CMS-4068-P-302

Submitter : Mr. Eugene Jacobs **Date & Time:** 09/27/2004 04:09:45

Organization : Mr. Eugene Jacobs

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

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,

Eugene H. Jacobs
505 Sawmill Creek Drive
Nellysford, VA 22958

Tel: 434-361-1975
Fax: 434-361-2226
E-mail: gji@juno.com

CMS-4068-P-303

Submitter : Mrs. Alison Kellagher **Date & Time:** 09/27/2004 04:09:04

Organization : Boulder Benzodiazapine Group

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

The exclusion of benzodiazapines by Medicare Part D will do harm to thousands of older adults. To switch from a benzodiazapine to another class of drug, or to discontinue use of a benzodiazapine is an extrememly difficult and dangerous process. The length of time needed to taper safely is much longer than is generally understood. When a Medicare recipient requests a switch to another type of drug, and when the benzodiazapine is discontinued, severe withdrawl symptoms will very likely ensue. A horrific and completely avoidable downward spiral could be put into motion, one which will cost far more than the original cost of the benzodiazapine. Even this is relatively insignifigant when compared to the cost in human suffering. I work with a non-affiliated support group for individuals trying to go off of a benzodiazapine. I witness the struggle on a near daily basis, am convinced of the extreme nature of this process, and I forsee a costly problem if this bill is passed unchanged.

Submitter : Dr. Sandra Leal **Date & Time:** 09/27/2004 04:09:39

Organization : El Rio Health Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Dear Sir or Madam:

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

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

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

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice. I run a pharmacist managed diabetes clinic which delivers comprehensive coordinated care for patients with diabetes, hypertension, hyperlipidemia, and polypharmacy issues in Tucson, Arizona. Our outcomes have been signification and our results will be published in Diabetes Care this year showing benefit to the patients we serve. Plans should be encouraged to use my service - to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to recognize pharmacists as the specific provider of MTM services.

Thank you for the opportunity to comment on these important regulations to the profession of pharmacy.

Sincerely,

Sandra Leal, Pharm.D., CDE
Clinical Pharmacy Supervisor
El Rio Health Center
839 W. Congress
Tucson, Arizona 85745
520-670-3805
sandral@elrio.org

CMS-4068-P-304-Attach-1.wpd

CMS-4068-P-305

Submitter : Mrs. marianne bartkowski **Date & Time:** 09/27/2004 04:09:15

Organization : Mrs. marianne bartkowski

Category : Individual

Issue Areas/Comments

Issues 1-10

BACKGROUND

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

September 27,2004
RE: Comments relating to Medicare Part D proposed regulations -
69 Fed. Reg. 46632 (Aug. 3, 2004).

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,

Marianne Bartkowski
oN480 Willow Rd
Wheaton, Il 60187
630-668-6613

Submitter : Mr. Richard Hammes **Date & Time:** 09/27/2004 05:09:08

Organization : University of Wisconsin

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

CMS rules must allow for hospital pharmacies to be included, not precluded. Plan sponsors should be required to establish CMS specified MTM services.

CMS should require all plan sponsors to provide for at least a minimum CMS-specified 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. Each plan should be required to pay for all 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 AND 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 can speak out against it depending on your decisions. 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, without regard to practice setting or specialty area. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program to justify their participation.

Thank you for your consideration.

Richard J Hammes, MS RPh BCNP;
Senior Clinical Pharmacist;
University of Wisconsin Hospital & Clinics;
Clinical Professor;
University of Wisconsin School of Pharmacy

CMS-4068-P-307

Submitter : Dr. Steven Ebert **Date & Time:** 09/27/2004 05:09:12

Organization : Pharmacy Society of Wisconsin

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

I strongly advovate reimbursement for Medication Management Services provided by pharmacists to the hospitalized patient. Hospitalized patients' physical status vary widely throughout their hospital stay, and pharmacists are uniquely qualified to ensure safe, appropriate, effective drug therapy. Clinical services provided by pharmacists in the inpatient setting include concentration-controlled dose adjustment of aminoglycosides, vancomycin, digoxin, anticonvulsants, theophylline, and cyclosporine; patient response-based dose adjustment of heparin, warfarin, and insulin; dose adjustment of other drugs (lepiridin, argatroban, eptifibitide, bivalirudin, abciximab, nesiritide, dofetilide, sotalol, renally eliminated drugs) in patients with impaired excretory function; conversion of intravenous drug regimens to their orally-administered counterparts; detection and prevention of drug interactions and adverse drug reactions; assistance in drug selection based on protocols/laboratory information; obtaining an accurate patient medication history on admission; documentation of medication allergies/contraindications; calculating electrolyte formulas for patients receiving total parenteral nutrition; ensuring appropriate doses of high-risk agents such as antineoplastic agents; communication with community provicers to ensure seamless care after discharge; and education of patients, caregivers, clinicians, and other health care professionals. All of these interventions are intended to provide optimum, safe, effective drug therapy to the patient as well as limit the length of hospital stay and minimize expenditures wherever possible. Although these interventions occur in a relatively brief period of time (i.e., within the hospital stay), they result in massive cost savings as well as in reductions in adverse events and errors.

CMS-4068-P-308

Submitter : Mrs. Sheri Schlenker **Date & Time:** 09/27/2004 06:09:43

Organization : St. Joseph HealthCare

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

am an MSW who's runs the indigent drug program for our hospital. I work with many elderly and low income individuals who do fall within the $600 tax credit. Many individual I assist live in Central and Eastern Kentucky and do not understand what all of this truely means. I have 2 primary concerns: 1. What if the patient's pharmacy does not accept the discount card that the patient has been provided? These individuals live in very rural areas and do not have all of the major chain pharacies. Many people that I see will just Give up and not persue this any longer if there is any hassle at all. 2. What if another discount card (such as the UShare Card) provide patients with a much better discount and better overall assistance than the card they currently posess. What are they to do? If they do have the option of changing plans who long will this take? Also another issue is there needs to be more help with indivual taking a specific medication called Plavix. I see patients typically on a daily basis who do not have access to an affordable way of paying for this medication. The discount for this medications is still around the $100 price range and this is not enough assistance. Most of the patients that I see have a monthly income of $700 to $900 a month and can not afford $100 for 1 medication. The $600 tax credit is nice but not nearly enough. I know all about the patient assistance programs for this drug but patients need more immedicate assistance than what is currently inplace.

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

BENEFITS AND BENEFICIARY PROTECTIONS

The cards should all provide the same benefits because many seniors medications will change. So one card may work for a while and then they see their physician and their medications are often changed. This could mean that a card that was once a benefit to them will not be as great of assistance to them

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

The plans should be more universal so it is not so difficult for seniors to choose. I don't think 1 plan shoudld be available but not 50+ like it is not with the discount cards.

Also, some companies are giving medications at not cost to low income indivuduals for some cards but not others and this makes it difficult for seniors to make an informed decesion. If 2 cards provide help for different medications it is hard for an indiviual to make a choice.

ELIGIBILITY, ELECTION, AND ENROLLMENT

INDIVIDUALS SHOULD BE ALLOWED OPPORTUNITIES THOUGH OUT THE YEAR TO CHANGE TO A NEW DISCOUNT CARD IF ONE THAT BETTER SUITS THEIR NEEDS BECOMES AVAILABLE

CMS-4068-P-309

Submitter : Ms. Judith Bertman **Date & Time:** 09/27/2004 06:09:52

Organization : Ms. Judith Bertman

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 (Aug. 3, 2004).

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.

CMS-4068-P-310

Submitter : Brian Roper **Date & Time:** 09/27/2004 06:09:02

Organization : Brian Roper

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, MD 21244-8014
Dear Dr. McClellan:
I 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, I 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. I 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).
I 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:
?h extending the deadline for switching their coverage from Medicaid to Medicare; and
?h 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.

I strongly believe that the concerns discussed above must be addressed in order to ensure access to mental health medications under the Part D drug benefit for the many Medicare beneficiaries who need them.
Thank you for your consideration of my comments.
Sincerely,

Brian A. Roper

Issues 11-20

GRIEVANCES, ORGANIZATION DETERMINATIONS AND APPEALS

Appeals Procedures (?? 423.562-423.604)

The appeals processes outlined in the proposed regulations are overly complex, drawn-out, and inaccessible to beneficiaries. Under these proposed rules, 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. In order to qualify for a hearing by an ALJ, beneficiaries must first request a coverage determination or exception from a tiered cost-sharing scheme or formulary which can take between 14 and 30 days, unless a plan honors a beneficiary?s request that the determination or exception be expedited in which case it could still take up to 14 days. To appeal adverse determinations or exception decisions, beneficiaries must request plans to review their decision again and make a redetermination within 30 days unless the beneficiary paid out-of-pocket for the medication at issue, in which case the plan has 60 days to decide. Even if a plan honors a request to expedite a redetermination, the deadline for plans to make a decision could be as long as 14 days. Following a redetermination, beneficiaries may appeal to a so-called independent review entity for a reconsideration of their case, but these entities will not be authorized to review or question the criteria plans use to evaluate exceptions requests. The proposed rules do not even set deadlines for reconsideration decisions. After receiving a reconsideration decision, beneficiaries are only allowed to appeal to an ALJ if the amount in controversy meets a threshold level of $100 and it is unclear how CMS will calculate whether a beneficiary has met this threshold.

In addition to imposing unreasonable delays and burdens on beneficiaries, these appeal processes are far from transparent. Drug plans would be authorized to establish their own criteria for reviewing determination, exceptions, and redetermination requests and these criteria will vary from plan to plan. Plans would also be authorized to establish varying degrees of paperwork requirements for beneficiaries and their prescribing physicians who wish to request exceptions from tiered cost-sharing schemes or formularies. Far from ensuring that beneficiaries? rights are protected, which should be their primary function, these procedures would actually impede the right of beneficiaries to a fair hearing.

These appeals procedures would be inaccessible for beneficiaries facing mental illness and must be significantly revised. As Michael Hogan, former chair of the President?s New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department has stated in a letter dated June 1, 2004 to CMS Administrator, Mark McClellan, ?patients with significant psychiatric illness, especially those that are disabled as a result of their illness, have an extremely limited capacity to navigate [grievance and appeals] procedures.? To accommodate the special needs of these beneficiaries and others facing disabilities or low income, CMS must 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, including individuals facing psychiatric crises, which should be modeled after the federal Medicaid requirement that states respond to prior authorization requests within 24 hours.

CMS-4068-P-311

Submitter : Mr. John Brislin **Date & Time:** 09/27/2004 06:09:52

Organization : Pharmacist Consultation Svs./ OptiMed Senior Care

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

I am a board-certified Geriatric Consultant Pharmacist. In January 2004, I opened the first independent Senior Care Medication Optimization Practice in the State of Kentucky. In this practice, OptiMed Senior Care/ Pharmacist Consultation Services, I work with seniors, their primary care physicians, and if desired, their adult children to review and optimize their medications and therapy to keep seniors living independently as long as possible.

Through this practice and working with the Area Agency on Aging, I go into senior's homes, apartments, or retirement facility to review their medications, prescription and non-prescription, in addition to the safety level of their living environment.

In the majority of cases, no one knows all of the medications the senior is actually taking or not taking. As an independent health care professional, I can act as an independent advocate for the senior with their physician(s) to often discontinue a number of their medications. This dramatically reduces the senior's medication side-effects, reduces drug and disease state interactions, reduces drug costs, and allows the senior to stay independent in their home longer since they have less stress about taking fewer meds per day.

Additionally, this reduces stress on adult children who are having to try to maintain full time jobs while now helping to care for their senior parent(s).

At the current time, my senior medication review and recommendation service is privately paid by the senior or their adult children. If I can keep the senior out of assisted living or especially long term care nursing homes for even 3 to 4 days over their lifetime, my initial fee has more than paid for itself.

28% of senior hospitalizations and 25% of senior nursing home placements are due to medication-related problems. Often seniors are seeing more than 1 physician/ specialist and each practitioner prescribes his/her own set of medications. There is no 1 practitioner who specifically is a geriatric pharmacology expert. That is why we need geriatric pharmacist and general pharmacist consultant services to be paid for under a Medicare Drug/Pharmacy Benefit.

Imagine how many thousands and millions of dollars I save for my patients, families, and ultimately the State and Federal governments by improving medication therapy in seniors. Simply keeping seniors out of nursing homes for 1 to 12 months could have a dramatic savings impact on our local, state, and federal health care budgets.

I feel it is important to adequately and fairly pay for pharmacist consulting services. My fees range from $150 to $200 per hour. When considering that nursing home costs can range from $50,000 to $60,000 per year and nursing home drug costs are 2 to 3 times what these costs are from a community pharmacist, medication therapy management by pharmacists is a win-win for every party involved.

If you have questions or would like additional information about how I help seniors and their families, please call me at 859 971-1655 or email johnuky@alltel.net

Thank you for your time and consideration.

John M. Brislin, B.Sci., B.Pharm., R.Ph., FASCP, CGP
169 E. Reynolds Rd., Suite 202-C
PO Box 25163
Lexington, KY, 40524-5163

CMS-4068-P-312

Submitter : **Date & Time:** 09/27/2004 06:09:55

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I am making a comment about Subpart C with respect to the level playing field. I agree that beneficiaries should be able to obtain the same benefits at a community pharmacy as they can at a mail order pharmacy. I have worked at a community pharmacy and know there are certain people come to our business because of who we are and they trust us. Along with that, some of these people come from pretty good distances to get their prescriptions. Because they come from a long distance to get their prescriptions they would like more than a thirty day supply. Whoever mandates to the pharmacy what the customer has to pay whether it is the insurance company or the drug company, they should not penalize the customer for going to a retail or community pharmacy if they choose. The pricing should be the same for retail and mail order services.

CMS-4068-P-313

Submitter : **Date & Time:** 09/27/2004 06:09:17

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Regarding subpart C: Level Playing Field

The price differentiation is not fair to the patients. By encouraing mail order through lowered costs, patients are losing the value of a pharmacist. The patients' health is also at risk because they do not have a pharmacist readily available and in person to them that has access to their drug history. Although patients have the option to speak with a pharmacist on the phone about questions they may have, the inconvenience and lack of personal care may discourage the patient from seeking medical advice. Also, a patient with OTC concerns would not be as familiar with the pharmacist they may have to consult, making them more hesitant to ask questions.

Submitter : Mr. James Richardson **Date & Time:** 09/27/2004 06:09:38

Organization : Cedar Lake Lodge, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

Issues 1-10

BACKGROUND

For the last 28 years I have been working for a private non-profit organization, Cedar Lake Lodge, Inc. Cedar Lake is a licensed ICF/MR and we serve 76 residents with MR/DD located in LaGrange KY. Most of those we serve are severely or profoundly MR and cannot represent themselves or communicate. Many are also indigent, abandoned, or do not have family actively involved in their lives. I would ask that my comments be considered on their behalf.

