 1998

Implemented YEAR
Revised MONTH/year, MONTH/YEAR

Pharmacy Practice Protocol
Peer Review Performance Review Evaluation Form
For
Pharmacists Practicing under Pharmacy Practice Protocols

Department of Pharmaceutical services
Medical Center
Name of the pharmacist undergoing evaluation:_____

☐ Initial Assessment (first three patients seen under protocol) Time frame for Evaluation:_____
☐ Ongoing Assessment Time frame for Evaluation:_____

Activity	**CE**	**MA**	**M**	**PM**	**FM**
1. Exhibits sound clinical judgment in the areas of pharmaceutical care outlined in the pharmacy practice protocol.					
2. Knows the limitations of the protocol and knows when to ask for assistance from a physician or nurse.					
3. Interacts well with patients and their representatives.					
4. Communicates all important and pertinent information in a timely fashion.					
5. Represents the service positively, when interacting with other medical center personnel and external entities.					
6. Communicates clearly; both verbally and in writing.					
7. Exhibits a professional demeanor at all times.					
8. Coordinates problem-solving efforts to ensure medical center standards are net for service and quality.					
9. Maintains current knowledge of recent developments in the field of specialization.					
10. Is a “team” player on the multidisciplinary team.					
11. Plans appropriately and manages time to enable completion of assigned work.					
12. Is dependable and responsible.					
13. Resolves conflict through appropriate interventions.					
14. Conducts/participates in quality improvement efforts for the service.					

Implemented YEAR
Revised MONTH/year, MONTH/YEAR

Pharmacy Practice Protocol

Please add any additional comments below:

_____ _____
Your name (MD)/Title MD Signature

_____ _____
Your name (Pharmacist)/Title Pharmacist's Signature

_____
Today's Date

Name: (insert name)
Title: (insert title)
Phone Number: (xxx) xxx-xxxx
Email address: xxx.xxxx@ccccc.org

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

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

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CMS-4068-P-681

Submitter : Dr. Asha Pai **Date & Time:** 10/01/2004 08:10:40

Organization : Hayes-Barton Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

I believe that the Medication Therapy Management responsibility should be placed with clinical pharmacists due to our area of expertise dealing mainly with medications and medication management. These consultations should be performed on a face-to-face basis with the patient and/or the caregiver. In circumstances in which the patient is not able to meet with the pharmacist, other means of communication will need to be used and properly documented. In order to ensure the continuity of care and to ensure improved health outcomes for each patient, regular communication with the patient's other health care providers should be maintained. In order to enhance this process, documentation of each encounter with a patient and/or health care provider should be maintained. The idea of this program is to decrease the overall cost to the healthcare system and by performing the services outlined in the Program Criteria (along with communication with other providers) this goal can be reached effectively. This being stated, I believe that as members of a healthcare team, clinical pharmacists should be reimbursed equally comparable to other health care providers for the time and effort of performing such services.

In conclusion, I do believe that providing coverage for Medication Therapy Management services will benefit the patient as well as the healthcare system. I am confident to say that clinical pharmacists, along with proper communication to various other healthcare providers, will be able to deliver such management with the necessary responsibility and knowledge required.

