CMS-4068-P-202

Submitter : Ms. Carmen Burns **Date & Time:** 09/22/2004 06:09:30

Organization : Kmart Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

CMS-4068-P-203

Submitter : Mr. Gregory Siegel, RPh., JD **Date & Time:** 09/22/2004 06:09:54

Organization : Mr. Gregory Siegel, RPh., JD

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Thank you for the opportunity to comment. Please consider the following: (1) Please allow all beneficiaries to have local access to Pharmacy services. (2) I hope you avoid anti-competitive regulations that allow preferred Pharmacies. CMS should require plans to offer a standard contract to interested Pharmacies. (3) Require qualified providers. Pharmacists are in a good position to help patients make safe and effective use of their medications. Thank you for considering my view.

Sincerely,

Gregory B. Siegel
632 Holbrook Ct.
Perrysburg, Oh 43551
gsiegel@mco.edu

Submitter : Mr. walter Mellinger **Date & Time:** 09/22/2004 06:09:58

Organization : ASCP

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

In the nursing home we have been providing cognitive services for freefree. It is most important responsibility. It sure would be nicenice to be paid for the effort and recognized for what we add to excellent patient care.

CMS-4068-P-205

Submitter : Mr. Michael Powell **Date & Time:** 09/22/2004 07:09:05

Organization : The Nebraska Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Pharmacists are contributing a great deal more to the public health. Pharmacists paid for cognitive services are capable of substantially reducing the costs of drug therapy. For example, I personally made recommendations that allowed her physician to reduce my aunt's medication costs from over $300 per month to less than $140 without any loss in clinical benefit.

CMS-4068-P-206

Submitter : Ann Wood **Date & Time:** 09/22/2004 07:09:59

Organization : NA

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

The instructions to use this Comment internet site are as confusing as the presc. drug benefit program itself. I feel the presc. drug program should be scrapped and reworked. It is a Mess! W/70 choices of cards, etc., is it any mystery why citizens aren't bothering to sign up? The presc. drug program is a MESS!!!/DISASTER!!! Who has time to dig thru the mud?

CMS-4068-P-207

Submitter : Dr. THOMAS GOCHENOUR **Date & Time:** 09/22/2004 09:09:49

Organization : ACCP

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

THE MOST HIGHLY TRAINED HEALTH PROFESSIONAL IN THE USE OF MEDICINE MUST BE IN CHARGE OF THE MEDICINE THERAPY MANAGEMENT PROGRAM. PHARMACITS HAVE WAITED DECADES FOR THIS MOMENT, WHEN THEY CAN USE THEIR EXPERTISE TO SAVE LIVES AND MONEY. PLEASE LOOK AT THE SCHOOL OF PHARMACY'S CURRICULUM AND YOU WILL SEE MORE COURES ON DRUGS THAN ANY OTHER HEALTH PROFFESSION, INCLUDING NURSING AND MEDICAL. WHAT DOES THIS MEAN, PHARMACIST SHOULD BE HELPING EVERBODY IN THE USA WITH THEIR MEDICATION NOT JUST SENIOR CITIZENS, BUT THEY ARE A GOOD STARTING POINT. THE IMPLEMENTATION OF THE MEDICINE THERAPY MANAGEMENT PROGRAM DEMANDS USING THE MOST PHARMACEUTICAL KNOWLEDGABLE HEALTH PROFESSIONAL, THE PHARMACIST.

CMS-4068-P-208

Submitter : Mrs. Roxanne Homar **Date & Time:** 09/22/2004 09:09:03

Organization : Wyoming Department of Health

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

September 24, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed rule detailing the Medicare prescription drug benefit.

Regarding subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans, I would like to commend CMS for recognizing the important role of pharmacists in Medication Therapy Management (MTM) services. Pharmacists are the ideal health care professionals to provide such services as their knowledge and experience create the perfect platform for this kind of work.

Recently in Wyoming, we have implemented a program called Wyoming PharmAssist. This program allows any interested Wyoming citizen to have a one-on-one consultation with a pharmacist licensed in the state. The goal of this interaction is to provide an in-depth review of a client's drug regimen to look for issues such as drug interactions, therapeutic duplication, and contraindications. In addition, the pharmacist and client discuss different cost saving strategies and work to develop an affordable and appropriate medication regimen.

The results of this program have been outstanding. Wyoming PharmAssist originally began as a pilot program in four communities. The following statistics are from the first six months of the program:
* 403 calls came into the hotline resulting in 405 information packets being mailed.
* 151 clients returned completed packets.
* 139 clients were referred to a registered pharmacist for consultation.
* 99 of these consultations had been completed as of June 30, 2004.
* An average potential savings of $178 per month ($2,136 per year) were achieved.

Seventy-five percent of clients who received a consultation receive Medicare benefits. This means that once Part D becomes effective in 2006, Medicare would benefit from a portion of the savings achieved by this program.

In conclusion, the Wyoming PharmAssist program is a great example of how pharmacists can provide MTM services resulting in savings to individual citizens, and insurance providers, including large public insurance providers such as Medicare.

Please consider including pharmacists as MTM service providers in the final regulation.

Sincerely,

Roxanne Homar, R.Ph.
State Pharmacist

CMS-4068-P-209

Submitter : Mr. Danny Thomas **Date & Time:** 09/22/2004 10:09:10

Organization : Mr. Danny Thomas

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Benefits and Beneficiary Protections
How are beneficiaries with Medicaid benefits impacted Will the Medicare formulary cover all medications I am responding to the proposed "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 beneit. CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of presecription 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. This is an especially personal matter because medicare and medicaid are all that I have to sustain me. The restrictions built into the "modernization" of medicare are not an affordable expense/risk for me. Thank you for considering my comments as you finalize the regulations.

CMS-4068-P-210

Submitter : Ms. Susan Worthing **Date & Time:** 09/22/2004 10:09:41

Organization : Ms. Susan Worthing

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

ESRD pt's require water soluble vitamins replacement to live well. If eliminated or excluded from medicare coverage it would be devastating to this patient population. Scientific evidence supports that Vit. B, folic acid etc. must be replaced to lower CVD risk asssociated with homocysteine levels, prevention of anemia, to help support the immune system and for cellular growth and maintenance. Exclusion of renal vitamin coverage would eliminate many, many patients from the ability to obtain these essential nutrients. Thanks

Submitter : Mrs. Helen Miramontes **Date & Time:** 09/22/2004 10:09:54

Organization : Mrs. Helen Miramontes

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

My concerns with the changes have to do with the Benefits section. Many people living with HIV/AIDS (PLWHA) are usually on a combination of antiretroviral medications that currently may be covered through Medicaid/Medicare. With the prescription benefit changes some of these essential medications may not be covered. These new prescription providers are not required to provide all the different antiviral medications. PLWHA must be protected from losing their current medications. Any change in the Medicare drug benefit must include the availability of these vital medications.