ELIGIBILITY, ELECTION, AND ENROLLMENT

September 27, 2004

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

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

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 (ICF's/MR). ICF's/MR have typically been catagorized as long term care facilities in both federal and state legislation and to remain consistent this should remain as a defining aspect.

* "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,
H. James Richardson, President
Cedar Lake Lodge, Inc.

GENERAL PROVISIONS

See my letter below.

Submitter : Ms. Rachel Paweltzki **Date & Time:** 09/27/2004 06:09:41

Organization : APhA/ASP

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I feel that beneficiaries should be able to obtain the same benefits at all pharmacies. There should be a level playing field for all pharmacies. For example, beneficiaries should be able to get the same day supply for the same price whether it be at a community phamarcy or mail-order. One pharmacy should not be "preferred" over another.

Submitter : Miss. Danielle Dykes **Date & Time:** 09/27/2004 07:09:31

Organization : Academy of Student Pharmacists

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

In regards to the Medication Therapy Management Program, a certain number of chronic disease states and certain number of drugs used should be specified. I believe two drugs and two disease states would be good criteria for those who would benefit from this program. Specifications should be made so it is set in stone who will benefit and not change on an individual basis.

Submitter : Miss. Jenilee Johnson **Date & Time:** 09/27/2004 07:09:01

Organization : Academy of Student Pharmacists

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I do not agree with plans establishing preferred and nonpreferred pharmacies. It should be the patients choice to choose the pharmacy and pharmacist that they wish to use.

Submitter : Dr. Ronald Maddox **Date & Time:** 09/27/2004 07:09:20

Organization : Campbell University

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I urge CMS to revise the regulation: to required plans to meet the TRICARE reqirements at the local level; to not allow aplan to have both preferred and non-preferred providers; to only allow price differentials for providing an extended drug supply based on cost of service and not on the differentials in drug costs; require MTMS to be preformed by pharmacists unless a plan has evidence their approach works as well as a pharmacist providing MTMS; make sure the proposed pyament for MTMS is adequate to encourage pharmacists participation. Thank you for consideration of my recommendations.

CMS-4068-P-319

Submitter : Mr. John Radcliffe **Date & Time:** 09/27/2004 07:09:32

Organization : State of Hawaii Employer-Union Trust Fund

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

COMMENTS ON File CODE CMS-4068-P

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

RE: Public Comment on CMS-4068-P
Part 423 ? Voluntary Medical Prescription Drug Benefit,
Subpart R- Payments to Sponsors of Retiree Prescription Drug Plans
Specifically that part defining the Definition of the term ?Sponsor?

FROM: John H. Radcliffe, Trustee State of Hawaii Employer-Union Health Fund Trust
Chair, Benefits Committee

Monday, September 27, 2004

Ladies and Gentlemen:

I am Chair of the Benefits Committee of the State of Hawaii Employer-Union Health Fund Trust, a close to $400 million a year organization, responsible for nearly 200,000 public employees, retirees, dependents and beneficiaries in Hawaii.

It very recently came to my attention entirely by accident, that officials of the State of Hawaii, without any notice to the Trust, and without any apparent rhyme or reason, are attempting to divert proposed Department of Health and Human Services funding from the State of Hawaii Employer-Union Health Fund Trust to the State?s General Fund in contravention of the intent of the Congressional intent of the legislation. Please do not fall for this. It is a ruse to fatten the State?s General Fund at the expense of retirees covered and to be covered by out Trust.

The Trustees of the Trust were never informed that Department of Health and Human Service Centers for Medicare and Medicaid Services had issued anything for public comment. We were not asked our views.

Unfortunately, I also do not have the letter which has been sent to you by someone in our state government who is attempting to negate or change your proposed rules. Not only have we not been provided it, state government officials would not even tell me (as Trustee) which Department has authored the proposal, let alone the name of the individual who authored it. This is clearly something that some individuals in the Executive Branch of State Government do not want others to know that they are doing?or else Trustees of the State of Hawaii Employer-Union Health Fund Trust would have been informed.

Therefore, for that reason alone, please do not change the definition of ?Sponsor? as it is currently proposed under Section (16) (B).

However, the substantial reason that the definition ought to stay as proposed, is that it now states in relevant part, ?or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan.? and that is precisely, and exactly the case here in Hawaii. We have a multi-employer situation in that the state of Hawaii and the four counties are employers and have five (5) members on the Board of the EUTF and a number of employee organizations are directly and legally represented by five (5) employee/retiree members. The definition as it stands is exactly as intended.

Thank you for your kind attention, and I hope that other interested parties will have time to respond to comment on the proposed rules.

Sincerely yours,

John H. Radcliffe
Associate Executive Director,
University of Hawaii Professional Assembly
Chair, Benefits Committee,
State of Hawaii Employer-Union Trust Fund

CMS-4068-P-319-Attach-1.doc

CMS-4068-P-319-Attach-2.doc

COMMENTS ON File CODE CMS-4068-P

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

RE: Public Comment on CMS-4068-P
Part 423 – Voluntary Medical Prescription Drug Benefit,
Subpart R- Payments to Sponsors of Retiree Prescription Drug Plans
Specifically that part defining the Definition of the term "Sponsor"

FROM: John H. Radcliffe, Trustee State of Hawaii Employer-Union Health Fund Trust
Chair, Benefits Committee

Monday, September 27, 2004

Ladies and Gentlemen:

I am Chair of the Benefits Committee of the State of Hawaii Employer-Union Health Fund Trust, a close to $400 million a year organization, responsible for nearly 200,000 public employees, retirees, dependents and beneficiaries in Hawaii.

It very recently came to my attention entirely by accident, that officials of the State of Hawaii, without any notice to the Trust, and without any apparent rhyme or reason, are attempting to divert proposed Department of Health and Human Services funding from the State of Hawaii Employer-Union Health Fund Trust to the State's General Fund in contravention of the intent of the Congressional intent of the legislation. Please do not fall for this. It is a ruse to fatten the State's General Fund at the expense of retirees covered and to be covered by out Trust.

The Trustees of the Trust were never informed that Department of Health and Human Service Centers for Medicare and Medicaid Services had issued anything for public comment. We were not asked our views.

Unfortunately, I also do not have the letter which has been sent to you by someone in our state government who is attempting to negate or change your proposed rules. Not only have we not been provided it, state government officials would not even tell me (as Trustee) which Department has authored the proposal, let alone the name of the individual who authored it. This is clearly something that some individuals in the Executive Branch of State Government do not want others to know that they are doing—or else Trustees of the State of Hawaii Employer-Union Health Fund Trust would have been informed.

Therefore, for that reason alone, please do not change the definition of "Sponsor" as it is currently proposed under Section (16) (B).

However, the substantial reason that the definition ought to stay as proposed, is that it now states in relevant part, **"or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan."** and that is precisely, and exactly the case

here in Hawaii. We have a multi-employer situation in that the state of Hawaii and the four counties are employers and have five (5) members on the Board of the EUTF and a number of employee organizations are directly and legally represented by five (5) employee/retiree members. The definition as it stands is exactly as intended.

Thank you for your kind attention, and I hope that other interested parties will have time to respond to comment on the proposed rules.

Sincerely yours,

John H. Radcliffe
Associate Executive Director,
University of Hawaii Professional Assembly
Chair, Benefits Committee,
State of Hawaii Employer-Union Trust Fund

COMMENTS ON File CODE CMS-4068-P

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

RE: Public Comment on CMS-4068-P
Part 423 – Voluntary Medical Prescription Drug Benefit,
Subpart R- Payments to Sponsors of Retiree Prescription Drug Plans
Specifically that part defining the Definition of the term "Sponsor"

FROM: John H. Radcliffe, Trustee State of Hawaii Employer-Union Health Fund Trust
Chair, Benefits Committee

Monday, September 27, 2004

Ladies and Gentlemen:

I am Chair of the Benefits Committee of the State of Hawaii Employer-Union Health Fund Trust, a close to $400 million a year organization, responsible for nearly 200,000 public employees, retirees, dependents and beneficiaries in Hawaii.

It very recently came to my attention entirely by accident, that officials of the State of Hawaii, without any notice to the Trust, and without any apparent rhyme or reason, are attempting to divert proposed Department of Health and Human Services funding from the State of Hawaii Employer-Union Health Fund Trust to the State's General Fund in contravention of the intent of the Congressional intent of the legislation. Please do not fall for this. It is a ruse to fatten the State's General Fund at the expense of retirees covered and to be covered by out Trust.

The Trustees of the Trust were never informed that Department of Health and Human Service Centers for Medicare and Medicaid Services had issued anything for public comment. We were not asked our views.

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However, the substantial reason that the definition ought to stay as proposed, is that it now states in relevant part, **"or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan."** and that is precisely, and exactly the case

here in Hawaii. We have a multi-employer situation in that the state of Hawaii and the four counties are employers and have five (5) members on the Board of the EUTF and a number of employee organizations are directly and legally represented by five (5) employee/retiree members. The definition as it stands is exactly as intended.

Thank you for your kind attention, and I hope that other interested parties will have time to respond to comment on the proposed rules.

Sincerely yours,

John H. Radcliffe
Associate Executive Director,
University of Hawaii Professional Assembly
Chair, Benefits Committee,
State of Hawaii Employer-Union Trust Fund

Submitter : Ms. Sara Colman **Date & Time:** 09/27/2004 07:09:26

Organization : Renal Support Network

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

Prescription Coverage of renal vitamins for dialysis patients

CMS-4068-P-321

Submitter : Georgia Wolfe **Date & Time:** 09/27/2004 07:09:36

Organization : The Advocacy Network

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

The Advocacy Network welcomes the opportunity to comment on the proposed rule recently published by CMS for the New Medicare Drug benefits effective January 1, 2006. The recently proposed rule fails to provide adequate safeguards to ensure that persons with mental illness get access to medicines they need. It is critical that this drug benefit provide coverage for all medically necessary mental health medicines. We urge that the rule be revised to ensure access to mental health medicines for the many Medicare beneficiaries who need them. These persons must be given special consideration.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. CMS must also address the real threat of adverse health outcomes facing dual eligibles. The formularies for low-cost plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Changing psychiatric medications is very difficult and dangerous. The seriously ill mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different. Unfortunately, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. We urge that the regulations be revised to provide for "grandfathering" coverage of mental health medications for dual eligibles into the new Part D benefit, as a number of states have done in implementing preferred drug lists for Medicaid programs.
Thank you for your consideration of these comments.

CMS-4068-P-322

Submitter : Mr. Raymond Jonas **Date & Time:** 09/27/2004 07:09:35

Organization : Mr. Raymond Jonas

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

I am on Medicare, but get my insurance to cover my drugs is paid from a supplement that is taxpayer subsidized. Any changes to the current law governing required participation of Medicaid or other public program participants could create a life threatening experience. The Medicare Drug benefit does not cover many of the more important treatments necessary for staying alive with this disease and the costs are well beyond my ability to pay out of pocket.
In addition, any mandatory participation in the new Medicare Drug Benefit will shift costs from a state and federal shared costs to a federal program only. This is not in the public interest.

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

Sincerely,
Raymond Jonas
PO Box 4002
Renton, Wa 98057
(425) 226-3812
<rjs4you@juno.com>

CMS-4068-P-323

Submitter : Mr. Thomas Henry III **Date & Time:** 09/27/2004 07:09:00

Organization : Kindred Hospital Pharmacy Services - Greensboro

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As a registered Pharmacist, I have several concrns about this regulation.

I have a concern that rural areas may not have adequate access to pharmacists unless TRICARE requirements are applied to determining access to pharmacy services.

I believe that the current language related to "preferred" and "non-preferred" pharmacies negates the "any willing provider" provision of the bill. Without the full benefit of "any willing provider" status, plans may attempt to drive patients toward a particular vendor and interfere with many long-standing relationships between pharmacists and patients. There is documented evidence that long-standing relationships with a single pharmacy provider provide a higher level of patient safety.

Further, any effort to encourage mail-order pharmacy through increased number of days supplies or different co-pays, should also be discouraged because of the lower level of patient safety associated with prescriptions being filled by a pharmacist who is not familiar with the patient and their medical conditions.

With regard to Medication Therapy Management (MTM) services, it is imperative that pharmacist be encouraged to oversee this responsibility. In the hospital where I work, through a series of initiatives that are pharmacist managed, we have reduced our average daily cost of drugs approximately 25% from where they were 4 years ago. Given an average rate of inflation in drug costs in the 12 to 13 percent range this represents a total cost avoidance of more than 50%.

One example of a pharmacist managed initiative within our hospital has been a pharmacist managed anemia protocol. We have been using this protocol for 10 months and have seen dramatic improvements in anemia levels of our patients, while holding the cost steady for erythropoetin alpha an expensive drug, treating more patients at lower doses and reducing the need for blood transfusions by 40 to 50%.

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

CMS needs to clarify that plans can not prohibit pharmacists from providing MTMS to non-targeted patients. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for these services.

All plans must be required to pay the same fees for MTMS to all providers, unless the difference in fees is tied to additional certifications. If the "preferred" vs. "non-preferred" designation previosuly mentioned as unwise is adopted, there should be no difference in the fee for MTMS at either facility.

Plans should be required to take all measures necessary to ensure that face-to-face interaction between the provider of MTMS services and the patient occurs on the initial assessment and at least annually thereafter.

Plans should be required to limit the provision of MTMS to patients within a given state to practitioners licensed within that state only. It is this writer's opinion that only physicians and pharmacists are adequately prepared to provide these services from an education standpoint.

Any plan that agrees to participate in the program must be required to pay a fee structure for MTMS that is commensurate with the local salary structure for the profession providing the services and the expected length of time for each type of assessment/intervention either initial or follow-up.

I Thank You for Considering My Opionion

Thomas E. Henry III, B.S., RPh

Director of Pharmacy Services
Kindred Hospital Pharmacy Services
2401 Southside Boulevard
Greensboro, NC 27406

Submitter : Mr. Mark Aylesworth **Date & Time:** 09/27/2004 07:09:24

Organization : The Monroe Clinic

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

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

Re: CMS-4068-P

To Whom It May Concern:

I write today to offer comments regarding the proposed Medicare Part D rules. As a hospital pharmacy director, The Monroe Clinic Hospital is deeply concerned with the rules as they are currently proposed.

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

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

? CMS rules must allow for hospital pharmacies to be included not precluded. Plan sponsors should be required to establish CMS specified MTM services.

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

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

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

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

Thank you for your consideration.

Sincerely,

Mark Aylesworth
Pharmacy Director, The Monroe Clinic

CMS-4068-P-325

Submitter : Mr. Byron Phillips **Date & Time:** 09/23/2004 12:09:00

Organization : K-Mart Pharmacy 9625

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

9-23-04 - Dear HHS; I am writing in refrence to file code CMS-4068-P to express my concerns regarding access and quality to the proposed regulations issued August 3,2004, that would implement the new Medicare Part D prescription drug benefit program beginning in 2006. My comments: The proposed regulations do not properly implement the so called TriCare pharmacy access standards included in the MMA; and therefore, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist. secondly; the regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications. Thirdly; the regulations must include more specificity in the medication therapy management (MTM) program. Currently, they do not define the nature and scope of MTM services the plans would have to provide, such as who would be eligible for these services, and how providers would be compensated for these services.