CMS-4068-P-682

Submitter : Mrs. Susan McKay **Date & Time:** 10/01/2004 10:10:41

Organization : Office of Susan B. McKay

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

There are perscription drugs that have been excluded from Medicare perscription drug coverage such as benzodiazepines except for smoking cessation and agents for anorexia, weight loss or weight gain and vitamins and minerals that should be considered for coverage. Benzodiazepines are medical necessary for the treatment of various anxiety disorders that are general and Panic disorder, Phobias, Post-Traumatic Stress Disorder, Obsessive Compulsive disorder and seizure disorders. They are also perscribed for bipolar disorder and for sleep disorders , treat Parkinson's disease, twitching ,schizophrenia and pain management. These drugs are also used in cancer chemotherapy as an antiemetic (to prevent nausea) and used to treat Irritable bowel syndrome and other gastrointestinal disorders and to control agitation caused by alcohol. There are many clients that can't take anti-depressant medications in place of benzodiazepines because these drugs would require them to become hospitalized due to certain medical conditions such as bipolar disorder. Benzodiazepines are also addictive. Withdrawl from these perscriptions require hospitalization. It is discriminatory to not include coverage of benzodiazepines for the mental ill population and maybe in violation of the ADA. Benzodiazepines must be included in all Medicare perscription Drug Formularies as an exception. Coverage of benzodiazepines would be cost effective as there would be less hospitalizations and misuse of other drugs that can not be subsituted for benzodiazepines.
There should also be an exception for coverage for agents used for weight loss or weight gain. There are clients in Homes that can not eat or swallow on their own and require agents for weight gain by feeding tubes. Agents for weight gain are also used in the treatment for anorexia. Without these agents the clients would die or have to be moved into a General Hospital. Also the eldery require certain agents for weight gain because they need protein in their diet and to help with the treatment of low salt, virus, and other medical conditons to restore good health. Agents for weight loss could be medical necessary for surgery.
Perscription vitamins and minerals are medical necessary for various condtions . Shots of B vitmins are medical necessary for treament of cancer and other conditons. Cetain vitamins are perscribed for heart condtions and mood disorders - these should be considered as an exception. The list of Drugs subject to Restriction is very Old
and outdated and Seniors and the Disabled Population must have access to the perscriptions they need

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Many insurance contracts will not provide benefits that a person is eligible to receive under a federal program such as Medicare. These are contracts are for the population of 3 million beneficaries that have coverage because an individual or their spouse is self employed are covered by an employer plans with less than 100 employees for those disabled under 65 and for those working over 65 with small employer plans with less than 20 employees- There should be no user fees to coordinate benefits for these Medicare beneficaires and their private plans

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

Only a psychiatrist is qualified to perscib an anti-depressent medication - Internists, and Cardiologists often perscrib these drugs without having the client monitored or evaluated by a qualifed professional- It should be required that Medicare beneficaries be evaluated by a psychiatrist to determine if they need an anti depressant medication and monitored by a therpist when given anti-depressents by an internist of other kind of doctor. often these clients require hospitalization because they have not been correctly perscribed an anti-depressant medication and have not been evaluated or monitored. Some of these clients turn out to have alheimer's disease or another medical issue like drug interaction

ELIGIBILITY, ELECTION, AND ENROLLMENT

It would be helpful for those who are already on Medigap plans that are currently getting enough perscription drug coverage on these plans to enroll onto Medicare perscription Drug coverage at a later time without penalty- This will be helpul with the transitional process in getting beneficaries enrolled into the program-and perserve Medicare costs
Also it is unfair to have Medicare beneficaries be subject to a penalty

because their current Medigap plan covers perscriptions that the Medicare perscription plans do not cover.

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

Medicare Benficiaries that have a Medigap plan or prestandardized plan and State Assisted perscription Drug coverage can be considered ineligible for medicare perscription drug coverage and can keep their benefits as is - Many State Assisted Plans require that members must enroll into plan that they are eligible to receive before providing benefits- These members should not be subject to Medicare perscription Drug premiums and their benefits should be all coordinated right at the pharmacy- no paper work to send in for reimbursements- Exemption from user fees is good also

CMS-4068-P-683

Submitter : Ms. Lila Richardson **Date & Time:** 10/01/2004 08:10:40

Organization : Vermont Coalition for Disability Rights

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

October 1, 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 writing on behalf of the Vermont Coalition for Disability Rights (VCDR). VCDR welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. VCDR is a cross-disability coalition of 27 member organizations.

VCDR is concerned that the proposed rule does not provide sufficient protections for Medicare beneficiaries with disabilities and chronic health conditions. We are also concerned that implementation of the proposed Medicare Part D benefit will result in a serious loss of pharmacy assistance to low-income Medicare beneficiaries in the state of Vermont.

Vermont has developed two pharmacy assistance programs under an 1115 waiver in order to provide its low income Medicare beneficiaries with necessary prescription coverage. We have reviewed comments from the state Office of Vermont Health Access which describe in detail how the Medicare Modernization Act and the proposed regulations will adversely affect the state's ability to continue to provide this vital coverage to vulnerable senior citizens and people with disabilities. We support the state's comments and hope that the final regulations will be changed to enable Vermont to continue to provide pharmacy coverage to supplement the federal Medicare prescription benefit without jeopardizing funding for other critical health care programs.