Submitter : Mr. Stephen Boulanger **Date & Time:** 09/22/2004 11:09:00

Organization : Mercury Pharmacy

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I would like to see standards for plans. The model is the Tricare pharmacy access requirements on a local level, rather than the overall service level.

I am worried about the proposed regulation which 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 copayments, negating the benefit of the access standards. CMS should require plans to offer one standard contract to all pharmacies.

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

Pharmacists at the point of dispensing are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide drug utilization review, geriatric assessment, teaching for diabetics, immunizations, etc... Plans should be encouraged to use my services and to let me help my patients make the best use of their medications.

CMS-4068-P-213

Submitter : **Date & Time:** 09/23/2004 12:09:48

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

I am not directly affected by this proposed rule. I don?t have HIV/AIDS, but I feel that people with HIV/AIDS should be entitled to the drugs they require for treatment.

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

Sincerely,

Tom Bellinger
4 East 32nd Ave
Spokane, WA 99203

CMS-4068-P-214

Submitter : Mr. Matt Ubelhor **Date & Time:** 09/23/2004 01:09:50

Organization : Mr. Matt Ubelhor

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist and I would like to make a brief comment on the new drug "benefit". First of all I think this whole program is an obvious attempt to buy votes by giving older people who tend to vote a benefit at the expense of younger people who don't. What this is going to do is make an incentive for older people to use more medicine and ultimately drive up cost. Why a 25 year old should have to pay higher taxes to help pay an elderly person's $300.00/month medical insurance bill when that same person has to pay his own 300.00/month car insurance bill is beyond me but I digress. I am very concerned that this new program will force medicare patients into managed care programs that will force or strongly encourage patients to use mail order pharmacies. My first concern is selfish on my part. I do not want to lose my customers and ultimately my job because of this program. I also think that patients will lose out if this does happen. If you talk to patients you will find that for the most part patients prefer to go to a community pharmacy and talk to familiar people as opposed to getting their medicines filled by a stranger through the mail. I don't mind if a patient wants to get the medicines through the mail but if they choose to get their medicines from the neighborhood drug store they should not be penalized. As I'm sure you know mail order outfits get better prices on pharmaceuticals than retail pharmacies because of what I suspect are agreements between companies. These discounts are not based on volume but solely on the type of practice the pharmacy has. If retail pharmacies were given an equal price footing based on something more logical such as volume we could compete with the mail order houses and the patients would be more satisfied with their service. If you truely want a satisfied patients you would give the patient a choice and not try to herd patients into a place they really don't want to go. Thank you for your time.

Matt Ubelhor Rph

Submitter : Dr. Kathy Vu **Date & Time:** 09/23/2004 01:09:13

Organization : American College of Clinical Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Dear Congressional Leader,
Pharmacists may be able to provide some relief in cost management of medication therapy. Currently cost cutting seems to revolve around penny-pinching deals made with pharmaceutical companies and buyer-groups. Though I believe that this competition is a useful savings strategy, I believe that patient education of both medications and their disease states is even more crucial. Changing from one drug to a less expensive one with similar action may save a few cents, maybe even a few dollars. However, I believe time spent educating patients helps arm them with the knowledge to help prevent and/or delay further complications in progressive or chronic illnesses. Chronic heart failure, cardiovascular disease, diabetes, chronic obstructive pulmonary disease, and asthma are all disease conditions that often require multiple medications and intense therapy. Patient education and reinforcement by pharmacists, nurses, and other health care professionals on how to prevent exacerbations of these conditions can provide a substantial cost-savings by preventing hospitalization. Patients with fewer exacerbations have lower morbidity and mortality rates. Both of these points reguarding patient education decreasing hospitalizations and that exacerbations requiring hospitalizations increase morbidity have been shown in medical literature. Thus, with education, patients could maintain better health, and the system could still preserve its budjet. Therefore, policy allowing financial support for cognitive services for pharmacists, nurses, and other health care professionals qualified to provide high quality education to patients should be proposed and accepted. Thank you

CMS-4068-P-216

Submitter : Mrs. Christine Murphy **Date & Time:** 09/23/2004 07:09:21

Organization : Ohio State University College of Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

CMS should expand Medicare patients' choices to access local pharmacies and not force them to choose a sole or from a limited number of preferred provideror pharmacies. As the proposal now stands, patients' could be forced to use only one pharmacy, if a plan coerced members by allowing these preferred pharmacies to charge a lower co-pay. If CMS required plans to offer a standard contract to all pharmacies, the patients would have broader access to local pharmacies, as Congress intended.

I suggest that the pharmacy access standard be revised to require plans to meet the TRICARE pharmacy access requirements NOT on the plan's overall service level, but instead on a local level.

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

Pharmacists are trained by the Colleges of Pharmacy in the USA to be the medication experts. Currently, each pharmacy student spends 4 years devoted to medication related courses, medicinal chemistry, pharmacology, therapeutics, drug literature evaluation, etc. They also spend their senior year in clinical settings where the emphasis is placed on MTM in a variety of health care settings. No other health care professional's training includes this same level of expertise in MTM as does a pharmacist's.

The effect of medication therapy on health care costs goes far beyond the cost of the medication. 20-30% of all hospitalizations and nursing home placements of people 65 years of age and older are the results of inappropriate medication use, e.g. wrong drug, wrong dose. Much of this inappropriate medication use is a result of the ever changing number of new drugs, new uses for old drugs and ongoing changes in evidence based medicine. If more pharmacists are given the opportunity to be the MTM leaders as part of the health care team, many of these hospitalization and nursing home placements can be avoided -thus savings significant Medicare dollars.

I realize that CMS recognizes that pharmacists as the primary providers of Medication Therapy Management, but I am very concerned that plans may allow other health care professionals with much less education and knowledge about medications to provide MTM services.

As a faculty member at the Ohio State University College of Pharmacy, I provide MTM services, with the help of junior and senior pharmacy students. My students and I provide these services by way of home visits to apartments of low income seniors in Columbus, Ohio. One obese senior we provided these services for had diabetes, high cholesterol and high blood pressure. She was not taking the new blood pressure medication as the doctor prescribed because she thought it was 'too strong'. She was taking 1/3 of the dose prescribed. Her blood pressure at that visit was 185/90 (goal for most people is 120/80)putting her at high risk of stroke, kidney damage and a myocardial infarction. After we met with her and cleared up her misunderstandings, she agreed to start taking the medication as prescribed. Three weeks later when we met with this patient again, her blood pressure was down to 135/85.

Another senior that my students and I worked with was not taking Lipitor prescribed by her physician for high cholesterol. She was very afraid of the side effects that she had read and heard about. We met with her several times over the school year educating her about the benefits of taking the drug versus the risk of adverse effects and she finally agreed to take Lipitor.