CMS-4068-P-326

Submitter : Mr. Eugene Lutz **Date & Time:** 09/27/2004 09:09:43

Organization : Pharmacy Services, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

APPLICATION PROCEDURES AND CONTRACTS WITH PDP SPONSORS

Pharmacy is very concerned about PDP sponsors and Prescription Drug Benefit (PBM)organizations having too much leeway in deciding how the program is administered by them. There are two issues, at least one of which CMS should have some ability to have an effect upon. First, PBM's should be required to have completge transparency in all dealings with CMS, Pharmacy, Drug Manufacturers, Prescribers and Patients. I realize that the legislation provided for a 'little' transparency, but it left a lot of questions to be answered. History has shown that there are a lot of ways to manipulate costs and prices and PBM's are masters at doing so. There is at least one professor at Creighton University in Omaha, NE that has done research that shows major discerpancies and manipulations in prices paid, prices reported and income received under various arrangements between PBM's, purchasers of PBM services and pharmacies. I urge CMS do demand transparency in every contract and every arrangement between PBM's and others who have a stake in this area.

Secon, is the issue of purchasing of covered medications by PBM's. The legislation says that the government is NOT to be directly involved in the negotiation of prices paid for drugs covered under the plan. I understant that that is not something CMS may be able to do much about, but I do believe that it is a major mistake and could wind up bankrupting the program if it is not fixed. The theory of the legislation was to let 'marketplace' forces keep the prices in line because of 'competition'. Experience suggests that this will not happen- all you need to do is look at the large health plans and you can see that increases in drug pricing has been increasing faster as more and more people have prescription drug coverage. There is NO competition, when a handful of PBM's controls 75-80% of the marketplace.

CMS should also require that participatin PBM's utilize standard contracts in their dealings with providers AND that these contracts not be tied to any other contract that a pharmacy may have with a PBM. They should stand on their own. PBM's should be required to indemnify pharmacies against acts or actions that are not under the pharmacy's control. They also should be required to post bond's guaranteeing payment for drugs and services in the case of a defaulkt by the PBM.

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

I want to urge that CMS listen to the pharmacy profession as it developes the regulations surrounding Medicare Part D. Congress listened to pharmacy when it included Medication Therapy Management Services (MTMS)as a KEY component of the new Medicare drug benefit. The provision of MTMS by pharmacists has almost UNIVERSAL backing by the pharmacy community and the support of ALL major national pharmacy organizations and nearly all state pharmacy associations as well. As President Elect of the American Pharmacists Asso. and owner of my own community pharmacy, I have seen how pharmacist involvement with patients in helping them manage their medications has improved outcomes. Unfortuneately, the pressures of dispensing and the lack of compensation for such services have tended to minimize the amount of time pharmacists are willing to devote to such activities. With the advent of Medicare Part D and MTMS CMS has the opportunity to help pharmacists make "dramatic" improvement in medication adherence and greatly reduce medications errors. This also will result in less hospital and doctor visits and less emergency room visits by seniors, all of which will enhance their lifestyle AND with the added benefit of helping reduce overall medical costs. It is important that the system used for payment be easy to use and that compensation be fair and reasonable, in order for pharmacists to devote sufficient time to MTMS to make it of value.

The organizations who administer MTMS services should be required to make MTMS services a separate reimbursement from prescription drug reimbursement. MTMS should NOT be tied to dispensing, nor should payment of MTMS services vary based on dispensing activity.

CMS-4068-P-327

Submitter : Sherilyn Kent **Date & Time:** 09/27/2004 09:09:57

Organization : Mental Retardation Association of Utah

Category : Other Association

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

September 27, 2004

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

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

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,

Sherilyn J. Kent
Secretary, Mental Retardation Association of Utah
895 N. 900 E.
American Fork, UT 84003
801-763-4008 (phone)
801-763-4214 (fax)

CMS-4068-P-328

Submitter : Ms. Ruth Daley **Date & Time:** 09/27/2004 09:09:58

Organization : Ms. Ruth Daley

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Sept. 24, 2004

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

To Whom It May Concern,

I just received an urgent letter from an associate in the Benzodiazepine Awareness Network, informing me of the decision that Medicare and Medicaid have made in
excluding Benzodiazepines from their drug benefits list as of 2006.

Although I am encouraged by the wisdom of those in charge of this decision as to keeping people off this highly addictive class of drugs by not covering it, I would also entreat you to please make allowance for those that have already been prescribed them.

As I am sure you know, coming off Benzodiazepines requires a slow taper period, with the withdrawal in many cases being so excruciatingly difficult that many people have to revert back to taking the drug. I am particularly concerned for the addicted elderly patients that may be inadvertently thrown into a cold turkey withdrawal if their access to this class of drugs is suddenly removed.

I implore you to review and make allowance on your list for those already prescribed Benzodiazepines.

Sincerely,

Ruth Daley
1110 S. Missouri Ave. # 107
Clearwater, Florida 33756
Owner: www.BenzoLiberty.com

CMS-4068-P-329

Submitter : Mr. John Kolesari **Date & Time:** 09/27/2004 10:09:57

Organization : Froedtert Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

I believe it is imperative that Pharmacist are designated as "providers" in the new Medicare Modernization Act. Pharmacists must be included in the language as providers to allow them to continue to efficiently and effectively manage therapy for patients in a variety of inpatient and outpatient settings. Our hospital currently has a very active Medication Therapy Management Service which actively manages patients placed on oral anticoagulation therapy. Our pharmacists, working in collaboration with our physicians, manage the anticoagulation therapy outcomes of more than 640 patients. With our pharmacist involvement we have demonstrated our ability to significantly reduce adverse events leading to fewer hospitalizations and ER visits. Through pharmacist education and one on one patient teaching we have also been able to improve medication compliance. Our patients are very pleased with our service because they feel they receive prompt, professional care, optimizing their outcomes while minimizing the time impact this therapy management has on them. In a 15-20 minutes office visit our pharmacists effeciently determine the patients current therapeutic blood level of the drug, assesses the patient's diet and medication needs as they relate to their anticoagulation therapy management, recommend dose changes that are need to keep the patient in line with the physicians target goals, discuss any relevant issues with the patient and educate them at the same time. The patients leave fully informed about the current status of their therapy.

This is just one example of Medication Therapt Management performed by pharmacist that can lead to more efficienient use of health care resourrces and improved therapeutic outcomes for the patients we serve.

Thank you for your consideration.

Sincerely;
John T. Kolesari, RPh
Assistant Director
Pharmacy Services
Froedtert Hospital
Milw., WI 53226

CMS-4068-P-330

Submitter : Mr. Urbin Harvey **Date & Time:** 09/27/2004 10:09:05

Organization : Pharmacist

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

In conclusion, I urge CMS to revise the regulation to include the listed recommendations I have addressed.

Sincerely,
Urbin Harvey (Pharmacist/Owner) Medicap Pharmacy Marion, IN
urbharvey@netscape.net

Issues 1-10

BACKGROUND

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

BENEFITS AND BENEFICIARY PROTECTIONS

Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan's overall service level. Requiring plans to meet the standards on a local level is the ONLY way to ensure that ALL beneficiaries have convenient access to a local pharmacy and that my patients will be able to continue to use my pharmacy.
I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower c0-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 tocount their non-preferred pharmacies conflicts with Congress' intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

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

I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I alos appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. My pharmacy currently provides the following MTM serivces: Spirometry testing, Diabetes self-management training, Asthma and like lung disorder assessment and self-management training, Weight control, Smoking cessation, HRT therapy. Plans should be encouraged to use my services-to let me and my staff help our patients make the best use of their medications.

CMS-4068-P-331

Submitter : Elaine Greene **Date & Time:** 09/28/2004 12:09:08

Organization : Medicap Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

September 27, 2004
RE: CMS-4068-P

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

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

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Pharmacists are annually recognized as being the most accessible health professional and are the drug experts in evaluating medication treatments. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide the following MTM services in my practice: Diabetes Education, Asthma Self Management and Training, Spirometry Services, Blood Pressure monitoring, and Comprehensive Medication Reviews.

In conclusion, I urge CMS to revise the regulations to ensure patients have equal access to local pharmacies at equal copays, and receive MTM from Pharmacists, the medication expert.

Thank you for considering my view.

Sincerely,
Elaine Greene, R.Ph.
jgreene@indy.rr.com

CMS-4068-P-332

Submitter : Ms. Amanda Hitterman **Date & Time:** 09/28/2004 12:09:02

Organization : National Catholic Aids Network

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

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

I know many HIV patients who will be unable to afford the life saving medications covered by the old insurance plan. Please be aware that the decision you make on this bill may be a death warrant for those in need of retroviral medications not covered by the new plan. The right to life of many Americans may be taken away by furthering this bill.

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

Sincerely,

Amanda Hitterman

CMS-4068-P-333

Submitter : Ms. Melissa Gorecki **Date & Time:** 09/28/2004 01:09:58

Organization : Academy of Student Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposed regulation allows plans to designate pharmacies as "preferred" or "non-preferred" this means that a co-pay may be higher at "non-preferred" pharmacies which will hurt a lot of them.

CMS must clarity that plans cannot require beneficiaries to obtain MTMS from a specific provider which could disrupt existing patient-pharmacist relationships.

Plans must be required to pay the same fee for MTMS to all providers. They should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service

CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.

Pharmacists and physicians should also be able to identify eligible beneficiaries.

CMS-4068-P-334

Submitter : Jennifer Fedyna **Date & Time:** 09/28/2004 01:09:42

Organization : Campbell University Pharmacy Student

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Subpart C - Benefits and Beficiary Protections -- I am concerned that Tricare pharmacy access requirements should be specified to a more local area, such as within a county or group of counties. This would help to eliminate the chance of someone getting overlooked, or left out of the averages in many rural areas. Also the idea of preferred vs nonpreferred pharmacies has the potential to cause discrimination of smaller, "hometown" pharmacies. This would cause patients who have been going to their smalltown pharmacies for years to switch to a "preferred" pharmacy in order to save money. This pharmacy is new to them, they do not have the rapport that has been established over years of continued care that the smaller town pharmacies have provided to them. This would also cause problems for the small town pharmacies because of decreased business because they are not "preferred." There should be more of a standard for all pharmacies since all pharmacies are eligible to participate.

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

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans -- I believe this is an excellent idea for pharmacists. Pharmacists are in the most ideal role for providing Medication Therapy Management services. I believe however that there should be specific guidelines as to who qualifies for such coverage. Rather than someone with "multiple" disease processes or on multiple medication therapies, it should be more defined, such as 2 different diseases or more than 3 medications and so forth. I like the idea that other health care providers may also not only provide these services, but also help to identify them. I do not have direct pharmacy experience, but I do work in an emergency room as an RN, and I frequently take care of patients who are in need of additional counseling and drug therapy monitoring. Knowing a place to refer them to would leave them more satisfied with their care, and it would also benefit them to be able to go to the most qualified health care professional -- a Pharmacist. There are concerns though about the additional cost of providing MTMS - I understand there is a reimbursement to pharmacies, but where will the additional monies come from, and how much will it be. Pharmacists are already facing a shortage, will there be enough money reimbursed to pay for additional staff to support MTMS for an already overwhelmingly busy pharmacy? Another concern is the level of education, and continuing education -- will the pharmacists practicing today be prepared by January 2006 to provide these services? I know there is continuing education, but what about all of the practing Pharmacists with Bachelor's degrees, or those that just do the minimums to maintain their registry? How will they be ready by Jan 2006 to provide these services? I think this is a wonderful idea, and it gives me even more inspiration as I am starting my pharmacy education, and I look forward to the opportunity to participate in MTMS in order to help better the community, its citizens and hopefully, reduce hospital visits, medications errors, and adverse reactions, as well as closer follow up on therapeutic management of disease processes and drug therapies.

Submitter : Dr. Elizabeth Green **Date & Time:** 09/28/2004 03:09:13

Organization : psychologist in private practice

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Please make necessary revisions to ensure that dually diagnosed persons with mental health and substance abuse problems have access to the medications vital to their recovery with minimal disruption.

CMS-4068-P-336

Submitter : Dr. Nicole Visitacion **Date & Time:** 09/28/2004 04:09:01

Organization : Dr. Nicole Visitacion

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

Targeted Beneficiaries
*Patients with 2 or more chronic diseases and/or 2 or more chronic medications should qualify for medication therapy management services.
*Beneficiaries of MTM will change, so plans should be required to identify new beneficiaries monthly.
*Plans should be required to inform pharmacists of eligible patients for MTM.
*Physicians & pharmacists should also be able to identify eligible beneficiaries for MTM.
*Plans must inform patients they are eligible for MTM and their choices (including pharmacy) for obtaining MTM.
*Once eligible, a beneficiary should remain eligible for one year.
*CMS must clarify that plans cannot exclude or prohibit pharmacists from providing MTM to non-targeted beneficiaries. MTMS is not a coverd benefit in non-targeted beneficiaries and pharmacists should be able to bill patients directly for these services.

Providers
*Pharmacists are medication experts and the ideal provider for MTMS.
*CMS must clarify that plans cannot require beneficiaries be limited to a specific provider.

Fees
*Plans must be required to pay the same fees to all providers of MTMS.
*CMS must ensure that the plans proposed fees for MTMS is high enough to encourage pharmacist to provide the service.

Services
*MTMS are independent of, but can occur in conjunction with, the provison of a medication product.
*Face-to-Face interaction is the preferred method of MTMS delivery whenever possible and should always be the intial assessment.
*

CMS-4068-P-337

Submitter : **Date & Time:** 09/28/2004 04:09:13

Organization :

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

Due to the amount of training that Pharmacists receive, both in school and in practice, I feel that they are the natural choice to be the providers of MTM services.

CMS-4068-P-338

Submitter : Mrs. Susan Long **Date & Time:** 09/28/2004 11:09:47

Organization : Mrs. Susan Long

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I 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, I 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).

I 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.

Submitter : Dr. David Kaufman **Date & Time:** 09/28/2004 01:09:33

Organization : St. Vincent Catholic Medical Centers of New York

Category : Physician

Issue Areas/Comments

Issues 1-10

BACKGROUND

As an HIV Physician since the beginning of the epidemic in 1980 I have cared for thousands of patients with this disease. The treatment of HIV Disease has evolved into a highly complex field requiring multiple medications, constant surveillance, and often frequent changes in medication regimens. This large and growing universe of patients clearly meets the criteria to be defined as a "Special Population". For clear and well established reasons, they have always been treated that way by programs such as New York State Medicaid.

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

The current law will allow PBMs to establish a limit of two drugs per category. It will also force patients with medicaid drug benefits to be shifted to the medicare program. The implications of these two changes is mind boggling. The daily management of patients with HIV/AIDS frequently includes three to five drugs from a class. The treatment regimens are constantly evolving with new combinations being tried. To place an arbitrary limitation on these drugs would be tantamount to dooming thousands of patients to the development of resistant HIV disease, treatment failure and death.