The following are critical recommendations:

CMS should not include recipients of Vermont's pharmacy-only benefit programs for Medicare beneficiaries as dual eligibles in calculating Vermont's phased down state contribution.

The appeal and grievance mechanisms for individuals needing prescriptions not covered by a plan formulary must be strengthened to provide basic due process rights including adequate notice and opportunity for hearing and prompt resolution of disputes. Without these protections vulnerable Vermonters will lose access to medically necessary drugs.

Transitions from Medicaid coverage to Medicare coverage for dual eligible low-income beneficiaries must be made with as little disruption to existing treatment as possible.

CMS should treat recipients of home and community based waiver services the same way as it treats individuals in institutions for eligibility for full low income subsidies. There is no logical basis for distinguishing between the two populations.

VCDR strongly supports the suggestion in the proposed rule
that certain populations require special treatment due to
their unique medical needs and the enormous potential for

serious harm (including death) if they are subjected to
formulary restrictions and cost management strategies envisioned for the Part D program. Certain groups must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply at least to individuals in nursing homes, to individuals receiving benefits under the home and community based waiver and to individuals who have pharmacologically complex condition such as multiple sclerosis, serious mental illness and HIV/AIDS.

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

Sincerely,

Lila Richardson
Vermont Coalition for Disability Rights
P.O. Box 606
Montpelier, Vt. 05601

CMS-4068-P-684

Submitter : Ms. Therese E. Aprile **Date & Time:** 10/01/2004 08:10:59

Organization : Long Island Center for Independent Living, Inc.

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from Disability Community.

CMS-4068-P-684-Attach-1.doc

To Whom It May Concern:

The Long Island Center for Independent Living, Inc. (LICIL) welcomes the opportunity to
provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. LICIL is a general advocacy organization dedicated to the rights, interests and empowerment of persons with disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

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

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

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

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

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

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

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the

regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

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

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

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

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

Thank you for your consideration of our views.

Very truly yours,

Therese E. Aprile, M.A.
Director of Systems Advocacy

CMS-4068-P-685

Submitter : Mrs. Kathy Migita **Date & Time:** 10/01/2004 08:10:13

Organization : LACERA

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

See attached.

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

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CMS-4068-P-686

Submitter : Linda Scherer **Date & Time:** 10/01/2004 08:10:47

Organization : Voice of the Retarded (VOR)

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

RE: Comments related to Part D proposed Regulations - 69 Fed Red 46632(AUG 3, 2004)

I strongly support the comments that VOR(Voice of the Retarded) has sent to you explaining the need for ICFs/MR, Intermediate Care Facilities for the Mentally Retarded, be included in the ***long term care facilites*** that serve folks with combination Medicare/Medicaid.

Individuals who choose an ICF/MR setting are among the most medically fragile of persons who have mental retardation - oftentimes very sensitive to many medications. All should be covered - individuals residing in an ICF/MR, persons who might choose that level of care in the future and also home and community based waiver recipients as well because these regulations must allow for the best medical decisions based on each person's need and not on where that person happens to live.

Thank you.

Sincerely,
Linda D. Scherer
MCAR(MD Coalition of Advocates for the Retarded) and VOR(Voice of the Retarded)
11 Colgate Ct
Catonsville, MD 21228
410-744-7421
fax:410-744-0481
lscherer@bcpl.net

CMS-4068-P-687

Submitter : Ms. Heidi Margulis **Date & Time:** 10/01/2004 08:10:57

Organization : Humana Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find comments from Humana regarding the CMS proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program

CMS-4068-P-687-Attach-1.doc

Humana Inc.
500 West Main Street
Louisville, KY 40202

October 1, 2004

The Honorable Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

Attn: CMS 4068-P and CMS-4069-P

Dear Dr. McClellan:

The purpose of this letter is to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program enacted in Title I and Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We have also attached a recent letter Humana submitted to you regarding the regional PPO program.

Humana Inc., headquartered in Louisville, Kentucky, is one of the nation's largest publicly traded health benefits companies, with approximately 5.8 million medical members located primarily in 15 states and Puerto Rico. We offer coordinated health insurance coverage and related services - through traditional and Internet-based plans - to employer groups, government-sponsored plans, and individuals. As of January 2004, Humana serves over 350,000 Medicare beneficiaries in markets across the nation.