These are just a couple of examples of the positive impact that pharmacist led MTM services can have on the health care of seniors.

Submitter : Dr. Travis Stallbaumer **Date & Time:** 09/23/2004 12:09:38

Organization : Nemaha Valley Community Pharmacy/Harsh Drug INC

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Medication Therapy Management services should be provided by pharmacists. Pharmacists are the medication experts in the healthcare chain. Pharmacists are trained in medications much more extensively than nurses, doctors, or any other healthcare professional.
Adequate reimbursement needs to be mandated by law for these services to compensate for the time and efforts exerted by pharmacists.

CMS-4068-P-219

Submitter : Mr. Francis Herrmann **Date & Time:** 09/23/2004 02:09:37

Organization : Penn State Hershey Medical Center

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed pharmacist in the state of PA. Currently, pharmacists are not recognized as a provider under Medicare services.

Pharmacists have much to offer patients in terms of medication management and education. I am currently serving in an anticoagulation clinic. We provide patients taking the medication warfarin with services that surpass those provided by most local medical practices. Warfarin is known as the one of the top ten "most litigated medications." There is a fine line between too little (leading to strokes) and too much (leading to bleeding). Proper management is essential to provide patients with the most benefit from this medication.

Our services are currently limited to about 700 patients because the institution cannot afford any further staffing. There are many many more patients who could be provided services by pharmacists if reimbursement were available.

Thank you for your consideration of this docket.

CMS-4068-P-220

Submitter : Dr. Angel Heyerly **Date & Time:** 09/23/2004 02:09:06

Organization : Lutheran Health Network

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

September 23, 2004

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

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

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

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

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

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

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently provide an anticoagulation clinic in my practice. Plans should be encouraged to use my services ? to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to

- require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level

- require plans to offer a standard contract to all pharmacies

- require a pharmacist to be the provider of MTM services

Thank you for considering my view.

Sincerely,

Angel Heyerly, PharmD
Lutheran Health Network
7950W Jefferson Blvd.
Fort Wayne, IN 46804

(260)435-7441
aheyerly@lutheran-hosp.com

CMS-4068-P-221

Submitter : Mr. Joe Adkins **Date & Time:** 09/23/2004 04:09:31

Organization : Safeguard Medical Devices/Disintegrator Products

Category : Device Industry

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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 both Senate and House members, as evidenced in letters to CMS Administrator Mark McClellan from U.S. Senators DeWine and Voinovich (5/20/04) and the U.S. House of Representatives (7/19/04). The members of the Coalition for Safe Community Needle Disposal, including 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.

With input from various organizations, including OSHA and the CDC, the Environmental Protection Agency recently revised their guidelines for disposal of needles in the home, recommending several safe options that include Home Needle Destruction Devices ("medical devices" approved by the FDA for in-home use). The benefits of safe needle disposal far outweigh the cost (less than $25 annually per self-injecting patient when using a home destruction device), thus expanding the proposed definition of "supplies associated with the administration of insulin" to include FDA approved & EPA recommended needle disposal options would appear to be merited.

CMS-4068-P-221-Attach-1.doc

Congress of the United States

House of Representatives

Washington, DC 20515

July 19, 2004

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
314G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

We are writing to request that the Centers for Medicare and Medicaid Services (CMS) work with Safeguard Medical Devices, Inc. to determine the appropriateness of covering approved home needle disposal methods, including insulin needle and lancet destruction devices, under Medicare. Proper disposal of needles and lancets is both necessary to patient safety and critically important to the public health.

We understand that in August 2002, Safeguard wrote to CMS requesting a benefit category determination for the Disintegrator Plus insulin needle and lancet destruction device. In that letter, the manufacturer indicated that the device appeared to best fit into the category of durable medical equipment (DME). A September 10, 2002 response from CMS indicated that needle destruction devices were considered to be precautionary/self-help devices and, as such, would be excluded from the definition of DME. However, according to Safeguard Medical, a strong case can be made that proper needle disposal is not simply a precautionary or self-help measure, but a medically necessary step in the patient's treatment regime. This argument is echoed by the Coalition for Safe Home Needle Disposal, whose members include the AMA, APhA, AADE, NACDS, NSWMA and similar organizations. Proper needle disposal is inherent to proper and safe care of the patient. The societal benefits of proper needle disposal should also be taken into serious consideration.

An estimated three billion needles are used in the home each year. Needles on syringes have the potential to cause injury through cuts or puncture wounds. In addition, needles contaminated with blood or body fluids can transmit serious communicable diseases such as Hepatitis, HIV, tetanus, and other potentially fatal diseases. Improperly discarded sharps can injure family members, waste and recycling workers, or end up in places where they are a danger to the public, such as local playgrounds and public beaches. A great deal of attention has been given to the issue of improper needle disposal by home-injecting patients. The Environmental Protection Agency (EPA) has recently revised their guidelines for home needle disposal, suggesting several preferred disposal methods that include home needle destruction devices.

The new Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173), includes coverage for insulin "and devices associated with the administration of insulin, as determined by the Secretary." Safeguard argues that this provision should be interpreted to authorize coverage not only for the syringes used for insulin injections, but also for approved home disposal solutions. This interpretation derives from the fact that disposal of the syringe is an inevitable function of insulin administration, and safe disposal is crucial to patient safety. We would appreciate your thoughts on this interpretation of the new law.

Other public programs recognize the importance of proper needle disposal. In Ohio and Wisconsin, the Medicaid program provides coverage for sharps disposal containers for self-injecting patients. With the recent revisions in Medicare coverage for patients with diabetes, and the EPA's new suggested disposal methods, we feel that consideration of the Disintegrator Plus device and other home needle disposal methods for inclusion under MMA is merited. Your assistance in this effort would be appreciated.

Sincerely,

SHERROD BROWN
Member of Congress

STEVE LATOURETTE
Member of Congress

TED STRICKLAND
Member of Congress

PAUL GILLMOR
Member of Congress

STEPHANIE TUBBS-JONES
Member of Congress

TIM RYAN
Member of Congress

DARRELL E. ISSA
Member of Congress

cc:
The Honorable Joe Barton, Chairman, Committee on Energy and Commerce
The Honorable John Dingell, Ranking Member, Committee on Energy and Commerce
The Honorable William Thomas, Chairman, Committee on Ways and Means
The Honorable Charles Rangel, Ranking Member, Committee on Ways and Means

CMS-4068-P-222

Submitter : Mr. Jeffrey Klein **Date & Time:** 09/23/2004 04:09:36

Organization : Mr. Jeffrey Klein

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

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

In this country, the wealthiest in the world, every individual should have free access to medical care including prescriptions. If every person in the US needed to use our healthcare system and discovered first hand how poor it is, there would be a public revolt.
It is a crime that senior citizens and those on Medicare have to chose between medications and food. We need to change this! I would personally volunteer my time to help this cause. I hope that someone there at the Medicare office in Baltimore gives a damn and really wants to make this a better program.