The medicaid program provides pharmaceutical access to a large universe of critically important medications and nutritional supplements. The financial and rationing restrictions imposed by the switch to a medicare drug program would be catastrophic for the comprehensive care of this special population of patients.

After 24 years of progress, these regulations represent a misguided giant step backwards even as the number of infected patients in this country grows.

Submitter : Mr. Terry Collins **Date & Time:** 09/28/2004 02:09:47

Organization : Medical Clinic & Neighborhood Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

It has been discussed by many pharmacists, and may be pushed, that only one (1) card would decrease confusion for medicare recipients and the pharmacies providing the prescription service. There are so many supposed medicare approved cards now that we can no longer help our patients choose the appropriate card, nor keep up with the different types. We request the use of only one card when the system is implemented. PLEASE!!! HELP THE PROFESSIONALS TRYING TO PROVIDE THE SERVICE. If the pharmacies are going to take the financial burden (discounts) then ask them what they would like to see happen with this program.

Submitter : Dr. William Greenberg **Date & Time:** 09/28/2004 02:09:08

Organization : New Jersey Psychiatric Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The New Jersey Psychiatric Association has reviewed the proposed regulations for the new Medicare drug benefit and we have concerns regarding its application to people with mental illness. Medicare patients are already burdened with a 50% co-payment for mental health services, and the drug benefit provides some but little help. Our concern here is with the proposed restrictive drug formularies planned for the Prescription Drug Plans (PDP?s). While affecting everyone, the burden will fall particularly hard on the dual Medicaid/Medicare patients, many of whom have mental illness, who will be mandated to join the Medicare drug plans.

Psychotropic drugs for the most part are NOT INTERCHANGEABLE. Even within a chemical class such as SSRI antidepressants, a patient may respond to one drug and not to another. A drug may have intolerable side effects for some patients and not others. Switching medications usually requires a long period of cross-tapering and trial of the new drug to find out if it is effective and lacks serious side effects. Quick changes (as often are required by changes in formularies) often lead to relapse of the illness. This unique issue for the mentally ill was recognized by Congress in its Conference Report (109-391, pp. 769-770):?The Conferees believe?the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different.? We urge that mentally ill patients be permitted to continue drugs that have been effective for them, and have a special unrestricted formulary as noted in the Proposed Regulations p. 46661 for this special population.

The proposed policies of ?fail first? and ?step therapy? can cause irreparable harm to these patients, since each delay and relapse can permanently worsen the course of the illness, leading to disability, costly hospitalizations and the risk of death by suicide. Prior authorization delays, appeals, and requests for ?exceptions? are prohibitive, as they are mentally unable to negotiate the complex system of multiple levels of appeals. The cost estimates at the end of the regulations estimate 30 minutes for the prescribing physician to request an exception, a tremendous cost burden, and only 20 per year per PDP, which is a totally unrealistic number.

We are particularly concerned about the patients with serious mental illness who comprise a high number of the dual eligible Medicare/Medicaid patients, who will be MANDATED to move to the Medicare Part D drug program. We urge you to maintain New Jersey?s lack of co-payment for Medicaid patients under the new rules. These patients will be required to join the lowest cost Medicare drug plan, which presumably will have the most restrictive formulary. New Jersey Medicaid currently has a formulary with minimal restrictions for psychotropic drugs, and none for the atypical antipsychotic drugs, which are essential to keeping patients out of the hospital. With these provisions, we have been able to maintain many seriously mentally ill patients in the community and avoid the high cost of relapse and hospitalization, as well as the risk of suicide and violence. If the proposed rule is unchanged, there will be no safeguards to ensure that patients can continue the drugs which are helping maintain their health, and to access drugs which may be essential.

We strongly urge your recognition of the unique needs of the mentally ill population by providing a non-restrictive formulary which will fulfill the intent of ensuring effective treatment and maximal control of psychiatric illness.

Sincerely,

William Greenberg, M.D., President
New Jersey Psychiatric Association

Linda Gochfeld, M.D.
Chairperson, Public Psychiatry Committee

CMS-4068-P-341-Attach-1.doc

NEW JERSEY PSYCHIATRIC ASSOCIATION

A District Branch of the American Psychiatric Association

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Aijaz Nanjiani, M.D. (Residents)

Executive Director
Carla A. Ross

Email: psychnj@optonline.net

WebSite: www.psychnj.org

September 26, 2004

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

Dear Doctor McLellan:

The New Jersey Psychiatric Association has reviewed the proposed regulations for the new Medicare drug benefit and we have concerns regarding its application to people with mental illness. Medicare patients are already burdened with a 50% co-payment for mental health services, and the drug benefit provides some but little help. Our concern here is with the proposed restrictive drug formularies planned for the Prescription Drug Plans (PDP's). While affecting everyone, the burden will fall particularly hard on the dual Medicaid/Medicare patients, many of whom have mental illness, who will be mandated to join the Medicare drug plans.

Psychotropic drugs for the most part are NOT INTERCHANGEABLE. Even within a chemical class such as SSRI antidepressants, a patient may respond to one drug and not to another. A drug may have intolerable side effects for some patients and not others. Switching medications usually requires a long period of cross-tapering and trial of the new drug to find out if it is effective and lacks serious side effects. Quick changes (as often are required by changes in formularies) often lead to relapse of the illness. This unique issue for the mentally ill was recognized by Congress in its Conference Report (109-391, pp. 769-770):"The Conferees believe…the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different." We urge that mentally ill patients be permitted to continue drugs that have been effective for them, and have a special unrestricted formulary as noted in the Proposed Regulations p. 46661 for this special population.

The proposed policies of "fail first" and "step therapy" can cause irreparable harm to these patients, since each delay and relapse can permanently worsen the course of the illness, leading to disability, costly hospitalizations and the risk of death by suicide. Prior authorization delays, appeals, and requests for "exceptions" are prohibitive, as they are mentally unable to negotiate the complex system of multiple levels of appeals. The cost estimates at the end of the regulations estimate 30 minutes for the prescribing physician to request an exception, a tremendous cost burden, and only 20 per year per PDP, which is a totally unrealistic number.

We are particularly concerned about the patients with serious mental illness who comprise a high number of the dual eligible Medicare/Medicaid patients, who will be MANDATED to move to the Medicare Part D drug program. We urge you to maintain New Jersey's lack of co-payment for Medicaid patients under the new rules. These patients will be required to join the lowest cost Medicare drug plan, which presumably will have the most restrictive formulary. New Jersey Medicaid currently has a formulary with minimal restrictions for psychotropic drugs, and none for the atypical antipsychotic drugs, which are essential to keeping patients out of the hospital. With these provisions, we have been able to maintain many seriously mentally ill patients in the community and avoid the high cost of relapse and hospitalization, as well as the risk of suicide and violence. If the proposed rule is

unchanged, there will be no safeguards to ensure that patients can continue the drugs which are helping maintain their health, and to access drugs which may be essential.

We strongly urge your recognition of the unique needs of the mentally ill population by providing a non-restrictive formulary which will fulfill the intent of ensuring effective treatment and maximal control of psychiatric illness.

Sincerely,

William Greenberg, M.D., President

New Jersey Psychiatric Association

Linda Gochfeld, M.D.

Chairperson, Public Psychiatry Committee

CMS-4068-P-342

Submitter : Ms. Lynne Cleveland **Date & Time:** 09/28/2004 02:09:08

Organization : The Arc of The United States

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-342-Attach-1.doc

The Arc
PUBLIC POLICY COLLABORATION
UCP United Cerebral Palsy
1331 H STREET, NW, SUITE 301 WASHINGTON, DC 20005
(202) 783-2229 (202) 783-8250 - FAX
WWW.THEARC.ORG EMAIL: PUBLICPOLICY@THEARC.ORG

Proposed Medicare Rules Fail to Protect Beneficiaries with Disabilities; Dual Eligibles at Risk

Your Comments to CMS Needed by October 4th to Win Changes

Background

The Centers for Medicare and Medicaid Services (CMS) at the U.S. Department of Health and Human Services (HHS) recently released proposed regulations to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We are gravely concerned that these proposed rules fail to provide adequate safeguards to ensure that beneficiaries with disabilities have access to the medications they need. The lack of needed protections under the rules will fall heavily on people with dual-eligibility for Medicare and Medicaid, because their drug coverage will shift from Medicaid to Medicare in 2006 under the new Medicare drug-benefit law. To win the addition of badly-needed consumer protections, many public comments must be submitted to CMS.

The 1,956-page proposed rule (which can be accessed at http://www.cms.hhs.gov/medicarereform.) is extremely complex. CMS poses several questions seeking input on a multiplicity of important issues. We are working with abroad coalition of advocates that represent Medicare beneficiaries to develop comprehensive comments on the regulations. Those comments can be found at http://www.familiesusa.org/site/PageServer?pagename=Medicare_Central_Index We are urging groups to sign on to these comments as well as submit their own letters and sending out action alerts to their members and other interested parties.

Provisions in the proposed rule which are of particular importance to Medicare beneficiaries with disabilities include: formularies (the drug benefit's list of covered drugs), to insure that beneficiaries obtain the drugs they need, making sure the benefit is affordable, and ensuring that the grievance and appeals process is workable and accessible for beneficiaries and physicians.

Advocates for Medicare beneficiaries with disabilities are also placing special emphasis on provisions affecting dual-eligibles because the new Medicare law (known as the MMA) leaves

these beneficiaries, many of who have significant health care needs, worse off than they are now. Medicaid currently provides prescription drug coverage for dual-eligibles. When the new Medicare prescription drug benefit takes effect on January 1, 2006, all dual-eligibles will obtain prescription drugs through private plans approved by CMS in accordance with MMA rules.

Currently, when both Medicare and Medicaid cover a service or benefit, Medicare serves as the primary benefit, and Medicaid "wraps around" that coverage. For example, Medicaid fills in the gaps in the Medicare benefit or pays for cost sharing associated with the benefit. However, under the MMA states will be prohibited from using Federal Medicaid funds to either pay for a drug a dual-eligible needs that may not be on the Medicare drug benefit plan's formulary or assisting the dual-eligible beneficiary with cost-sharing payments. Health policy experts and advocates are concerned that dual-eligibles with complex needs who require multiple medications may not be able to obtain the drugs they need. Individuals who have unique needs requiring newer, more costly medications are especially at risk for losing access to the medications they need.

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Status

The proposed regulation is open for public comment until next **Monday**, **October 4, 2004.**

Action To Be Taken

Your letter (including one original and two copies) must reach CMS by October 4th (a postmark of October 4th is not sufficient).

In the alternative, you may submit your letter electronically to http://www.cms.hhs.gov/regulations/ecomments. E-mail comments must be received by COB on October 4.

Follow these steps after clicking on this link:

1) Click on the first bullet that says "SEND"
2) On the table, find Docket ID-CMS - 4068-P (Medicare Program; Medicare Prescription Drug Benefit) and then click on "Go"
3) Fill in information (your zip code, etc) on the Docket Management Comment Form and click "Continue"
4) In the text box under "General Comment" heading, type in "please see attached file from the disability community" and then click on "Continue"
5) Follow the instructions for attaching your letter/Word document and then click the yellow "Attach File" button

We urge you to use the sample letter attached to write CMS and to widely distribute this action alert. While we have identified numerous concerns with the regulations the sample letter highlights our priorities:

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

- Expand outreach to Medicare beneficiaries with disabilities
- Designate special populations who will receive affordable access to an alternative formulary
- Impose new limits on cost containment tools
- Strengthen and improve inadequate and unworkable exceptions and appeals processes
- Require plans to dispense a temporary supply of drugs in emergencies

CMS counts the numbers of comments it receives on all issues. Therefore it is critical for us to generate as many comments as possible on these priority issues.

Sample Letter is attached.

Thank you!

CMS-4068-P-343

Submitter : Gary Boone **Date & Time:** 09/28/2004 02:09:52

Organization : USA Drug

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment in support of NACDS' proposal to build on Option 2, as described on FR page 46706, to include pharmacies in the single point of contact system. NACDS refers to this online real time COB-TrOOP system as SPOCS (Single Point of Contact System).

The inherent nature of coordination of benefits (COB hereafter) is such that beneficiaries almost never understand it. An online real time COB would be equally beneficial to both Medicare beneficiaries and the provider/supplier community. Certainly for Medicare beneficiaries, the SPOCS is easier to understand and more convenient than other options.

Secondary payor information is a major hurdle for pharmacy claims. Separate response payment segments from SPOCS will eliminate the current confusion in these cases. The beneficiary would only need to present their Medicare card with SPOCS and the claim can be routed to the appropriate primary and secondary payors.

Another important consideration is that of the independence with which SPOCS would perform their function. There would not be a potential conflict of interest managing patient identifiable health care information and pharmacies' confidential payment rates.

There are other strong arguments for adoption of the NACDS proposal but they are readily apparent in the NACDS proposal itself.

I strongly urge CMS to give due consideration to the this idea.

CMS-4068-P-344

Submitter : Mr. james utrie **Date & Time:** 09/28/2004 02:09:20

Organization : WEA INSURANCE CORPORATION

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

We are a union sponsored insurance company in Wisconsin. We insure approximately 12,000 post age 65 memebers in our Employer Sponsored Group Health Plans. We find the benefit structure of the MDP makes offering either a supplemental plan or a primary plan financial suicide. Either plan will quickly enter an adverse selection death spiral.

Let me explain. The out of pocket limit is ill-conceived. Dollars that are reimbursed by insurance do not count toward the OOP limit. This makes the secondary plan liable for essentially all of the Catastrophic Benefit. In turn a rate is necsessary that makes a secondary plan a very poor decision for almost everyyone in this cohort.

Perhaps this was the thinking when the plan design was developed. I do not understand why the government makes a distinction between insurance reimbursed expense and uninsured expense. The $3600 OOP limit should apply to both types of dollars. Clearly this is not the case. Any hope that most employers or insurers will offer a primary or secondary plan to the MDP will not happen.

We conclude that the secondary plan we developed is a lousy buy for more than 80% of our members. We will probably recommennd they take the MDP and save the premium otherwise paid for a supplement.

CMS-4068-P-345

Submitter : Ms. Christine Curry **Date & Time:** 09/28/2004 03:09:07

Organization : Ms. Christine Curry

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I urge CMS to ensure the following concerns are addressed in the final implementation rules:

* People with HIV/AIDS risk life-threatening illness if drug plans are allowed to limit the number of HIV drugs covered. Drug plans must carry all the drugs people with HIV/AIDS need.

* Because restricted access to needed HIV/AIDS medications could lead to drug resistance or severe medical complications, Medicare should treat people with HIV/AIDS as a special needs population and require drug plans to offer them an open formulary.

* Individuals eligible for both Medicaid and Medicare (know as dual-eligibles) may get fewer benefits under Medicare than they now receive in Medicaid. CMS should ensure that new benefits are of equal or greater quality than those provided by Medicaid.