Humana is also a member of America's Health Insurance Plans (AHIP), the principal national trade association representing companies that provide health benefits to consumers and employers throughout the United States. We provided technical input into the AHIP's comments regarding the proposed rules for the Medicare Prescription Drug Benefit and the MA Program, and want to express our support for and agreement with the comments and recommendations submitted to CMS by this organization. Additionally, we are appending a copy of our recent letter to you reiterating our support for considering participation in the regional PPO program should there be fewer than 50 regions and our belief that the Secretary must use his authority to ensure that seniors, no matter where they live, have access to coverage choices with adequate provider networks.

As a strong supporter of the MMA, we commend the CMS' efforts to expeditiously issue proposed rules for both these programs as well as your outreach efforts to explain the provisions and seek guidance. Given the short timeframe for many of the Act's program effective dates, we urge CMS to promulgate the final regulations as quickly as possible to ensure that interested entities can make the kinds of decisions necessary for operational implementation. We believe the law and subsequent final regulations should strengthen the Medicare program and should protect and provide seniors with meaningful choices of affordable, quality health care coverage.

We appreciate the opportunity to provide these comments. Humana has enjoyed a long partnership with the federal Medicare program, and we look forward to working with you to strengthen the Medicare program for today's seniors and future generations. If you have any questions, please do not hesitate to contact me.

Sincerely,

Heidi Margulis

Heidi Margulis
Senior Vice President, Government Relations
Humana Inc.

CMS-4068-P-688

Submitter : Mr. Jeffrey Rogers **Date & Time:** 10/01/2004 08:10:54

Organization : Southern Tier Independence Center

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

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

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

Advocates, and the Social Security Administration, have worked hard over the last 10 years to remove disincentives to work for beneficiaries. Almost all beneficiaries reported that the loss of health care coverage was the greatest disincentive to work. In today's technology, anyone who can use a computer or swipe an object over a detector can work. The Americans with Disabilities Act addresses discrimination. So why did so many Americans with Disabilities not work? Simple answer: They stayed home to stay poor in order to get health care. As it stands now, the Part D program reinstates the same work disincentives advocates, and the Social Security Administration, have worked hard to eliminate for the last 10 years.

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

I recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

Thank you for your consideration of my views.

Yours sincerely,
Jeffrey S. Rogers MSC

CMS-4068-P-689

Submitter : Mr. Timothy Kremer **Date & Time:** 10/01/2004 08:10:35

Organization : Thrifty White Pharmacy

Category : Individual

Issue Areas/Comments

Issues 1-10

BACKGROUND

I am a district manager for a retail drug store chain servicing customers in small rural communities. I am very concerned about the amount of control this will give PBM's over the patients care.

Our customers should be able to have freedom of choice when it comes to which pharmacy they want to have their precriptions filled at.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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

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

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

ELIGIBILITY, ELECTION, AND ENROLLMENT

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

Submitter : Dr. Grace Chen **Date & Time:** 10/01/2004 08:10:09

Organization : Dean Health Systems

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Allow all pharmacists to be providers.

CMS-4068-P-690-Attach-1.doc

Center for Medicare and Medicaid Services
Dept. Health and Family Services
Attn: CMS-4068-P
Baltimore, MD 21244-8014

October 1, 2004

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare part D rules. As a pharmacist, I have worked in both community pharmacy and now in the clinic setting as part of a major health system in southern Wisconsin; I am deeply concerned with the rules as they are currently proposed.

First, I would like to express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I know that my concern and the concern of other pharmacists around the nation are being considered.

For this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all pharmacy providers that perform medication therapy management (MTM) services. I believe many pharmacy services are invaluable as pharmacists provide both clinical and practical information for patients and other health care providers. For example, in the clinic where I work currently, we often spend as much as 30 minutes per patient just to ensure they are receiving the proper medication through a home health agency.

Similarly, when a patient starts on anticoagulation therapy, we also spend as much as 60 minutes with the patient educating them on the importance of their medication and how to take them. Initially, achieving the proper therapeutic dose can be difficult. Pharmacists are equipped with a thorough understanding of pharmacodynamics, kinetics, and drug interactions that may or may not affect the titration of the medication. Again, this service is invaluable to the patient as pharmacists can explain these things so the patient is better able to understand what will and will not affect their drug therapy.