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

Sincerely,

Jeffrey Klein
1628 S Street NW #1
Washington, DC 20009

CMS-4068-P-223

Submitter : Mr. Eric Allison **Date & Time:** 09/23/2004 04:09:12

Organization : American Pharmacists Association - ASP

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

September 23, 2004

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

Dear Sir or Madam:

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

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

Sincerely,
Eric Allison
redgrover@hotmail.com
913-825-4744

CMS-4068-P-224

Submitter : Mr. Gary Wientjes **Date & Time:** 09/23/2004 04:09:15

Organization : Morehead Clinic Pharmacy

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

MTMP services should be provided by individual practioners, pharmacists, who know more about drug therapy than any other practitioner. In addition, pharmacists graduating today have taken a "Bioloby of Disease" course similar to the one completed by physicians. This educational background makes pharmacist the most appropriate choice as disease state or case managers.

My partner and I provide Diabetes Self Management training and Blood Thinner (anticoagulation) management for patients at Morehead Clinic. Jennifer Barker Pharm D has significantly affected outcomes of patients on blood thinners. Just recently, Medicare has indicated that in most situations they will no longer pay for her services. This is one area where patients need to be followed by a medication expert, a pharmacist, to reduce the possibility of stroke and other bleeding complications.

I provide Diabetes Self Management Training and have significantly improved blood sugar control in our patients. More management is needed for patients with asthma or other lung disease, hypertension and elevated cholesterol.

One on one intervention, with someone like their local pharmacist who they have a positive relationship with, is necessary to produce positive outcomes. In addition, patients visit their pharmacy 2-3 times a month, where they may only see another practitioner once every 6 months.

Fees paid to pharmacist must be reasonable and sufficient. Perhaps after a year or so, historic data can be used to pay pharmacist a percentage of what they have saved Medicare. The more they save Medicare, the more they make. Economic incentives almost always pay off.

Pharmacists are the best situated practioner to provide these services and monitor compliance. If I were paid for these services, I would hire a compliance officer to review patient records to red flag patients that need to be contacted by a pharmacist. Refill reminder programs are readily available in most pharmacy soflware packages.

Thank you for considering my opion on these matters.

CMS-4068-P-225

Submitter : Mrs. F Condon **Date & Time:** 09/23/2004 04:09:34

Organization : Mrs. F Condon

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist who is concerned about access and quality issues within the proposed regulations put forth on August 3, 2004 that would implement the new Medicare Part D prescription drug benefit program beginning in 2006. The proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA. Thus, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist. The regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications. Also, the regulations must specify the nature and scope of medication therapy management services that the plans would have to provide (eg. who would be eligible for these services and how providers would be compensated for these services).
File code CMS-4068-P must be changed to reflect the above concerns in order to assure a fair Medicare prescription marketplace. Thank you!

CMS-4068-P-226

Submitter : Mrs. Nan Miller **Date & Time:** 09/23/2004 06:09:18

Organization : Greene County Council on Aging

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

In my experience as a patient advocate specializing in prescription drug assistance, many seniors cannot or will not access benefits when there are too many choices or the procedures are too complicated. Trying to help seniors take advantage of the Medicare-approved drug discount cards was very frustrating because in our area there were nearly 50 cards to choose from. Very few seniors were able to select a card on their own without help. Most just didn?t bother because it was too complicated. It required access to the internet, which few seniors have, not to mention that most of them don?t even know how to use a computer. If we use a similar methodology to implement Medicare Part D, we will be doing a great disservice to the very population we are trying to help.

Recommend offering a Medicare plan option in all areas, not just where private plans are not available. If seniors want Part D and they?re capable and motivated to sift through all the data required to choose the best plan for them, great. But if they just can?t cope with all the information analysis required to sort through a variety of private insurance plans, they should be able to enroll in a Medicare sponsored plan. I hope we remember the lessons learned when Medicare supplements were introduced. There was so much confusion, Medicare had to step in after-the-fact and force the insurance companies to standardize their plans to make it possible for seniors to compare options and make sound decisions. We can do better, and we should.

If many private plans are offered, seniors need a central source for getting information and a way to help sort through the options and compared costs and benefits. Don?t waste money on mailings to all Medicare beneficiaries that are so general as to be useless. If you spend money on mailings, put in enough specifics for a person to be able to understand the issue and the action required on their part to pursue it. If these mailings contain specifics, seniors who need help can give them to family or friends who can assist them. The mailings used for the Medicare-approved drug cards were a waste of taxpayer funds.

Consider shifting the burden of dealing with private insurers from beneficiaries to Medicare. Let Medicare negotiate contracts with insurance providers to give seniors the best deal in their area. Medicare could set standards and monitor quality. Government agencies contract with private companies every day and have good procedures in place to review contractor costs to ensure reasonableness. They are able to build in a reasonable profit and allow the supplier to cover their costs when negotiating prices. I would hope that allowable costs would NOT include direct marketing to consumers. This adds to the cost of drugs and should be prohibited!

It?s unclear what will happen if a senior has assets that put them in one category upon enrollment in Part D, but subsequent events require spending those assets which would put them in a lower cost category. There should be a review process built in that would allow beneficiary costs to be lowered if income and assets are reduced.

Increased funding for SHIPs is a welcome change. It?s encouraging to see recognition of the one-on-one counseling that is required to implement such a program. The sums are paltry compared to the amounts that will be paid in subsidy to insurance companies and employers, and should be increased. Most SHIP counselors in Ohio are unpaid volunteers, but even they need access to quality training and support from paid experts.

Submitter : Dr. Andrew Frasco **Date & Time:** 09/23/2004 06:09:21

Organization : Virginia Commonwealth University

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs, and I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. I have been in practice as a pharmacist for two years, and I currently provide the following MTM services in my practice, diabetes screening and consultation, cholesterol screening and medication management, and blood pressure screenings and medication management. Plans should be encouraged to use my services to let me help my patients make the best use of their medications.

Submitter : Mr. Eugene Zylla **Date & Time:** 09/23/2004 06:09:54

Organization : Cargill, Incorporated

Category : Private Industry

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

September 23, 2004

Mr. Jim Mayhew
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

Attention: CMS - 4068

Subject: Alternative Retiree Drug Subsidy

Dear Mr. Mayhew,

I am the benefits manager for Cargill, Incorporated. Cargill has over 100,000 active employees and about 7,000 Medicare-eligible retirees.

When Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003 it wanted to encourage employers like Cargill to maintain their retiree health plans. Unfortunately, after review of the proposed regulations that were published August 3 in the Federal Register, there appear to be contradictions to achieving that goal.