* With the law cutting off Medicaid drug benefits for dual-eligibles on December 31, 2005, but not automatically enrolling them in the new Medicare drug program, dual-eligibles will be at risk for interruptions in drug coverage. Dual-eligibles with HIV/AIDS cannot risk a gap in coverage during the transition from Medicaid to Medicare, which would severely compromise their health.

* The draft grievance and appeals process is inadequate and must be enhanced to provide greater protections for Medicare recipients. Grievance and appeal processes must be effective and easy-to-access, and must include the right to get an emergency supply of medications while an appeal is under way.

* Proposed rules allow drug plans access to the names and medical histories of Medicare recipients in order to aid their marketing and enrollment strategies. Drug plans should not violate the privacy of people with HIV/AIDS and other Medicare beneficiaries

Submitter : Mr. Ken Lonergan **Date & Time:** 09/28/2004 03:09:09

Organization : University of Wisconsin Hospital and Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-4068-P

To Whom It May Concern:

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

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

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

? CMS rules must allow for hospital pharmacies to be included not precluded. Plan sponsors should be required to establish CMS specified MTM services.

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

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

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

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

Thank you for your consideration.

Sincerely,

Ken Lonergan, R.Ph.
University of Wisconsin Hospital and Clinics
Medication Management Pharmacy
Madison, WI 53792

CMS-4068-P-347

Submitter : Miss. Elizabeth Powell **Date & Time:** 09/28/2004 03:09:15

Organization : Miss. Elizabeth Powell

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Due to the new Medicare law enacted by Congress and President Bush last year, more than 80,000 Americans living with HIV/AIDS will become eligible for a new prescription drug benefit under Medicare. The vast majority of these individuals (some 60,000 nationwide) are currently receiving prescription drug coverage through Medicaid and will lose these benefits on December 31, 2005. They will then be forced to enroll in the new and potentially less comprehensive Medicare drug program.

The federal Centers for Medicare and Medicaid Services (CMS) recently released a 2,000-page draft document detailing how the government will implement the complex, new benefit. This short-changes people with HIV/AIDS and could severely compromise their health by interrupting HIV treatments and offering them sub-standard healthcare.

The following concerns need to be addressed in the final implementation rules:

* People with HIV/AIDS risk life-threatening illness if drug plans are allowed to limit the number of HIV drugs covered. Drug plans must carry all the drugs people with HIV/AIDS need.

* Because restricted access to needed HIV/AIDS medications could lead to drug resistance or severe medical complications, Medicare should treat people with HIV/AIDS as a “special needs population” and require drug plans to offer them an “open formulary.”

* Individuals eligible for both Medicaid and Medicare (know as “dual-eligibles”) may get fewer benefits under Medicare than they now receive in Medicaid. CMS should ensure that new benefits are of equal or greater quality than those provided by Medicaid.

* With the law cutting off Medicaid drug benefits for dual-eligibles on December 31, 2005, but not automatically enrolling them in the new Medicare drug program, dual-eligibles will be at risk for interruptions in drug coverage. Dual-eligibles with HIV/AIDS cannot risk a gap in coverage during the transition from Medicaid to Medicare, which would severely compromise their health.

* The draft grievance and appeals process is inadequate and must be enhanced to provide greater protections for Medicare recipients. Grievance and appeal processes must be effective and easy-to-access, and must include the right to get an emergency supply of medications while an appeal is under way.

* Proposed rules allow drug plans access to the names and medical histories of Medicare recipients in order to aid their marketing and enrollment strategies. Drug plans should not violate the privacy of people with HIV/AIDS and other Medicare beneficiaries.

CMS-4068-P-348

Submitter : Mr. Edward Rahn **Date & Time:** 09/28/2004 03:09:01

Organization : Mr. Edward Rahn

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist I ask that you consider the valuable services provided to patients by communty pharmacists. It is important that we have access to these programs and are reimbursed at a rate that considers the survival of the community pharmacist. The recipients will be best served in their communities. There will be many forces at work to deny community pharmacy its place in this network or to reimburse at levels to low to live with. It will take strong will and cooperation on the part of all players to make this a real benefit to Medicare recipients.

Thank you

CMS-4068-P-349

Submitter : Shawn Dunn **Date & Time:** 09/28/2004 04:09:06

Organization : Shawn Dunn

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

People with HIV/AIDS risk life-threatening illness if drug plans are allowed to limit the number of HIV drugs covered. Drug plans must carry all the drugs people with HIV/AIDS need.

Because restricted access to needed HIV/AIDS medications could lead to drug resistance or severe medical complications, Medicare should treat people with HIV/AIDS as a ?special needs population? and require drug plans to offer them an ?open formulary.?

Individuals eligible for both Medicaid and Medicare (know as ?dual-eligibles?) may get fewer benefits under Medicare than they now receive in Medicaid. CMS should ensure that new benefits are of equal or greater quality than those provided by Medicaid.

With the law cutting off Medicaid drug benefits for dual-eligibles on December 31, 2005, but not automatically enrolling them in the new Medicare drug program, dual-eligibles will be at risk for interruptions in drug coverage. Dual-eligibles with HIV/AIDS cannot risk a gap in coverage during the transition from Medicaid to Medicare, which would severely compromise their health.

The draft grievance and appeals process is inadequate and must be enhanced to provide greater protections for Medicare recipients. Grievance and appeal processes must be effective and easy-to-access, and must include the right to get an emergency supply of medications while an appeal is under way.

Proposed rules allow drug plans access to the names and medical histories of Medicare recipients in order to aid their marketing and enrollment strategies. Drug plans should not violate the privacy of people with HIV/AIDS and other Medicare beneficiaries.

CMS-4068-P-350

Submitter : Mr. Barry McCahill **Date & Time:** 09/28/2004 04:09:21

Organization : Mr. Barry McCahill

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

September 28, 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 support the attached comments submitted by Voice of the Retarded (VOR). We feel strongly that !V

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

?I !?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,

Barry McCahill
1741 South Willow Lake Way
Eagle, ID 83616
208-938-9994
bmccahill@earthlink.net

CMS-4068-P-350-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 of 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:

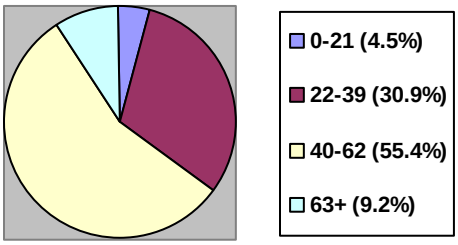
Mary McTernan
President
Voice of the Retarded
201 Brooksby Village Dr., Apt. 508
Peabody, MA 01960
978-535-2472 phone
978-535-0472 fax

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

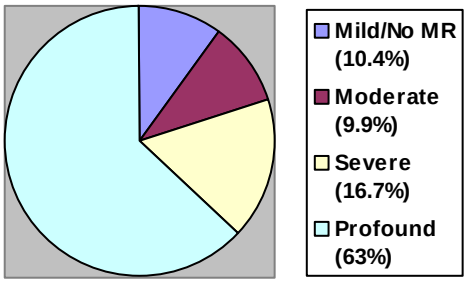
Characteristics of Residents of Large State MR/DD Facilities
June 30, 2002

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).

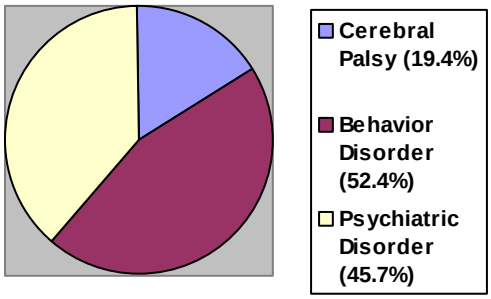
Age of residents



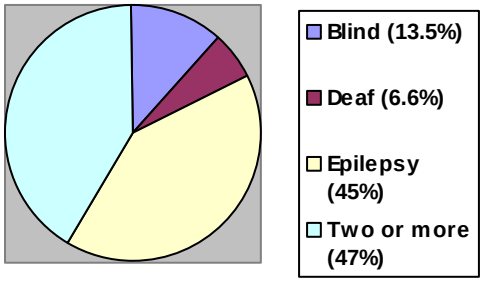
Level of mental retardation



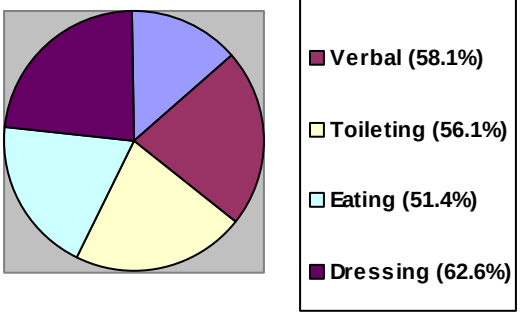
Additional conditions



Additional conditions



Functional limitations



CMS-4068-P-351

Submitter : Mr. Rob Camp **Date & Time:** 09/28/2004 04:09:57

Organization : Treatment Action Group

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

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

Sincerely,

Rob Camp

CMS-4068-P-352

Submitter : Mr. Robert Zincke **Date & Time:** 09/28/2004 04:09:47

Organization : The Kroger Co.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Dear Secretary Thompson & Dr. McClellan:
With nearly 1900 retail pharmacies around the country, Kroger is the nation's seventh-largest retail pharmacy operator. In 2003 we served millions of customers in our combination grocery & drug stores.

We are writing to express our concerns about the regulations issued August 3, 2004 that would implement the new Medicaid Part D prescription drug benefit in 2006. We fully support the objective of providing seniors with lower cost medications.

We are members of the National Association of Chain Drug Stores (NACDS) & the Food Marketing Institute (FMI). As members, we participated with NACDS & FMI in the preparaion of their comments. We support them in their entirety.

There are 4 main points that we would like to emphasize:

Equal Beneficiary Access to Maintenance Medications
There must be a level playing field between Mail Order & Retail Network Pharmacies. PDP or MA-PD plans must permit Medicare beneficiaries to obtain the same amount, scope, & duration of covered outpatient drugs and medication therapy management services at any community retail pharmacy that is in the plan's pharmacy network, as they offer through mail order pharmacies. Consistent with congressional intent, plans should not be able to use differential cost sharing to steer beneficiaries to mail order pharmacies.

Beneficiary Access to Pharmacies
According to the proposed rules, the standards for Medicare beneficiary access to pharmacies are being implemented in a manner that is inconsistent with Congressional intent, and will significantly reduce Medicare beneficiary access to and interaction with their local community pharmacy. We believe that each plan should be required to meet TriCare standards in each state in each region in which they operate. While the proposed regulation does not specify the service areas, the fact is that using an "average" could allow plans to permit much greater access for beneficiaries in certain urban areas of the region, while reducing access in other urban areas of the region. The same is true for the suburban & rural areas of the region.

Beneficiary Access to Medication Therapy Management (MTM)
Kroger supports the inclusion of MTM services in the Part D plans. CMS should be aware of conflicting incentives for PDPs versus MA-PDs. MA-PDs are at risk for all of the health care utilization of their enrollees while PDPs are only concerned with the drug expenditure portion. This may give PDPs a financial disincentive to promote comprehensive MTM programs. MTM services are likely to increase drug utilization while decreasing utilization of hospital and emergency room services.

Rules should be established to address standardized benefits, face-to-face consultation, separate payment for MTM services, etc. Also, we encourage CMS to specify that Community Pharmacists be primarily used for providing MTM services. Payment should be made on an hourly basis and made to the pharmacy and not the pharmacist, unless the pharmacist is the proprietor & owner of the pharmacy.

System to Coordinate Part D Plans with Other Drug Coverage
Kroger encourages the creation of a real time, online Coordination of Benefits (COB) system that contains all of the Medicare beneficiary's insurance information & the correct billing order to payers. A single point of contact system is important in order to be able to determine true out of pocket (TrOOP) expenditures by the beneficiary & to allow Part D enrollees to receive their prescription medications and services in a timely manner. Billing online is currently the industry standard. The addition of the Part D program will add a level of complexity that needs to be addressed with a real time system without additional costs to retail pharmacy.

We appreciate the opportunity to provide our comments on this important program. We want to preserve what our senior customers value most.
Sincerely, Robert Zincke, EVP, The Kroger Co.

CMS-4068-P-352-Attach-1.doc

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

Transmitted electronically on September 24, 2004
www.cms.hhs.gov/regulations/ecomments

Dear Secretary Thompson and Assistant Director Lieberman:

With nearly 1,900 retail pharmacies around the country, Kroger is the nation's seventh-largest retail pharmacy operator. In 2003 we served millions of customers in our combination grocery and drug stores.

We are writing to express our concerns about the regulations issued August 3, 2004 that would implement the new Medicaid Part D prescription drug benefit in 2006. We fully support the objective of providing seniors with lower cost medications.

We are members of the National Association of Chain Drug Stores (NACDS) and the Food Marketing Institute (FMI). As members, we participated with NACDS and FMI in the preparation of their comments. We support them in their entirety.

There are four main points that we would like to emphasize:

Equal Beneficiary Access to Maintenance Medications
There must be a level playing field between Mail Order and Retail Network Pharmacies. PDP or MA-PD plans must 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, as they offer through mail order pharmacies. Consistent with congressional intent, plans should not be able to use differential cost sharing to steer beneficiaries to mail order pharmacies. As one prominent Senator stated, "I would also expect that the Secretary of Health and Human Services would disapprove of any plan that would impose a differential charge that was intended primarily to steer Medicare beneficiaries to mail order pharmacies versus retail pharmacies."

Beneficiary Access to Pharmacies
According to the proposed rules, the standards for Medicare beneficiary access to pharmacies are being implemented in a manner that is inconsistent with Congressional intent, and will significantly reduce Medicare beneficiary access to and interaction with their local community pharmacy. We believe that each plan should be required to meet TriCare standards in each state in each region in which they operate. While the proposed regulation does not specify the service areas, the fact is that using an "average" could allow plans to permit much greater

access for beneficiaries in certain urban areas of the region, while reducing access in other urban areas of the region. The same is true for the suburban and rural areas of the region.

Beneficiary Access to Medication Therapy Management (MTM)
Kroger supports the inclusion of MTM services in the Part D plans. CMS should be aware of conflicting incentives for PDPs versus MA-PDs. MA-PDs are at risk for all of the health care utilization of their enrollees while PDPs are only concerned with the drug expenditure portion. This may give PDPs a financial disincentive to promote comprehensive MTM programs. MTM services are likely to increase drug utilization while decreasing utilization of hospital and emergency room services.

Rules should be established to address standardized benefits, face-to-face consultation, separate payment for MTM services etc. Also, we encourage CMS to specify that Community Pharmacists be primarily used for providing MTM services. Payment should be made on an hourly basis and made to the pharmacy and not the pharmacist, unless the pharmacist is the proprietor and owner of the pharmacy.