Having worked in community pharmacy, I have witnessed first hand the importance of the pharmacist to the patient in that setting. As a knowledgeable source of health information, the pharmacist can often identify a patient who needs to be seen by a physician. More importantly however, is the time spent on interventions such as drug allergies or drug interactions. Whether the interaction requires a change in medication or not, the pharmacist can counsel patients on what to be cautious of when taking medications that have even a slight interaction.

Ideally, all pharmacists would be providers, and CMS would provide a minimum requirement of MTM reimbursement, and plan sponsors could cover more than the required amounts. I agree there should be a different level of service. When a pharmacist spends 60 minutes on an initial consultation in anticoagulation clinic, reimbursement should be greater than an intervention made on a slight drug interaction. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber (such as kinetics dosing, anticoagulation management, etc.). In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In conclusion, pharmacy is an integral part of the health care system. Including pharmacists in the new Medicare benefit will allow them to perform the services they are best equipped to perform. These services include advising and counseling patients, as well as providing professional clinical input to the health care team. Medicare must make specific requirements of the plan sponsors, or many of the nation's foremost pharmacy practices may not be included in the various plan programs. Interested pharmacies must be allowed to participate fully and equally. Finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program, based on cost savings to the plan sponsors.

Thank you for your time and consideration. Sincerely,

Grace Chen, Pharm.D.

CMS-4068-P-691

Submitter : **Date & Time:** 10/01/2004 08:10:54

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

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 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 the 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 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.

In conclusion, I urge CMS to revise the regulation to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level.

Thank you for considering my view.

Sincerely,

Jenny Gibson PharmD, RPh

CMS-4068-P-692

Submitter : Ms. Jane Cheshire Gilbert **Date & Time:** 10/01/2004 08:10:55

Organization : Kentucky Teachers' Retirement System

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

Kentucky Teachers Retirement System (KTRS)
Medicare Modernization Act (MMA)
Comments on Proposed Rules Published in Federal Register Dated August 3, 2004
Submitted electronically to http://www.cms.hhs.gov/regulations/ecomments on October 01, 2004

Kentucky Teachers Retirement System, on behalf of our Medicare Eligible Health Plan and our Medicare Eligible retirees, thank CMS for the opportunity to submit comments relative to your specific request to hear from governmental entities who intend to remain primary payors for their existing drug plans and apply for the retiree drug subsidy available under the MMA.

KTRS has been offering health coverage to retired teachers since 1965, and currently covers over 18,000 Medicare eligible teacher retirees and eligible dependents. KTRS is not required by law to provide a medical benefit in addition to the pension benefit, but we have and would like to continue providing health care benefits to the extent that funding allows. Our fiscal year ended June 2004 brought an unwanted milestone where our medical expenditures exceeded our actual revenues in our Medical Insurance Fund. The subsidy for primary payors created by the MMA will be valuable to KTRS and one of many solutions to contain costs within our Medical Insurance Fund. KTRS simply requests that CMS keep the processes of implementation, administration, and recovery as least complex as possible so that our savings from the subsidy will not be eroded by added administrative costs or payments to outside vendors. More specifically, KTRS requests:

o Regarding the four payment methods, final settlement must be submitted by the start of the fourth month following the close of the calendar or plan year. Based upon our existing agreement with our pharmaceutical benefits manager, this deadline will be impossible and will prevent KTRS from remaining primary for the drug plan. We respectfully request the four months be changed to at least 9 months.

o In setting the criteria for actuarial equivalence, KTRS requests that CMS base this upon averages with much flexibility so that KTRS may remain primary.

CMS-4068-P-693

Submitter : Mr. Michael Suwalski **Date & Time:** 10/01/2004 08:10:15

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Under Subpart C please revise the access standards to ensure they meet TRICARE access standars by zipcode instead of averaging them over the larger areas. It is the only way to ensure access for all patients equally. It is also very important that you provide equal access for all community pharmacies and that plans can NOT favor mail order. These patients look to us for our help with their healthcare, and it is WRONG if you favor a plan that gives mail order pharmacies an advantage over their neighborhood stores.