Cargill has multiple benefit designs for its retiree plans and many different premium-sharing arrangements. The proposed rules require aggregation of all these arrangements so that Cargill will be treated as having just one plan when testing for actuarial equivalence. Although the majority of our retirees are in very generous plans, in aggregate our entire retiree health program is not actuarially equivalent.

Therefore, Cargill will not qualify for reimbursement of any of our retiree drug costs. Since we don?t qualify for reimbursement, we will be carving out Medicare Part D benefits from all our plans, in effect, defeating one of the goals of Congress. We believe and hope that you can remedy this situation in the final regulations. I am very pleased to discuss this in further detail if that would be beneficial.

Respectfully,

Eugene T. Zylla
Manager, Employee Benefits

CMS-4068-P-228-Attach-1.doc

Cargill

September 23, 2004 Sent electronically to: www.cms.hhs.gov/regulations/ecomments

Mr. Jim Mayhew
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

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Respectfully,

Eugene T. Zylla
Manager, Employee Benefits

12700 Whitewater Drive, MS 85
Minnetonka, MN 55343-9439

PO Box 5685
Minneapolis, MN 55440-5685

Submitter : Dr. Rhonda Harden **Date & Time:** 09/23/2004 07:09:02

Organization : CAVHCS

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I would like to offer the following comments for consideration as CMS develops its final regulations. The vast majority of my comments, unless otherwise indicated, are in regard to SUBPART D ? Cost Control & Quality Improvement Requirements for Prescription Drug Benefit Plans.

Medication Therapy Management Programs
There are a number of issues in which CMS has requested comment from the public on the proposed regulations. As you are aware, plans are required to establish a medication therapy management (MTM) program. In light of this requirement and the proposed regulations, please consider the following:
? Multiple Chronic Conditions should be specifically defined as two or more chronic conditions. For example, an individual with uncontrolled hypertension and diabetes could have very significant disease related morbidity and mortality, and are at risk of drug related problems, even if they have no further chronic conditions. I commonly see patients like this in my practice, and many of them currently benefit from the medication therapy management services I provide.
? Multiple Part-D Approved Medications should be defined as two or more drugs. Many of the drugs used in today?s practice are medications that require therapeutic blood monitoring (e.g. warfarin, theophylline, lithium, others) or blood monitoring for potential adverse events (e.g. HMG-CoA Reductase Inhibitors or ?statins?, certain antipsychotic medications, Alzheimer?s drugs, and others). The presence of even one of these chronic medications that require blood monitoring of some type places a patient at higher risk of drug related problems unless a pharmacist or other qualified health provider is actively involved in the management of the patient?s drug therapy. ?Polypharmacy? is defined by some

groups as six or more medications, which is a reasonable definition, but it fails to take into account the drug classes mentioned that require more stringent management. Any definition for multiple Part D medications must take drugs that require blood monitoring for efficacy and side effects into account.
? High Drug Spend should be defined in such a way as to provide as many patients as possible access to MTM services as a covered benefit. Drug spend is not a good indicator of adverse drug therapy outcomes. Rather, multiple medications and chronic illness is a better indicator of the likelihood of adverse drug therapy outcomes. If MTM services are made available to patients early during the patient?s ?spend cycle?, and well before they potentially could hit the gap in coverage as outlined by the Act, it is possible that pharmacists could assist many beneficiaries from ever hitting the coverage gap or the catastrophic coverage threshold. I would also like to highly recommend, for reasons stated in the previous paragraph), that if a patient is taking one or more medications that require therapeutic blood monitoring or blood monitoring for potential adverse events as recommended by FDA-approved manufacturer package labeling, that the beneficiary be exempt from meeting a high drug spend requirement and automatically qualify for MTM services if they meet the multiple chronic diseases and multiple part-D medications requirement. Additionally, PDP sponsors should be able to identify patients meeting the high drug spend qualification for the MTM services benefit using projections based upon the first 3 months of expenditures during the first year of the Medicare Part D benefit (2006). Future years could be determined based upon the expenditures of the previous year to determine qualification.
? More specific guidance must be given to Prescription Drug Plan (PDP) Sponsors on a number of issues left unspecified in the draft regulations.

CMS-4068-P-229-Attach-1.doc

CMS-4068-P-230

Submitter : Mr. Thomas Halterman **Date & Time:** 09/23/2004 08:09:12

Organization : Outcomes Pharmaceutical Health Care

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

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

CMS should look to established, tested, and successful models of Medication Therapy Management Services ("MTMS") currently operational in the US. One such program is administered by Outcomes Pharmaceutical Health Care ("Outcomes"). Outcomes was founded over 5 years ago to address the market need for MTMS. Since that time, the company has created a network consisting of thousands of "Outcomes Personal Pharmacists". These pharmacists do much more than count pills and pour liquids. Using their expertise in drug therapy and their personal knowledge and interaction with patients and physicians in the community, Outcomes Personal Pharmacists help physicians prescribe the most cost-effective medications and help patients get the best possible results from these medications - improving health care quality and reducing avoidable health complications and costs. The Outcomes model is currently operational for over 1 million recipients within the Florida Medicaid program as well as private employer groups in other states. We encourage CMS to learn more about this model by visiting the Outcomes website at www.getoutcomes.com and by contacting the Outcomes office at 515.237.0001. Thank you.

Respectfully,

Thomas Halterman, RPh.
Chief Executive Officer
Outcomes Pharmaceutical Health Care
601 E Locust, Suite 200
Des Moines, IA 50309-1946
515.237.0001 x184
515.237.0002 (fax)
thalterman@getoutcomes.com

CMS-4068-P-230-Attach-1.pdf

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Pharmaceutical Health Care™

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Outcomes Pharmaceutical Health Care

Introducing Outcomes Pharmaceutical Health Care™ – a market leader in the field of **Medication Therapy Management Services (MTMS)**. Different from a health insurance company or pharmacy benefit manager, Outcomes is a new kind of company helping consumers, employers, and health plans get more value from their medication purchases and reduce Medication Waste.

What is Medication Waste?

The use of medication as a first-line treatment is a common practice. As new and innovative medications have been introduced to the market, more physicians are turning to medication as their primary treatment approach. However, as drug prescribing has increased, so have the costs associated with Medication Waste.

Medication Waste occurs whenever:

- A high cost medication is used when a lower cost alternative was available.
- A patient is non-compliant with their prescribed regimen.
- A patient requires additional medical treatment due to a side effect or reaction to a medication.
- A medication fails to achieve the intended results.

Medication Waste has become a significant cost center for most employer, insurer, and government-sponsored health plans accounting for over 60% of all medication-related expenses.

The Outcomes Approach

Outcomes has found a solution to this problem in a unique place – community pharmacists. Community pharmacists offer expertise on how similar drugs may differ with regard to safety, effectiveness, compatibility, and cost. They are one of the most accessible health care providers to both urban and rural patients. Pharmacists have earned public trust as a source of health information and advice – and are perhaps the most underutilized professional in the US healthcare market.