System to Coordinate Part D Plans with Other Drug Coverage
Kroger encourages the creation of a real time, online Coordination of Benefits (COB) system that contains all of the Medicare beneficiary's insurance information and the correct billing order to payers. A single point of contact system is important in order to be able to determine true out of pocket (TrOOP) expenditures by the beneficiary and to allow Part D enrollees to receive their prescription medications and services in a timely manner. Billing online is currently the industry standard. The addition of the Part D program will add a level of complexity that needs to be addressed with a real time system without adding additional costs to retail pharmacy.

We appreciate the opportunity to provide our comments on this important program. We fully support the objective of providing seniors with lower cost medications. We want to preserve what our senior customers tell us they value most---the relationship and interaction with their local pharmacist. Our pharmacists are on the front line of providing health care for seniors every day. It is a role and a trust we treasure.

Sincerely,

bcc: Don Becker, Dave Dillon, Lincoln Lutz, Don McGeorge, FMI, and NACDS

CMS-4068-P-353

Submitter : Dr. Stevan Gressitt **Date & Time:** 09/28/2004 05:09:24

Organization : Maine Benzodiazepine Study Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This is to forward an attachment. I have tried several toimes to send comments with no success to date.
Stevan Gressitt, M.D. 207-441-0291

CMS-4068-P-353-Attach-1.doc

September 25, 2004

Benzodiazepines, a group of medications commonly prescribed to America's older adults for the treatment of insomnia and anxiety, are not covered by the new Medicare prescription drug benefit. This has already caused some specific patients to lose coverage in the State of Maine. As an emergency measure, the State of Maine has provided benzodiazepine coverage for those patients within the Drugs for the Elderly Program (DEL). This is not a solution to a federal problem.

Benzodiazepines include such branded drugs as Xanax, Ativan, Restoril and Valium and their generic equivalents. Researchers estimate that benzodiazepines are prescribed to 1 in 5 Medicare recipients (see http://www.noemaine.org/benzo/reports/mbsg2003.pdf). Many Medicare recipients are unlikely to pay out-of-pocket for continued benzodiazepine therapy. Dual-eligibles we work with do not have the resources to pay out-of-pocket for on-going benzodiazepine therapy.

Abrupt cessation may cause severe withdrawal symptoms, such as seizures, that require Medicare-funded emergency room treatment and hospitalization. Benzodiazepine withdrawal is frequently difficult and carries more physiological risk of seizures than opiate withdrawal. Over 40 years ago, Hollister described withdrawal with severe consequences, including psychosis if benzodiazepines were abruptly stopped (see: Withdrawal Reactions from Chlordiazepoxide, Leo E. Hollister, Francis P. Motzenbecker & Roger O. Dean, Psychopharmacologia 2, 63-68 (1961).

Despite their low cost and evidence-based efficacy at treating short-term anxiety and insomnia, benzodiazepines were specifically and categorically excluded by Congress when it created Medicare's new prescription drug benefit program, Medicare Part D.

The benzodiazepine exclusion was reaffirmed in proposed rules recently published by the US Department of Health and Human Services and its Centers for Medicare & Medicaid Services. See "Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)" at http://www.cms.hhs.gov/medicarereform/ or at http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/pdf/04-17234.pdf.

The consequences of this exclusion — which affects 41.2 million Medicare recipients, including 6.4 million dual-eligibles currently covered under Medicaid — clearly were inadequately assessed by Congress and the Administration.

On January 1, 2006, when the majority of Medicare drug benefits begin, some physicians expect that many poor and older adults will ask that they be switched from their benzodiazepine prescription to a covered drug. These switches may come abruptly, leading to harmful drug interactions or drug withdrawal. An additional worry is that some users will be switched to more costly branded alternatives, when no medication may be best, and when some alternatives have not been adequately studied for abuse, misuse, or dependence.

This exclusion as anticipated will not permit needed use or address inappropriate use. Most likely an increase in diversion, Internet drug sales, and illegal controlled substance importation will occur. This class of pharmaceutical has been inadequately tracked, poorly monitored, and relatively neglected as a component of drug related deaths, overdoses, and toxic exposures. Pharmacovigilince of benzodiazepines is poorly developed. The class has been the subject of warnings from the Chief Medical Officer of Great Britain (see http://www.dh.gov.uk/assetRoot/04/07/01/76/04070176.pdf) relating to overuse and the need for careful treatment and withdrawal and increased resources to provide this. Only recently has DAWN released a report on benzodiazepines (see http://dawninfo.samhsa.gov/pubs_94_02/shortreports/files/DAWN_tdr_benzo_visits.pdf) that makes it clear this is the class of pharmaceutical most mentioned in emergency rooms across the United States and arguably the class in most need of public health attention, not abrupt termination.

It is noteworthy that the CMS itself identifies benzodiazepines as to be considered one of "the drug therapeutic classes and groups (and in a few cases subgroups) that contain the drugs most commonly needed by Medicare beneficiaries." See "Medicare-Approved Prescription Drug Discount Card and Transitional Assistance Program Solicitation for Applications (for non-Medicare Managed Care Contractors)" at www.cms.hhs.gov/discountdrugs/solicrevise.pdf Attachment 2, pages 69 and 72 January 14, 2004, (revised).

In the best interests of health care, CMS must find a way to include benzodiazepines as a covered drug under Medicare Part D. There is an opportunity to discuss State specific clinical guidelines, dispensing supervision, lack of policy toward this DEA Schedule IV pharmaceutical class, and better Pharmacovigilance. Along with direct attention to pharmaceutical diversion and smuggling, this situation may turn into one that improves the public health without excessive spending and continues to offer evidence-based medical therapeutics to the US population.

We look forward to the opportunity to provide further information as requested.

Stevan Gressitt, MD
Acting Secretary
Maine Benzodiazepine Study Group
www.noemaine.org/benzo/benzo.htm

Medical Director, Northeast Occupational Exchange
Bangor, Maine

The Maine Benzodiazepine Study Group was formed to study the use, misuse, and abuse of benzodiazepines in late 2001.

CMS-4068-P-354

Submitter : Mr. Gregory Celebre **Date & Time:** 09/28/2004 05:09:52

Organization : Mr. Gregory Celebre

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-4068-P

To Whom It May Concern:

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

First i would like to express my appreciation for this oppertunity to offer the Centers for Medicare and Medicaid Services (CMS)my constructive oppinion of the rulles 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 incorperate rule language that will ensure compensation for all hospital pharmacy providers that perform MTM services.

CMS rules must allow for hospital pharmacies to be included not precluded. Plan sponsors should be required to establish CMS specified MTM services.

CMS should requirw all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponcerscould 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 eligable 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 reqired to have a plan to direct recipients to MTM service providers. MTM servive payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the oppertunity to provide MTM services.
In closing , pharmacies can be an integral component of the new Medicare benefit. Midicare 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 paln sponsers otherwise many of the nations foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacies must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you for your consideration.

Sincerly

Gregory T. Celebre RPh

CMS-4068-P-355

Submitter : Ms. mary grover **Date & Time:** 09/28/2004 06:09:32

Organization : The Mental Health Association of the Cinti. Area

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

Please do not institute restrictive drug formularies for persons receiving Medicail/Medicare. As a mental health professional, and more importantly as a mental health consumer (I have two diagnoses), I can attest to how vitally important it is to have full access to medications. I am lucky.. I have private insurance. And even so, it has taken my doctor and me three years to develop the right medication regime for me. If I had had to rely on a resptritive formulary, I would not be able to receive the optimal treatment to control my symptoms. Without adequate treatment, I would have to leave my job (as I had to do four years ago), stay in my home, compromise my parenting, and a host of other destructive results. Mental Illness (brain diseases) are complicated diseases and must have individualized treatment for the optimal outcome. Please do not put Mental Health Consumers at risk for decompensating, abenteeism at work, lost productivity, and accidents. In addition, without the recommended durg regime, mental health consumers are left to use hospital emergency rooms, a very high cost. In the long run, it is less expensive to treat the brain disease well in the beginning, than to deny proper treatment with the financial consequences. Please consider my letter. I am grateful.

CMS-4068-P-356

Submitter : Dr. Deborah Gillard **Date & Time:** 09/28/2004 06:09:51

Organization : Dr. Deborah Gillard

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

I write today to offer comments re: the proposed Medicare Part D rules. As a pharmacist practicing in a pharmacist managaed anticoagulation clinic, I am deeply concerned with the rules as they are currently proposed. In order for this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all hospital pharmacy providers that perform MTM services. CMS rules must allow for hospital pharmacists to be included note precluded. Plan sponsors should be required to establish CMS specified MTM services. CMS should require all plan sponsors to provide at least a specified 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 to provide that service. All prescribers eligible for payment under Medicare should be allowed to refer patients in need of MTM services to a provider of MTM services. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber. In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services. In closing, pharmacies can be an integral component of the new Medicare benefit. Medicare recipients often rely on their pharmacist for advice and counsel. Pharmacists will be able to assist in making this new benefit successful or they will speak out against it. Medicare must make specific requirements of the plan sponsors otherwise many of the nation's foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacists must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.
Thank you for your consideration.
Sincerely,
Deborah Gillard, Pharm.D.
Anticoagulation Clinic
Froedtert Memorial Lutheran Hospital

CMS-4068-P-357

Submitter : Mrs. margaret Neuworth **Date & Time:** 09/28/2004 07:09:37

Organization : Froedtert Hospital

Category : Other Health Care Professional

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 hospital pharmacist I am deeply concerned withthe rules as they are currently proposed.
First, I would like to express my appreciation for this opportunity to offer CMS my constructive opinion of the rules developrd for the implementaion 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 wanr this program to work.
Inorder for this program to be successful, I urge CMS to incorporate rule language that will ensure compensation for all hospital pharmacy providers that perform MTM services.
CMS rules must allow for hospital pahrmacies to be included NOT precluded. Plan sponsers should be required to establish CMS specified MTM services.
CMS should require all plan sponsers to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsers could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise. plan sponsers should be directed to allow any pharmacist who receives as 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. 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 an ddrug therapies, plans should be required to have a plan to direct recipients to MTM service providers.MTM service payment must be sufficient to warrent 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 makingthis new benefit successful or they will speak out against it.Medicaremust make specific requirements of the plan sponsers 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 fully and equally. And finally, pharmacy providers must receive adequate payment for services they provide to recipients of the program.
Thank you for your consideration.
Sincerely.
Margaret P. Neuworth RPh

CMS-4068-P-358

Submitter : Ms. Lisa Stamps **Date & Time:** 09/28/2004 07:09:33

Organization : Helping Parents Help Kids

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-358-Attach-1.doc

28 September 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:

Helping Parents Help Kids welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. Helping Parents Help Kids is an advocacy organization which helps parents learn how best to help their children with special needs survive in the public schools. 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.

Submitter : Dr. Stephan Foster **Date & Time:** 09/28/2004 07:09:08

Organization : University of Tennessee

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

September 28, 2004

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.

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different MedicationTherapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer. In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In
my opinion, patients with two or more diseases and taking two or more medications should qualify.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I have followed diabetic patients for the last 26 years and clearly have benefited there therapy?.all without reimbursement. Pharmacists are healthcare providers that provide services and should not be excluded from payment for these services independent from dispensing fee.

Thank you for considering my comments.

Sincerely,

Stephan L. Foster, Pharm.D.
Associate Professor
University of Tennessee College of Pharmacy
Memphis, TN 38163
901-448-6806

CMS-4068-P-360

Submitter : Dr. Elizabeth DeVore **Date & Time:** 09/28/2004 07:09:45

Organization : Dr. Elizabeth DeVore

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

As a community pharmacist, I am concerned with three aspects of the Medicare part D proposed rules and recommend that CMS enable the following three policies:

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

Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies.
Recipients should not be economically coerced into using one pharmacy over another unless the plan sponsor for defined quality reasons prefers the preferential pharmacy. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. Plan sponsors should also be prohibited from promoting pharmacies in which they have ownership interest.
Plan sponsors should be required to establish specified MTM services.
CMS should require all plan sponsors to provide at least a specified (by CMS) set of medication therapy management services. Plan sponsors could provide additional MTM services, beyond the minimum required, but each must meet the CMS minimum requirements. Likewise, plan sponsors should be directed to allow any pharmacist who receives an order for an MTM service to provide that service.

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

In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.
Medicare recipients often rely on their pharmacist for advice and counsel. To date, I have received numerous requests to explain the proposal to senior clients. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. Interested pharmacies must be allowed to participate equally and fully. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

CMS-4068-P-361

Submitter : **Date & Time:** 09/28/2004 07:09:16

Organization : Academy of Student Pharmacists

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

We believe preferred vs. non-preferred pharmacy status can be beneficial in reducing patient co-pays, but we are concerned that it may negatively effect patient compliance. A patient is currently using a certain pharmacy because that pharmacy accepts the patient's insurance plan. The patient is compliant in medication administration, satisfied with their patient/pharmacist relationship, and pleased with the services provided by the pharmacy. Suddenly, this pharmacy is not a preferred pharmacy on their insurance plan. This could cause many problems in the fact that the patient may need to change pharmacies and could become less compliant due to decreased satisfaction.

CMS-4068-P-362

Submitter : Mr. Ruel Nolledo **Date & Time:** 09/28/2004 08:09:45

Organization : Mr. Ruel Nolledo

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe 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-363

Submitter : Dr. Kennedy Blount **Date & Time:** 09/28/2004 08:09:59

Organization : Pitt County Memorial Hospital

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

I am a Clinical Pharmacist Practitioner (CPP) who practices in a hospital clinic. I see hospital employees and dependents who are covered under the hospital's medical plan. The hospital accepted the compelling data on how a pharmacist can reduce health care claims by managing patients with chronic diseases and polypharmacy issues. Although, the services provided by CPP's are costly, in the end they can prevent the even more costly complications of an uncontrolled chronic disease. I urge you to accept this bill.

Submitter : Mr. Russell Jensen **Date & Time:** 09/28/2004 08:09:10

Organization : Dean Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

I write today to offer comments regarding the proposed Medicare Part D rules. As a director of pharmacy for a hospital and clinic system, 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.

Pharmacists provide services within the clinic setting that reduce complications and lower health care costs in managing patients on anticoagulation therapy. Our data parallels the literature in demonstrating that patients managed by pharmacists through a clinic have fewer hospitalizations and other complications. We have pharmacists that manage patients with DVT?s on an outpatient basis and manage patients on home infusion therapy. Pharmacists need to be able to bill for these services to allow expansion of these services.

I would be happy to provide additional information or data. I can be reached at 608-258-6550 or Russ_Jensen@ssmhc.com

Thank you for your consideration

Submitter : Kori Dahlkoetter **Date & Time:** 09/28/2004 09:09:16

Organization : University of Missouri School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Pharmacy Access Standards - While I appreciate the intent of using the TRICARE requirements to determine access across the plan's coverage area, I am concerned that the plan does not address access on a local level. Please work to make sure that patients in all areas have access to a local pharmacy, not just an average of the patients.
Any Willing Provider - Plans should not be allowed to classify pharmacies as preferred and non-preferred. If this is truly to be an equal access program, beneficiaries should not be coerced into abandoning their current pharmacy. Cost is a MAJOR issue for these patients and creating a preferred network unfairly channels beneficiaries to the least expensive alternative, which WILL NOT allow pharmacists to provide the highest quality of care.
Level Playing Field - I am concerned that plans will be allowed to charge more for obtaining an extended days supply at a pharmacy rather than through mail order. Congressional intent, as identified in the colloquy of Senators Grassley and Enzi, opposes
making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice.