Under subpart D please also make sure that all community and neighbor hood pharmacies are included in the delivery of medication therapy management services. These patients see us on a daily basis and the face to face contact with their neighborhood pharmacists is critical to the success. Patients trust their neighborhood pharmacists and constantly look to us for help, please don't prevent us from helping these patients.

CMS-4068-P-694

Submitter : Mr. James Goodale **Date & Time:** 10/01/2004 08:10:51

Organization : Walgreen Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to submit comments on the proposed regulation regarding the new Medicare prescription drug benefit.

As a pharmacist, I am concerned about my patients' equal access to service from pharmacy providers of all types (retail nad mail-order pharmacies). There is a broad spectrum of pharmacy services offeredin today's environment, and it is important for patients to have a choice in who fills their prescriptions and how their prescription are ultimately delivered. I am opposed to any restriction placed on a patient that would prevent them from using their local retail pharmacy.

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

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

Thank you for making the needed revisions to best serve all Medicare beneficiaries.

CMS-4068-P-695

Submitter : Miss. Jennifer Scott **Date & Time:** 10/01/2004 08:10:20

Organization : Miss. Jennifer Scott

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

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

Submitter : Mrs. Rebecca Snead **Date & Time:** 10/01/2004 09:10:38

Organization : Virginia Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Virginia Pharmacists Association would like to offer the following comments relating to the proposed Medicare part D regulations. The Virginia Pharmacists Association (VPhA), founded in 1881, represents the practicing pharmacists, pharmacy faculty, student pharmacists, pharmacy technicians, and others interested in advancing the profession in Virginia.

Thank you for your consideration of the views of Virginia?s pharmacists. Please contact James Pickral, Director of Policy at jpickral@vapharmacy.org or 804-285-4145 with any questions.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Pharmacy Access Standards:

We feel that by requiring plans to only meet the Tricare standard on average CMS will be limiting the access beneficiaries have to pharmacy services. It is our belief that CMS should revise the proposed regulations to require plans to meet the Tricare standards on a local level and not ?on average? across a plan?s overall service level.

Any Willing Provider:

We are strongly opposed to allowing plans to place pharmacies into ?preferred? and ?non-preferred? classes. We feel that this will affect our ability to serve our patients. This also runs counter to Congressional intent. We should avoid allowing plans to coerce beneficiaries to use certain pharmacies and discourage the use of others.

Level Playing Field:

CMS must direct that the difference in price from mail order and community pharmacy for a maintenance supply should be based solely on service price and not the cost of the medication. This would assure that the cost difference not be used to coerce beneficiaries from using the pharmacy of their choice. Congress clearly wanted to prevent plans from charging beneficiaries a higher fee based on arbitrary factors and was concerned that plans would charge higher fees to drive beneficiaries to mail service pharmacies.

Dispensing Fee:

We support a dispensing fee that adequately reflects the varied services provided by pharmacists. We also would urge CMS to add a requirement to the final regulation that plans must consider all of the costs associated with the processing, preparation, and delivery of the prescription drug product, including basic professional services such as basic patient counseling and overhead costs. We would further requests that the Agency consider the use of a tiered dispensing fee based on the level of complexity associated with preparing the product for the beneficiary.

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

Medication Therapy Management (MTM):

We respectfully submit the following recommendations for CMS to consider as it finalizes its rules regarding MTM Programs.

1. Due to the adverse incentive for PDP to provide MTM Programs, CMS must provide specific direction and requirements to the plans in order to ensure appropriate medication therapy for beneficiaries.
2. CMS must outline a specific baseline level of MTM services in the final rule to ensure equitable beneficiary access to MTMP.
3. CMS must provide specific direction to PDP to ensure that MTM Programs are patient-specific, individualized services and not population-based services.
4. CMS must outline specific requirements related to the range of MTM services, different levels of MTM services, and appropriate providers of MTM services.
5. CMS must outline specific quality assurance requirements that PDP must report in order to ensure appropriate implementation and ongoing operations of MTM.
6. CMS must protect beneficiary choice and the maintenance of ongoing beneficiary-provider relationships when determining the best provider for MTM.
7. CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.