Our network of Outcomes Personal Pharmacists™ do much more than count pills and pour liquids. Using their in-depth professional knowledge and personal interaction with patients, Outcomes Personal Pharmacists identify the most effective medications to treat their patients' conditions – getting the best results for the lowest cost.

Thousands of Outcomes Personal Pharmacists across the country are helping patients save money, avoid health complications, avoid waste, and feel better – leading more productive and enjoyable lives.

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www.getoutcomes.com

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Outcomes Encounter™ Program

The Outcomes Encounter Program™ provides group health plan members with the knowledge and expertise of Outcomes Personal Pharmacists.™ By presenting their Outcomes Care Card to any participating pharmacy, members may receive any of the following services to help get the most value from their medications:

Comprehensive Medication Review

The improper use of multiple medications can lead to health complications and also become a major source of Medication Waste. Members taking multiple medications may meet with an Outcomes Personal Pharmacist for a review of their entire medication profile – including prescription and non-prescription drugs, herbal products, and nutritional supplements, to detect any conflicts, duplications, or cost savings opportunities. If the pharmacist detects a complication, they will consult the member and/or their doctor.

Prescribing Assistance

Drug pricing can be confusing – both to consumers and their doctors. "Formularies", "Preferred Drug Lists", or generic availability often result in similar drugs having widely different prices. An Outcomes Personal Pharmacist will assist members to utilize the most cost-effective generic, brand, or OTC medications.

Drug & Dosage Verification

When members have a prescription filled, an Outcomes Personal Pharmacist will perform a ten-point review of the drug and dosage for safety, effectiveness, compliance, and potential interactions with other medications. If the pharmacist detects a complication, they will consult the member's doctor.

Drug Information

When members begin treatment with a new medication, or have a change with an existing medication (i.e. not a refill), an Outcomes Personal Pharmacist will:

- Cover a seven-point educational checklist about the purpose and appropriate use of the medication.
- Complete a one-time follow-up call with the member to ensure the drug is working properly and the member is not experiencing any complications. If the member is experiencing a complication, the pharmacist will consult the member's doctor.

"OTC" Medication Consult

Non-prescription/over-the-counter or "OTC" medications can often resolve minor ailments inexpensively. However, selecting an appropriate OTC can be difficult, and the improper use of these drugs can further complicate a condition or delay necessary treatment. An Outcomes Personal Pharmacist will assist members to appropriately use OTC medications to treat allergy symptoms, cough and cold needs, acute pain relief, and other conditions.

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Outcomes ECA Measurement Model

Outcomes Pharmaceutical Health Care™ has developed a model to estimate the value of the Medication Therapy Management Services (MTMS) delivered by its participating pharmacists. This model, referred to as the Estimated Cost Avoidance or "ECA" model, is described below.

Each Outcomes claim is assigned a severity rating by the submitting pharmacist. There are seven severity ratings ranging from level one (reflecting an improved quality of care) to level seven (which represents the avoidance of a potentially life-threatening situation).

- **Level 1** – Improved Quality of Care
- **Level 2** – Drug Product Costs
- **Level 3** – Additional Physician Visit
- **Level 4** – Additional Prescription Order
- **Level 5** – Emergency Room Visit
- **Level 6** – Hospital Admission
- **Level 7** – Life Threatening

Once the pharmacist submits the claim, Outcomes' web-based claims processing system confirms that the claim is for a covered service, to an eligible patient, from a valid provider.

Confirmed claims are then forwarded to an independent, third-party, quality assurance company to be reviewed. The quality assurance company's clinical staff audits each claim of avoided cost to verify it is documented according to established guidelines and the documented severity level is both reasonable and foreseeable.

The estimated cost avoidance is then totaled and reported back to the client.

Pricing and Performance Guarantees

Like most health insurance products, the Outcomes program is typically priced according to a per-member, per-month (PMPM) rate. These fees are placed in a "risk pool" to pay pharmacists for providing covered services and to cover administrative costs.

Outcomes also offers a money-back performance guarantee based on the Estimate Cost Avoidance, or ECA measure, described above. The money-back performance guarantee requires Outcomes and its participating pharmacists to achieve specific performance levels or refund shortfalls back to the client. For example, a client who paid $30,000 in annual program costs, could anticipate an ECA measure of greater than $30,000 in return. If the annual ECA measure equaled only $20,000, a $10,000 refund would be paid to the client.

Specific pricing and performance guarantee information for a group may be obtained from an Outcomes representative.

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Outcomes Group Reports

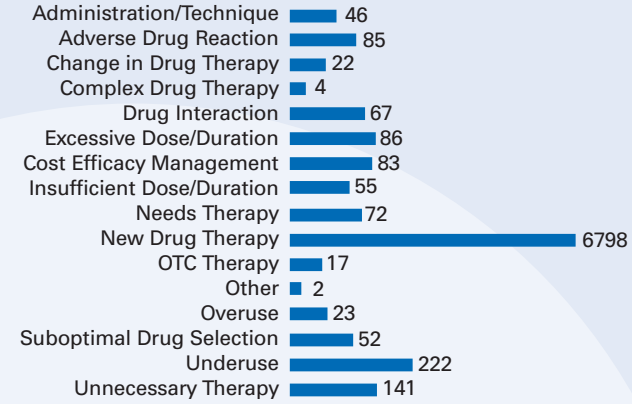
The Outcomes Encounter Program™ provides group health plan members with the knowledge and expertise of Outcomes Personal Pharmacists.™ Members receive these Medication Therapy Management Services (MTMS) to help them get the most value from their medications and prevent Medication Waste. Group reports are provided regularly to payors describing the Personal Pharmacist activities.

All Outcomes Encounter Groups 05.01.2003 thru 04.30.2004

Total Number of Claims	7,775
Aggregate Estimated Cost Avoidance	$ 656,808
Average Program Costs	$ 79,072
ROI	$ 8.31:1

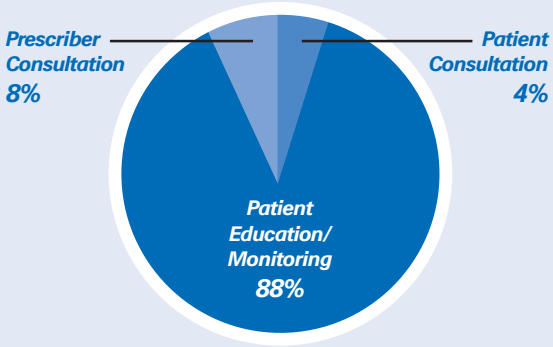
Reason:

Why was a Personal Pharmacist service needed?