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

Medication Therapy Management Program - This piece of legislation is on the right track! However, a couple of things need to be clarified. First, 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. Also, 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. Finally, face-to-face interaction between the beneficiary and the MTMS provider is the preferred method of delivery whenever possible. Pharmacists are the drug experts on the health care team and should be the primary providers of MTMS.

Submitter : Mrs. TRACY DRYER **Date & Time:** 09/28/2004 10:09:38

Organization : RED CROSS PHARMACY

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

PHARMACISTS SHOULD BE THE ONLY PROVIDERS IN CONTROL OF ALL MEDICATION THERAPY MANAGEMENT. WE ARE THE EXPERTS IN MEDICATION THERAPY AND INTERACTIONS. IT'S QUITE DISTURBING FOR ME TO CHECK THE 'OTHER HEALTHCARE PROVIDER' IN THE BEGINNING OF THIS COMMENTARY. I CAN'T IMAGINE WHY PHARMACISTS AREN'T AT THE FOREFRONT OF THOUGHT WHEN WE ARE TALKING ABOUT A PRESCRIPTION DRUG BENEFIT CARD. THE PHARMACIST WILL HAVE SUCH AN IMPACT ON DRUG THERAPY AND SAVING THE PROGRAM MONEY IF WE CAN COUNSEL OUR PATIENTS FACE-TO-FACE. BECAUSE OF THIS POTENTIAL IMPACT, I STRONGLY SUGGEST THE PHARMACISTS' FEES ARE EQUAL ACROSS THE BOARD. I DO NOT THINK IT IS RIGHT TO HAVE DIFFERENT FEES FOR NON-PREFERRED PHARMACIES, ETC. I AM ALSO HIGHLY AGAINST MAIL-ORDER COMPANIES HAVING AN ADVANTAGE OVER THE COMMUNITY PHARMACIES. IT SHOULD BE AN EVEN PLAYING FIELD FOR BOTH OF US. PATIENTS DON'T HAVE A TRUE CHOICE IN PHARMACIES IF THEY ARE BEING COERCED INTO USING A MAIL-ORDER PHARMACY BECAUSE THEY SAVE A COUPLE OF DOLLARS. IT ALSO NEEDS TO BE ADDRESSED THAT IN THE LONG RUN---MAIL-ORDER DOES NOT SAVE AN INSURANCE COMPANY MONEY. LET'S GET BACK TO REAL HEALTHCARE. LET'S GET BACK TO REAL FACE-TO-FACE INTERACTION. LET'S GET BACK TO REAL COMPASSION AND NOT A BOTTOM NUMBER.

CMS-4068-P-367

Submitter : Dina Kancepolsky **Date & Time:** 09/28/2004 10:09:02

Organization : APLA

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe 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-368

Submitter : Mr. Andrew Signey **Date & Time:** 09/28/2004 10:09:02

Organization : CHW-CARE Program and Clinics

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As the assistant director of Long Beach California's largest HIV/AIDS provider I would like to make you aware of how important the California ADAP program is to our patients. As we move forward with the Medicare Prescription Drug Benefit I would ask that you provide our patients with an "exception" in order to continue serving our patients in a manner that is compassionate and that ensures that the opportunity to both receive and adhere to current medications is kept. Thank You, Andrew M. Signey asigney@chw.edu

CMS-4068-P-369

Submitter : Mr. Bradley Land **Date & Time:** 09/28/2004 11:09:36

Organization : None

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe 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.

My cocktails, as a person living with AIDS have been very complicated at times, involving a variety of different kind of medications. Not one or two, but I have had to take up to 22 different types of medications a day... I would have died without the assistance...

Sincerely,
Bradley Land

CMS-4068-P-370

Submitter : Mr. Robert Mason **Date & Time:** 09/28/2004 11:09:51

Organization : Mr. Robert Mason

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe 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.

Be sure to add your own personalized comments. If you're on Medicare, write about how these regulations will affect you. Otherwise, write a few sentences about the need for people with HIV to have full access to treatment, regardless of ability to pay.

Some background:

On December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. This legislation provides seniors and people living with disabilities with a prescription drug benefit, more choices and better benefits under Medicare, the most significant improvement to senior health care in nearly 40 years.

Last July, The Centers for Medicare and Medicaid Services (CMS) proposed regulations to provide a voluntary prescription drug benefit in Medicare and new health plan choices, including regional preferred provider organizations (PPOs), to provide better benefits, higher quality care, and substantial cost savings for Medicare beneficiaries. CMS will use public meetings and comments on the regulations to assure that the new benefits are implemented as effectively as possible less than 18 months from now, in January 2006.

Medicare is a major source of health care for people living with HIV/AIDS. Approximately 19 percent of all people living with HIV/AIDS who receive regular health care qualify for and receive coverage under Medicare. In 2002, Medicare spent an estimated $2.1 billion providing health care services to people living with HIV/AIDS, making Medicare the second largest source of funding for HIV/AIDS care after Medicaid.

CMS-4068-P-371

Submitter : Mrs. Martha Walker **Date & Time:** 09/28/2004 11:09:36

Organization : Mrs. Martha Walker

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

September 28, 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 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,

Mrs. Martha Walker
1919 Berkshire Lane
Colorado Springs, CO 80909
(719)637-0931
walkspgs@juno.com

CMS-4068-P-372

Submitter : Tom Chenault **Date & Time:** 09/28/2004 11:09:52

Organization : Tom Chenault

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed Medicare Drug plans will be inadequate to serve the needs of People Living With HIV/AIDS. Many individuals living with HIV/AIDS now and a great many more in the future, will not have access to the medications necessary to help keep HIV under control. Limited formularies will actually harm individuals showing resistance to the limited drugs available and not only cost more lives to be lost but a much greater financial burden to the Medicare system paying out for increased opportunistic disease burdens as these individuals' health declines. HIV/AIDS needs to be a special category with an open formulary for all the drugs necessary to combat this disease and the many complications related with it.

As a long-term survivor living with HIV/AIDS, many of the approved medications to combat HIV will no longer work for me. I have been on HIV durg therapy since 1995. Some drugs were lost due to lack of drugs for an effective "cocktail", some from severe reactions/tolerence/side-effects and some just from long-term use. I have not lost use of medications from non-compliance yet many are not appropriate. I will need access to all the avialable HIV medications to survive this disease. Please make HIV/AIDS a special category with an open formulary.

CMS-4068-P-373

Submitter : Ms. CATHRYN LEWIS **Date & Time:** 09/28/2004 11:09:25

Organization : AIDS SUPPORT NETWORK

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I believe that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit. CMS must designate people living with HIV/AIDS as a special population and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.
I work on a daily basis to insure that the low income clients are not denied access to all medications and health needs.Please make sure that you do not hurt their efforts to stay and achieve the quality of life all people should be able to have.

CMS-4068-P-374

Submitter : Mr. John Riley **Date & Time:** 09/28/2004 11:09:27

Organization : Mr. John Riley

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment.

CMS-4068-P-374-Attach-1.doc

October 20, 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 welcome the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am a person living with HIV/AIDS and a benefits counselor who serves SSI/SSDI Beneficiaries with the Work Incentives & Ticket to Work Programs. I am concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. My recommendations appear below:

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. My concerns, notwithstanding the best intentions or efforts by CMS, is 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 sheer implausibility that it is possible to identify, educate, and enroll 6.4 million dual-eligibles in six weeks (from November 15th – the beginning of the enrollment period to January 1, 2006), I recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months and that these beneficiaries be able to have Medicaid access to cover the cost gaps created by Medicare Part D. I consider these critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. This may require a legislative change and hope that CMS will acknowledge the relevance of these adjustments and actively support such legislation in the current session of Congress.

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

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-incomes, is vitally important in the enrollment process. I 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.

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

For people with serious and complex medical conditions, such as HIV/AIDS, access to Anti-Retroviral Therapy (HAART), medications can sustain their living in the community, being gainfully employed, and leading a healthy and productive life. Not having access to these therapies, or having them interrupted due to a coverage gap could result in an existence of bed rest, unnecessary hospitalizations and eventual death. Often, people with disabilities need access to the neIst medications, because they have feIr side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for the doctor to be able to prescribe the best medication for the individual. Often that process takes time since many people with significant disabilities must try multiple medications and only after much experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

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

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

Impose new limits on cost management tools:

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of my recommendations.

Respectfully,

John J. Riley
3524 Winslow Drive
Los Angeles, CA 90026
323-660-6458
jjriley@mac.com

CMS-4068-P-375

Submitter : Mr. Stuart Baron **Date & Time:** 09/29/2004 12:09:17

Organization : Orange County AIDS Services Foundation

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.
As an individual and a person working with HIV/AIDS clients,
I believe that the rule as authorized does not provide sufficient protection for people with HIV/AIDS who will get their treatment using this benefit. CMS needs to define those people living with HIV/AIDS as a ?special population? and guarantee that they get access to an open formulary of prescription drugs and availability 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 anti-retrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.
Public meeting and bureaucracies will not guarantee that our needs will be met. PPO?s and HMO?s may be cost effective, but they cater to the lowest denominator and do not guarantee effective healthcare. Other programs I have used have caused unnecessary hardships in order to get prescriptions in a timely manner, their formularies have refused necessary drugs prescribed by healthcare doctors, and have caused massive financial problems in is ancillary costs.

CMS-4068-P-376

Submitter : Mr. Wil Bowers **Date & Time:** 09/29/2004 12:09:12

Organization : Mr. Wil Bowers

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rules for the Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe 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-377

Submitter : Mrs. Jan McClure **Date & Time:** 09/29/2004 01:09:07

Organization : none

Category : Other

Issue Areas/Comments

Issues 1-10

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

This is not prescription relief for those on Medicare, it is a waste of taxpayers money since the costs of the drugs are not controlled!

CMS-4068-P-378

Submitter : Miss. Jan McClure **Date & Time:** 09/29/2004 01:09:24

Organization : none

Category : Other

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

As a former diabetes educator and now an epidemiologist I have seen the cost of diabetes for the society and for the client/family. Coverage of testing supplies is a vital part of the necessary feedback to the client. Without coverage for supplies clients cannot measure the effect of their lifestyle and cannot adjust their lifestyle/treatment to lower their blood glucose level.
Costs need to be controlled as the price of test strips is outrageous. Our tax dollars need to go toward the true cost not the inflated cost the drug companies charge. We cannot affort corporate subsidies and we cannot afford to take short cuts on diabetes.

CMS-4068-P-379

Submitter : Betty Kilburn **Date & Time:** 09/29/2004 01:09:56

Organization : Community member of AIDS Prevention & Education in

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

We must help People With AIDS in these rural areas. Medications are very important, and also funding for AIDS Prevention & Education has to be addressed now as our funds for rural areas are to now go to the metropolitan areas.....how unfair for our folks with AIDS.

Submitter : Connie Cihil **Date & Time:** 09/29/2004 01:09:11

Organization : Connie Cihil

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

28 September 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 support the comments submitted by Voice of the Retarded (VOR). We feel strongly that !V

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

?I !?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,
Connie Cihil

CMS-4068-P-380-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 22, 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:

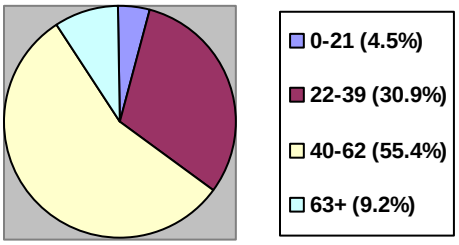
Mary McTernan
President
Voice of the Retarded
201 Brooksby Village Dr., Apt. 508
Peabody, MA 01960
978-535-2472 phone
978-535-0472 fax

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

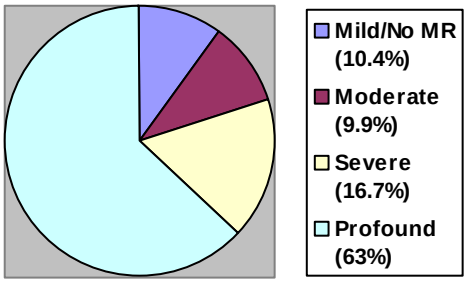
Characteristics of Residents of Large State MR/DD Facilities
June 30, 2002

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).

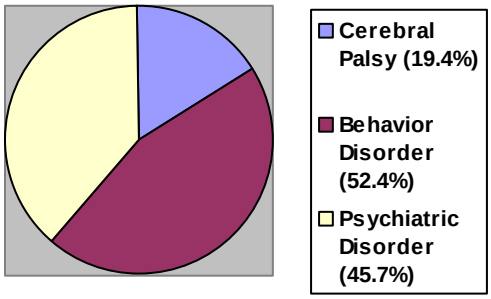
Age of residents



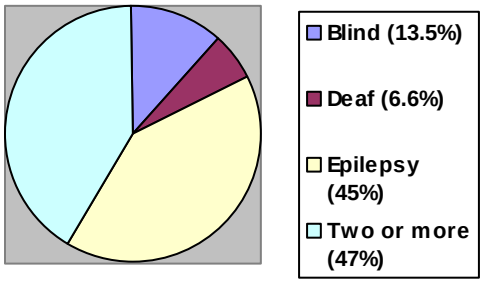
Level of mental retardation



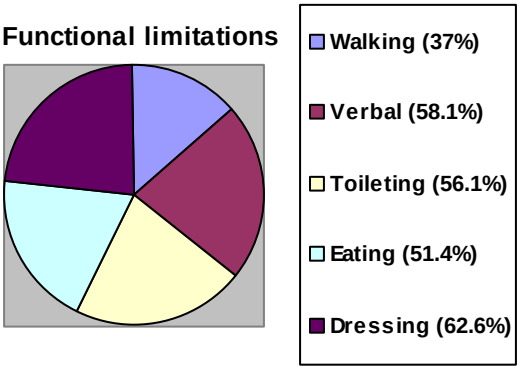
Additional conditions



Additional conditions



Functional limitations



CMS-4068-P-381

Submitter : Mr. Kevin Underwood **Date & Time:** 09/29/2004 01:09:11

Organization : Wisconsin Parents Coalition for the Retarded, Inc.

Category : Consumer Group

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

September 28, 2004

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

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

The Wisconsin Parents Coalition for the Retarded, Inc. supports the comments submitted on September 24, 2004 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 of these comments.