CMS-4068-P-696-Attach-1.pdf

CMS-4068-P-696-Attach-1.pdf

CMS-4068-P-696-Attach-1.pdf

Medication Therapy Management Services
Definition and Program Criteria

Original: 4-May-04 (APhA MTM Services Working Group)
Last Revised: 7-Jul-04 (Pharmacy Profession Stakeholders)

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

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

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

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

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

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

CMS-4068-P-697

Submitter : **Date & Time:** **10/01/2004 09:10:16**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please require that plans meet the Tricare Pharmacy access requirements on a local level. This is very important to ensure that beneficiaries have access to the local pharmacy of their choice. The Centers for Medicare and Medicaid Services should make sure that the intent to provide a level playing field for community pharmacies is realized. Plans cannot favor mail order pharmacies. This would be a tragedy for healthcare in our great country.

Also, community pharmacies need to be included in the delivery of MTM services. Our local pharmacists are the best educated and most skilled of our healthcare professionals to provide such services. These services must be provided face-to-face to be effective.

CMS-4068-P-698

Submitter : Miss. Rhonda Leschisin **Date & Time:** 10/01/2004 09:10:58

Organization : St. Mary's Hospital Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As a pharmacist, I am deeply concerned with the rules as they are currently proposed.

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

In order for this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all pharmacy providers that perform MTM services.

Specifically, CMS rules must allow for pharmacists to be included, not precluded. Plan sponsors should be required to establish CMS specified MTM services.

CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

Pharmacists at our hospital provide valuable patient care services. Specifically, we have pharmacists trained to provide pharmacokinetic monitoring of certain drugs, such as warfarin and vancomycin. These drugs have very narrow therapeutic ranges, and can be very harmful to patients if not within range. We also have pharmacists trained to order and monitor parenteral nutrition. Again, these pharmacists are providing highly specialized assistance to prescribers who have patients in need of IV nutrition therapy.

All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber.

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

In closing, pharmacists can be an integral component of the new Medicare benefit. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerely,

Rhonda K. Leschisin, PharmD
Pharmacy Practice Resident
St. Mary's Hospital Medical Center
707 S. Mills Street

Submitter : Mrs. Roxanne Homar **Date & Time:** 10/01/2004 09:10:57

Organization : WY Department of Health

Category : Other Health Care Provider

Issue Areas/Comments

Issues 1-10

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

REVISED
October 1, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed rule detailing the Medicare prescription drug benefit.

Regarding subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans, I would like to commend CMS for recognizing the important role of pharmacists in Medication Therapy Management (MTM) services. Pharmacists are the ideal health care professionals to provide such services as their knowledge and experience create the perfect platform for this kind of work.

Recently in Wyoming, we have implemented a program called Wyoming PharmAssist. This program allows any interested Wyoming citizen to have a one-on-one consultation with a pharmacist licensed in the state. The program reimburses pharmacists $70 for each patient consultation. These are normally limited to one consultation per six months. The goal of this interaction is to provide an in-depth review of a client's drug regimen to look for issues such as drug interactions, therapeutic duplication, and contraindications. In addition, the pharmacist and client discuss different cost saving strategies and work to develop an affordable and appropriate medication regimen.

The results of this program have been outstanding. Wyoming PharmAssist originally began as a pilot program in four communities. The following statistics are from the first six months of the program:
* 403 calls came into the hotline resulting in 405 information packets being mailed.
* 151 clients returned completed packets.
* 139 clients were referred to a registered pharmacist for consultation.
* 99 of these consultations had been completed as of June 30, 2004.
* An average potential savings of $178 per month ($2,136 per year) were achieved.

Seventy-five percent of clients who received a consultation receive Medicare benefits. This means that once Part D becomes effective in 2006, Medicare would benefit from a portion of the savings achieved by this program.

In conclusion, the Wyoming PharmAssist program is a great example of how pharmacists can provide MTM services resulting in savings to individual citizens, and insurance providers, including large public insurance providers such as Medicare.

Please consider including pharmacists as MTM service providers in the final regulation.

Sincerely,

Roxanne Homar, R.Ph.