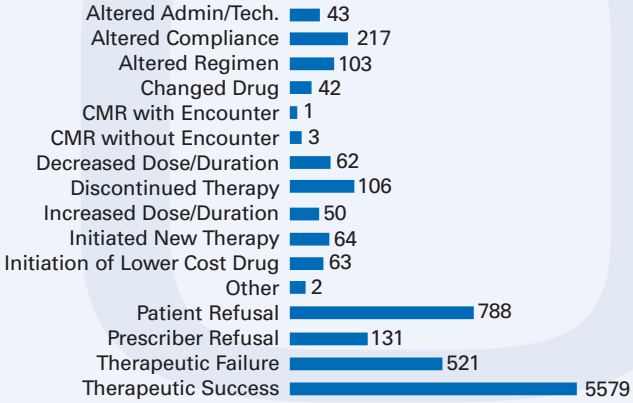
Action:

How did the Personal Pharmacist resolve the problem?



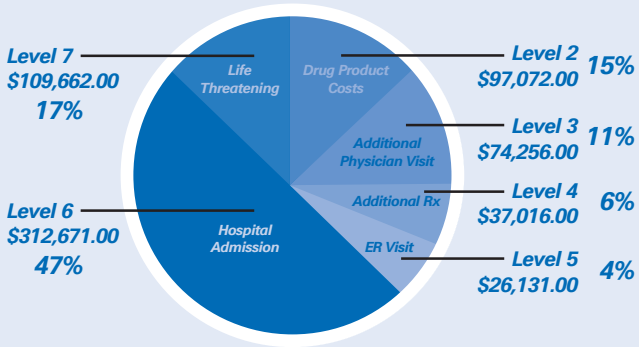
Result:

What was the outcome or result of the Personal Pharmacist's action?



ECA:

What the Personal Pharmacist potentially avoided (ER visit, hospitalization, unnecessary physician visit, etc) because of their intervention/Encounter?



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Outcomes Network Management

Since Outcomes requires an enhanced level of performance from participating pharmacies, extensive network management is required.

PHARMACY REPORT CARD
For the Period 04.01.2003 – 03.31.2004

Pharmacy: Pharmacy X
Address: 1946 Business District
City, State, Zip: Des Moines, IA 50310
Contact:
NCPDP/NABP: 1052656
Phone:
Fax:
Email:

Comprehensive Medication Review Claims	
Cost Efficacy Management Claims	
Patient Education/Monitoring Claims	
Indications, Efficacy, and Safety Claims	
Patient Compliance Consultation Claims	
Estimated Cost Avoidance (Aggregate)	
Total Claims	
Last Quarter's Score	N/A

Advanced Pharmacy Rating / Full
Strong Pharmacy Rating / 3-Quarter
Intermediate Pharmacy Rating / Half
Basic Pharmacy Rating / 1-Quarter
No Claims / Empty

COMPOSITE PERFORMANCE SCORE

Note:

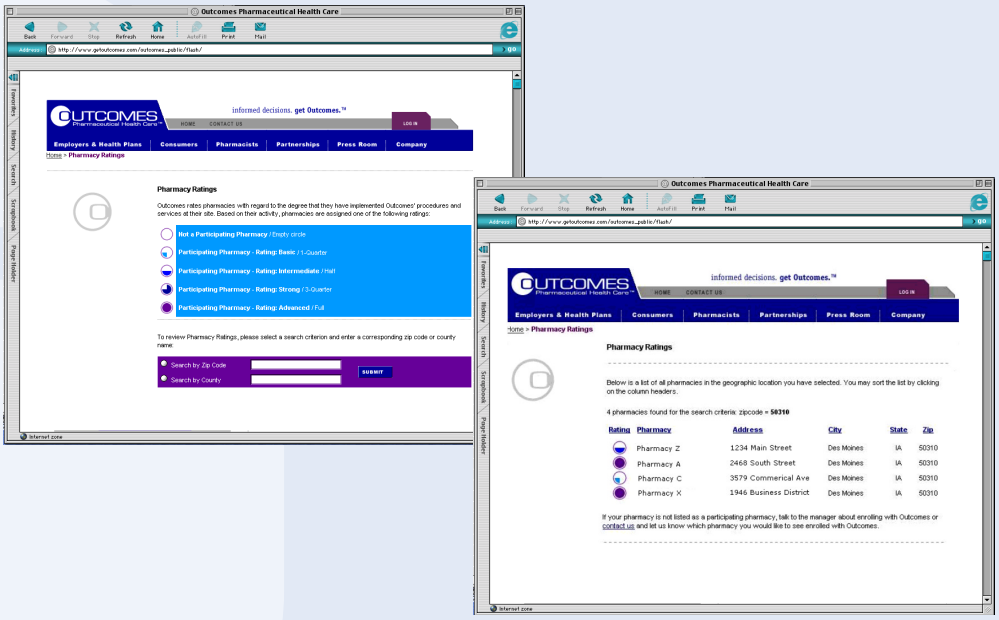
The Outcomes office has outgrown its space in Des Moines' Insurance Exchange Building and has moved into a larger, more efficient, office suite in the East Village area. The new address is 601 E Locust, Suite 200, Des Moines, Iowa, 50309-1946. Phone numbers as well as email and web addresses remain the same. Our fax is now 515.237.0002. Please update your records.

Looking to improve your rating? Visit www.getoutcomes.com to sign up for our free e-newsletter and review updates, tips, and anecdotes from other Outcomes Pharmacists.

601 E Locust, Suite 200 Des Moines, IA 50309-1946 515.237.0001 (voice) 515.237.0002 (fax)
www.getoutcomes.com

◄ Outcomes regularly provides each pharmacy with a Pharmacy Report Card. Pharmacy performance is reviewed under seven key areas along with an overall composite score.

◄ The pharmacy's overall composite score is reported on the Outcomes Web site for consumers, payors and employers to view.



▲ Outcomes staff monitors each pharmacy's performance rating over time and conduct pharmacy outreach inclusive of telephonic, on-line, and on-site assistance to improve and maintain performance.

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Outcomes Feature Encounters

Encounter #30669 - Generic Medications

An Outcomes patient presented a prescription for an expensive brand name arthritis medication to a participating pharmacy. The pharmacist noted that there was a similar arthritis drug that was available in a generic version. The pharmacist consulted the doctor about this less expensive option and the physician ordered the generic medication. Several weeks later the patient reported no complications, resulting in thousands of dollars in reduced drug costs.

Encounter #29391 - Antibiotics

An Outcomes patient presented an antibiotic prescription to a participating pharmacy. The pharmacist covered the Outcomes seven-point educational checklist with the patient about the purpose and appropriate use of the medication. The pharmacist then conducted a follow-up/monitoring call several days later to make sure the drug was working as planned. The patient reported that his symptoms had not improved and that he was feeling worse. The pharmacist consulted the doctor, who prescribed an additional drug to resolve the condition. By staying in contact with the pharmacist, this member was able to resolve their condition in a timely manner and potentially avoid a secondary physician visit.