Sincerely,

Kevin Underwood
President, Wisconsin Parents Coalition for the Retarded, Inc. (WPCR)
669 McCarthy Drive
Hartford, WI 53027
Home Phone (920) 474-4201
WPCR Phone/Fax (920) 474-4129
EMail: krr.underwood@verizon.net

CMS-4068-P-382

Submitter : STEPHEN BOLAN **Date & Time:** 09/29/2004 01:09:02

Organization : STEPHEN BOLAN

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit. CMS must designate people living with HIV/AIDS as a special population and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

Without theses potections many people infected with HIV will die. New medications are rapidly being appkroved by the FDA and must be made available to all Americans regardless of their financail situation.

CMS-4068-P-383

Submitter : Mr. Bryan Hinman **Date & Time:** 09/29/2004 04:09:21

Organization : APLA

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

I'm writing regarding the proposed rule Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

I believe 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.

Submitter : Mrs. Priscilla Mounce **Date & Time:** 09/29/2004 04:09:55

Organization : Mrs. Priscilla Mounce

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

As an American Diabetes Association Advocate and Certified Diabetes Educator, I speak with patients daily concerning Self Management of their diabetes, which is often limited due to inability to purchase the medicals and supplies they need to self manage their diabetes. The Diabetes Care Center I work for is participating in the Institute of Medicine National Diabetes Program. If patients cannot get the supplies they need to monitor and care for themselves then we, the US government, are responsible for the rising cost of diabetes care for the complications that will continue to rise instead of decreasing.
The Diabetes Control and Complications Trial (DCCT) and United Kingdom Perspective Diabetes Study results showed that patients who intensively self manage their diabetes - frequent glucose monitoring, regular follow-up with their provider, aggressive and appropriate Diabetes medication use - reduced the risk of complications by 30-73%.
The Prescription Drug Benefit is one step to insure patients with diabetes can achieve these same risk reductions.
Thank you from one who has self managed my own Type 1 diabetes for 30 years.

CMS-4068-P-385

Submitter : Mr. James Torr **Date & Time:** 09/29/2004 05:09:38

Organization : University of Tennessee College of Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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.

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.

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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.'

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

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.

CMS-4068-P-386

Submitter : Mr. Richard E. Bardsley **Date & Time:** 09/29/2004 05:09:55

Organization : Mr. Richard E. Bardsley

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-386-Attach-1.doc

September 28, 2004

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention: CMS-4068-P

P.O. Box 8014

Baltimore, MD 21244-8014

To Whom It May Concern:

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

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

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower

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

Congress.

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

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

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

For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side

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

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies

envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:

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

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100%

cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe the best medication for the individual including off-label uses of medications which are common for many conditions. We strongly recommend that the final rule prohibit plans from placing limits on the amount, duration and scope of coverage for covered part D drugs.

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

We are also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We strongly recommend CMS establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs. We believe that the proposed rule fails to meet Constitutional due process requirements and fails to

satisfy the requirements of the statute. Under the proposed rule, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving a truly independent review by an administrative law judge (ALJ) and the timeframes for plan decisions are unreasonably long.

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

treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

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

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

Thank you for your consideration of our views.

CMS-4068-P-387

Submitter : Dr. Jerry Lail **Date & Time:** 09/29/2004 06:09:02

Organization : Orange County HIV Planning Council & Housing Comm.

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

I am concerned with proposed rule changes to the Medicare Program; Medicare Prescription Drug Benefit, 69 FR 46632.

As a person living with HIV, I am concerned that the Drug Benefit program without the provisions described below will not allow me to get the medications that I need.

I believe that the current rule does not provide sufficient protection for people like me who live 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 your attention to these concerns and to addressing them before the benefits guidelines are finalized.
Warmest regards and blessings of luv, joy, peace & health,

Jerry Lail, PhD.,
Chair of the Orange County HIV Planning Council's Housing Committee and member of the Planning council and Priority Setting & Allocation Task Force and member of the HIV housing needs assessment steering committee.

CMS-4068-P-388

Submitter : Mr. Greg Sanchez **Date & Time:** 09/29/2004 06:09:15

Organization : Mr. Greg Sanchez

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I want to comment on both issues. I have ADHD and I don't quite understand what the difference is between each issue, I think most people don't understand in general how to have a voice because it gets so complex if you don't understand , bills , ammendmants ..and so on and so forth. I think what is happening with Medicare is good for some and for many individuals including myself with AIDS this is could have a devastating impact on my health my life. Here are my comments as follows....

Due to the new Medicare law enacted by Congress and President
Bush last year, more than 80,000 Americans living with HIV/AIDS will become eligible for a new prescription drug benefit under Medicare. The vast majority of these individuals (some 60,000 nationwide) are currently receiving prescription drug coverage through Medicaid and will lose these benefits on December 31, 2005. They will then be forced to enroll in the new and potentially less comprehensive Medicare drug program.

The federal Centers for Medicare and Medicaid Services (CMS)recently
released a 2,000-page draft document detailing how the government will implement the complex, new benefit. I am concerned that the proposal short-changes people with HIV/AIDS (including I)and could severely compromise their(my) health by interrupting HIV treatments and offering them sub-standard healthcare.

I desperately urge CMS to ensure the following concerns are addressed in the final implementation rules:

* People with HIV/AIDS risk life-threatening illness if drug plans are allowed to limit the number of HIV drugs covered. Drug plans must carry all the drugs people with HIV/AIDS need. HIV/AIDS is a very complex disease as CMS may or may not know. When you have AIDS/HIV there are things that come about threating the immune system that damage organs of the body, make one suseptible to new diseases. I am not trying to lessen other individuals with diabetes , cancers or other ailments but HIV/AIDS Can for example have not only the issues of keeping the immune system working but then possably maintaining heart disease, diabetes, neurapathy, and a bad liver all at once. The treatments vary and I know that when I have checked out the list of medications that are available that are covered ...ALOT of the necasary medications are not.

* Because restricted access to needed HIV/AIDS medications could lead to drug resistance or severe medical complications, Medicare should treat people with HIV/AIDS as a "special needs population" and require drug plans to offer them an "open formulary."

* Individuals eligible for both Medicaid and Medicare (know as "dual-eligibles") may get fewer benefits under Medicare than they now receive in Medicaid. CMS should ensure that new benefits are of equal or greater quality than those provided by Medicaid.

* With the law cutting off Medicaid drug benefits for dual-eligibles on December 31, 2005, but not automatically enrolling them in the new Medicare drug program, dual-eligibles will be at risk for interruptions in drug coverage. Dual-eligibles with HIV/AIDS cannot risk a gap in coverage during the transition from Medicaid to Medicare, which would severely compromise their health.

* The draft grievance and appeals process is inadequate and must be enhanced to provide greater protections for Medicare recipients. Grievance and appeal processes must be effective and easy-to-access, and must include the right to get an emergency supply of medications while an appeal is under way.

* Proposed rules allow drug plans access to the names and medical histories of Medicare recipients in order to aid their marketing and enrollment strategies. Drug plans should not violate the privacy of people with HIV/AIDS(incuding my life) and other Medicare beneficiaries.

Submitter : Mr. Michael Shoop **Date & Time:** 09/29/2004 06:09:20

Organization : Mr. Michael Shoop

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

do what is right for those in need.....

CMS-4068-P-390

Submitter : Mr. Santo Garro **Date & Time:** 09/29/2004 08:09:26

Organization : Mohawk Valley Pharmacists Society

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Pharmacists of the Mohawk Valley Pharmacists Society strongly reccommend the inclusion of 2 articles that are inherently important for prescription drug delivery to Americans, pharmacy freedom of choice and collaborative physician/pharmacist activity, the pharmacist to be paid for his/her services by Medicare part B. Freedom of choice (without mandatory mail-order provisions) for patients will insure patient comfort and confidence in the qualified pharmacist THEY choose, not one chosen by a plan administrator. Pharmacists qualified under collaborative agreements with physicians will insure patient compliance, best and LEAST EXPENSIVE drug choice and appropriate therapy resulting from this 2-pronged professional collaboration.

Yours to Good Health
Santo Garro, President
Mohawk Valley Pharmacists Society

CMS-4068-P-391

Submitter : Mr. Gregorio Valdivia **Date & Time:** 09/29/2004 09:09:53

Organization : http://us.geocities.com/gvcofile

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Regarding Medicare Prescription Drug Benefit(69 FR 46632) comments for the current submission session, there are not sufficient protection for people in the HIV communty. This program must designate people living with HIV as a special population in order to ensure that they have access to an open formulary. Please follow the recommendation by the Public Health Service HIV treatment guidelines and offer HIV-positive individuals affordable access antiretrovirals. All approved formulations are vital to this community.

Your time and attention make a difference. Thank you.

CMS-4068-P-392

Submitter : Ms. Cynthia Murchison-Grice **Date & Time:** 09/29/2004 11:09:05

Organization : New Vision Outreach Ministry of Hampton Roads

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I have an elderly mother who is disabled. Before receiving Medicaid services for my mother, we were unable ot get all of her medications. The ones she needed for mental health treatment were too costly for us. At the time through Medicare she had to pay for medications. She currently receives assistance from Medicaid and is able ot get all of her medications. She would be unalble to get these medications without hte help of Medicaid. Medicare does not allow the cost of most of her medications. Please maintain the assistance she and others are receiving through the perscription and medical benefits our seniors are receiving from Medicaid.
Cynthia G Murchison-Grice

CMS-4068-P-393

Submitter : Mr. John Savageau **Date & Time:** 09/29/2004 12:09:52

Organization : Mr. John Savageau

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

regardimg cms4068-p The new prescription drug plan must keep local pharmacists as the hub of the distribution system. This is the only way the public can be protected from the PBM's and the medical community. Attempts to pay pharmacy technicians or congeners for services that only pharmacists are trained to do is an attempt by organizations other than pharmacy to control the drug delivery. The consequence of such action would result in a huge loss of oversight for the publics interest. Study after study have proven, especially for cholesterol control that pharmacists do a much better job at getting patients to goal. This holds true for asthma clinics and anticoagulation clinics. The new program will be a huge failure and large windfall for industry by removing this check in the system.

John Savageau RPh

CMS-4068-P-394

Submitter : Mr. James Cooper **Date & Time:** 09/29/2004 12:09:53

Organization : Mr. James Cooper

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

As a person living with AIDS, your decision in this matter greatly concerns me. I would appreciate your consideration in deciding the level of care I can anticipate to be available to me in the near future. Cetainly, a comprehensive plan would help improve my odds of living with this disease.

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

Sincerely,

James C. Cooper

CMS-4068-P-395

Submitter : Mrs. Jennifer Tucker **Date & Time:** 09/29/2004 01:09:54

Organization : Univ of Tenn-College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

September 28, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014
Dear Sir or Madam:
Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I offer the following comments for consideration as CMS develops the final regulation.
Beneficiary Access to Community Retail Pharmacies
I am concerned about the proposed rule regarding the pharmacy access standard. Under the proposed regulation, each prescription drug benefit plan is allowed to apply the Department of Defense?s TRICARE standards on average for each region. I recommend that CMS require plans to meet the TRICARE standards on the local (zip code) level rather than ?on average? in a regional service area.
To address the situation where it is impossible to meet the TRICARE standard for a particular zip code because access does not exist at that level (no pharmacy in the zip code), the regulation should require that the access standard be the greater of the TRICARE standard or the access equal to that available to a member of the general public living in that zip code.
Requiring plans to meet the standard on a local level is the only way to ensure patients equal and convenient access to their chosen pharmacies.
Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical pharmacists,? as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?
Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.
Thank you, J.Tucker

CMS-4068-P-396

Submitter : Mr. Moses Tafarki **Date & Time:** 09/29/2004 01:09:26

Organization : Student National Pharmaceutical Association

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Delivering and promoting healthcare to our underserved population remains the primary mission of our organisation. Thank you for the oppurtunity to comment on such an important issue.

CMS-4068-P-396-Attach-1.doc

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

Dear Sir or Madam:

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

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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.

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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,

Moses Tafarki
National President
Student National Pharmaceutical Association.

CMS-4068-P-397

Submitter : Mr. Adrian Slattery **Date & Time:** 09/29/2004 01:09:42

Organization : Design Interface Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

The definition of Covered Part-D Drugs includes "medical supplies associated with the administration of insulin." However, the proposed definition of these supplies does not include provisions for the safe disposal of more than 3 billion needles used annually in the home. Disposal of the used needle is an inevitable function of insulin administration, and safe disposal is crucial to the safety of the patient. This issue is supported by members of both the House and Senate and the Coalition for Safe Community Needle Disposal, including such organizations as the American Medical Association, the American Pharmaceutical Association and the American Association of Diabetes Educators agree that proper needle disposal is a medically necessary step in a patient's treatment regime. The societal, environmental and public health benefits of proper needle disposal should also be taken into serious consideration.

CMS-4068-P-398

Submitter : Dr. Deana Washington **Date & Time:** 09/29/2004 01:09:38

Organization : CaremarkPCS

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

I appreciate the fact that CMS recognizes the need for MTM programs for targeted beneficiaries. Patients who will benefit from MTMS change on a continuous basis; therefore, plans should be required to identify new-targeted beneficiaries on a regular basis (monthly). Pharmacists and physicians should also be allowed to identify beneficiaries. I also appreciate CMS' recognition that pharmacists should be the primary providers of MTM services. However, I feel that CMS must clarify that plans should not be allowed to make the decision on who would be considered a qualified provider. Pharmacists, the medication experts, are the ideal MTMS. CMS must evaluate each plan's application to provide an MTM benefit to ensure the pay for services is high enough to entice pharmacists to provide MTMS. I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004.

CMS-4068-P-399

Submitter : Mr. Andrew Finney **Date & Time:** 09/29/2004 01:09:18

Organization : UT College of Pharmacy (4th year pharmacy student)

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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.
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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.?

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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.

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.

Sincerely,

Andrew L. Finney

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

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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.

CMS-4068-P-400

Submitter : Mr. Jerry Fu **Date & Time:** 09/29/2004 01:09:44

Organization : Academy of Student Pharmacists

Category : Health Care Professional or Association

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.

Sincerely,

Jerry Fu

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

Multiple Dispensing Fees Needed
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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.?

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.

ELIGIBILITY, ELECTION, AND ENROLLMENT

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.

GENERAL PROVISIONS

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.

Submitter : Mrs. Janet Ketcham **Date & Time:** 09/29/2004 01:09:46

Organization : McMains Children's Developmental Center

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-401-Attach-1.doc

McMains Children's Developmental Center

1805 College Drive
Baton Rouge, Louisiana 70808
(225)923-3420 / fax (225)922-9316

September 29, 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 McMains Children's Developmental Center welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The McMains Children's Developmental Center serves children who have cerebral palsy, developmental delays, or learning disabilities, as well as their families. We are a non-profit agency started in 1954, and we provide services to residents of East Baton Rouge and surrounding parishes. 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. Cerebral palsy is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. A recent study found that approximately 38% of children with cerebral palsy have epilepsy. Many individuals with cerebral palsy also use medications to treat dystonia and muscle spasticity As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

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

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the

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

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

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

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

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

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

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

The provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the

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

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

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

Thank you for your consideration of our views.

Sincerely,

Janet Ketcham, L.C.S.W.
Executive Director

JK/cl