State Pharmacist

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CMS-4068-P-700

Submitter : Ms. Linda Garibaldi **Date & Time:** 10/01/2004 09:10:45

Organization : Legal Services of New Jersey

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

I was uable to fit the text for the following issues areas into the space provided. Eligibility, Election, and Enrollment as well as Grievances, Organizations Determinations and Appeals.

Therefore I have attached a document containing the text for the two areas in question.

Issues 1-10

BACKGROUND

Our first comment is not specific to a particular section but concerns the complexity and serious, far-reaching effects of the proposed regulations themselves. We welcome the expansion of the Medicare program to include a much needed drug benefit for seniors and the disabled. In addition, we appreciate that CMS has acknowledged the importance of including input from advocates who have firsthand experience with Medicare beneficiaries? health-related conditions and their critical need for necessary medications. However, a comment period of only sixty days is inadequate for the review of this very important and very extensive regulation.
Unarguably, access to prescription medicine is essential for the treatment of individuals with disabling conditions and for adults as they age. The Part D benefit should literally allow millions of people to live longer and more independently. Therefore, the regulations that direct the implementation of this benefit are vitally important. To allow a credible opportunity for meaningful input from beneficiaries and advocates, we urge the extension of the current time period for public comment. In the alternative, we strongly urge a second public comment period for these proposed regulations as well as the regulations to implement the Medicare Advantage program.

BENEFITS AND BENEFICIARY PROTECTIONS

?423.120(b)(1)(ii) Access to covered Part D drugs
We agree with the need for members on the pharmacy and therapeutic (P&T) committees to be ?independent and free of conflict? to assure that development and maintenance of the formularies of PDP sponsors and MA organizations reflect scientific evidence and best practices standards. Every member of the P&T committees should have no financial stake in the formulary determinations.
We also agree with the need for P&T committee makeup to include physicians and pharmacists with experience in health care for the elderly and disabled. However, we strongly recommend that at least one half of the members of the P&T committees must be physicians and pharmacists with demonstrated professional experience in health care for the elderly and disabled.

?423.120(b)(5) Provision of notice regarding formulary change
In most instances, an enrollee will have to get an appointment with their physician before they will be issued a prescription for a new medication. Many enrollees will not be able to obtain such an appointment within 30 days, especially if the enrollee does not get the notice immediately (may be hospitalized or away from home for any reason). We do not believe that 30 days is sufficient time for effective notice under an enrollee?s right to due process when a benefit is being denied. We recommend that a 90 days notice period be required and, in the alternative, 60 days.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

?423.464(e) Coordination with State Pharmaceutical Assistance Programs
The SPAPs have been a lifesaver for their low-income enrollees. We are pleased that CMS will be coordinating benefits with these plans. We urge CMS to begin this effort, especially as to the exchange of information, as soon as possible to assure that beneficiaries do not face a gap in prescription coverage.

GENERAL PROVISIONS

Legal Services of New Jersey (LSNJ) is the state support organization for the local legal services projects in New Jersey. Besides national and statewide advocacy for the legal rights of low income individuals and formal training to legal services case handlers throughout the state, LSNJ also provides free direct civil legal services to thousands of low-income residents each year through our statewide hotline and our different representation units. Many of these low income individuals are dually eligible for Medicare and Medicaid benefits, and many are solely covered by Medicare for their health care costs. We have provided direct legal advice and representation to nearly two thousand low income residents of New Jersey who are unable to obtain necessary and quality health care through our Health Care Access Project.

We respectfully submit the following comments concerning the proposed regulations to implement the Medicare Prescription Drug Benefit of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Issues 11-20

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

?423.782(a)(2)(iii) Cost-sharing subsidy

Individuals who are disabled or elderly are eligible for both Medicare and Medicaid only because they have drastically minimal income. Because these beneficiaries are elderly and/or disabled, they have a critical need for prescription medicines. Most dual eligibles take several prescription medicines each month, without which they cannot function and many cannot survive. Because of this, Medicaid has covered the cost of their medications which has allowed the poorest of the Medicare beneficiaries to stretch their income for shelter, food, clothing and other necessities. They cannot afford to pay co-pays for these medications. We urge CMS to eliminate all cost-sharing for dual eligibles.

Thank you again for this opportunity to provide you with comments for your consideration. Once again, we urge CMS to institute a second comment period to allow for adequate input from the public on these very important regulations.

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