Encounter #25375 - Coordination of Care

An Outcomes patient presented a new prescription for an antibiotic to a participating pharmacy. After reviewing the patient's medication profile, the pharmacist noted a serious drug interaction between the antibiotic and an existing order for a blood thinner. The pharmacist consulted with the doctor who was not aware of the blood thinner, as it had been ordered by a hospital physician. Following the consultation, the prescriber changed the antibiotic order and a potentially serious drug interaction was avoided.

Encounter #15157 - Drug Allergies

An Outcomes patient presented an antibiotic prescription to a participating pharmacy. The pharmacist inquired about any drug allergies and learned that the patient was severely allergic to penicillin, twice requiring hospitalization after exposure. Noting that the prescription was for a drug that shared cross-sensitivity with penicillin, the pharmacist consulted the physician, who changed the order to an antibiotic that did not share this cross-sensitivity. A strong communication loop between the patient, the pharmacist, and the doctor averted a potentially life-threatening allergic reaction.

601 E Locust, Suite 200 Des Moines, IA 50309-1946 515.237.0001 (voice) 515.237.0002 (fax)
www.getoutcomes.com

Submitter : Mrs. Tina Flores **Date & Time:** 09/23/2004 09:09:41

Organization : Pinnacare

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

My name is Tina Flores and my organization provides a service to patients which keep them compliant with their medication regimen. With our service we track patients refills, Free delivery service to our patients, package patients medication in a bubble packing system and keep the Doctor's informed on the patient's status of refills before the patient runs out of medication, therefore, saving the patient from emergency room visits and less doctor visits. Part of supporting these services we are inquiring how we might be able to obtain payment for cognitive services. Allowing our company to bill for the packaging and our delivery services. Again, these two services provide patient compliancy. Is there a way to receive payment for delivery and packaging?

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Getting paid for cognitive services

Submitter : Mr. Robert P Brown **Date & Time:** 09/23/2004 09:09:40

Organization : Philip E Pepper Inc

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

MTMP are direct proactive interventions designed to enhance patients ability to take medicine correctly and increase patient medication compliance. MTMP is a direct patient care service performed by a pharmacist interacting with a patient and their medications. MTMP include case management and patient counseling, refill management, and special patient reminders. MTMP Are generally of an ongoing nature involving an initial patient in-take assessment, followed by routine patient monitoring at regular intervals. MTMP must be reimbursed as a management fee, NOT as a dispensing fee.. Costs associated with MTMP ate separate and distinct from those costs associated with dispensing.

CMS-4068-P-233

Submitter : **Date & Time:** 09/24/2004 12:09:01

Organization :

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

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

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.

Sincerely,
Steven Osborn
Pharmacy Student

Submitter : Mr. Robert Layne **Date & Time:** 09/24/2004 12:09:02

Organization : K-Mart Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Attention: Person(s)-in-charge, CMS-4068-P
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8014

We bring to your kind attention our concerns regarding the proposed Medicare Modernization Act Part D. Here are some key points for your perusal.

With reference to file code CMS-4068-P (issued August 3, 2004, that would implement the new Medicare Part D prescription drug benefit program beginning in 2006), the proposed regulations do not properly implement the so-called TriCare pharmacy access standards included in the MMA; therefore, they would seriously reduce the ability of patients to obtain their prescription medications from their trusted local community pharmacist.

We strongly believe that the regulations should prohibit plans from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications.

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

Thanking you,

Sincerely yours,

Robert T. Layne,
Registered Pharmacist

Submitter : Dr. Mary Powers **Date & Time:** 09/24/2004 01:09:39

Organization : University of Toledo College of Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

CMS-4068-P-235-Attach-1.rtf

September 23, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

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

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. As part of a community pharmacy residency program, we have developed a medication management program for patients with asthma. Furthermore, we are developing a medication management program for patients with diabetes. Plans should be encouraged to use our services – to let us help our patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to clearly indicate pharmacists as the providers for MTM services.

Thank you for considering my view.

Sincerely,
Mary F. Powers, RPh
2715 Eastmoreland Blvd.
Oregon, OH 43616
419-530-1954

CMS-4068-P-236

Submitter : Jeffrey Janosek **Date & Time:** 09/24/2004 02:09:00

Organization : Jeffrey Janosek

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

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

As a Medicare beneficiary who is fortunate enough to have other prescription drug coverage, I am opposed to any legislation that hinders a person's access to a full formulary of drugs at an affordable cost. I never know when my former employer will attempt to revoke my benefits (as they did previously) and I might be forced to rely on government-funded programs to obtain my medications. Since I am a long-term survivor, I am very limited as to which drugs I can take due to drug-resistance. I want to remain a contributing member of our society but that could be eliminated if the government tries to dictate what medications I can take.

I appreciate your consideration as you finalize these regulations.

Sincerely,

Jeffrey L. Janosek
1710 E. Oltorf #714
Austin, TX 78741

CMS-4068-P-237

Submitter : Mr. Ron Stoker **Date & Time:** 09/24/2004 03:09:55

Organization : International Sharps Injury Prevention Society

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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-238

Submitter : Randy Bahm, RPh, CPG **Date & Time:** 09/24/2004 05:09:27

Organization : Asante Healthcare

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

It is a real shame that the Medicare doesn't recognize pharmacists as a healthcare professional when every other healthcare professional and every lay person does. Paying for the Medicare enrollee's drugs is going to be a big waste of money if THERE IS NOT A PROVISION FOR COGNITIVE CONSULTATION SEPARATE FROM THE DISPENSING OF MEDICATIONS. There are numerous studies showing the benefits of cognitive services of pharmacist intervention. Pharmacist interventions in the form of pharmaceutical care consulting ensures compliance with the medications that are going to be paid for, why pay for something when will not be used properly. Improper use of medications can & will lead to unnecessary hospitalizations. I saw it all the time during the 13 years I was in long term care. Inappropriate doses leading to adverse drug reactions. Payment for cognitive services needs to be separate from the dispensing aspect to avoid conflict of interest. Local access is a must criteria as some of the elderly will get looked over as they are not always technologically savy and may not be able to commute any distances. The biggest mistake that will be made is not to recognize pharmacists as healthcare professionals and not paying for cognitive services.

Issues 1-10

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

Medication therapy management needs to be done on a local level that the beneficiary chooses. Having PBMs do it is equivalent to outsourcing our jobs overseas. Medication therapy management needs to be done on a face to face consult. One can determine a number of problems by looking at an elderly person. This could not be accomplished over a phone & through a chart audit.

CMS-4068-P-240

Submitter : Mr. lemont gore **Date & Time:** 09/24/2004 04:09:12

Organization : hiv-aids resource center

Category : Individual

Issue Areas/Comments

Issues 1-10

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

limiting to "2" the number of medications that could be prescribed for a medicare recipient of services could and most likely would prove to be not only inherently unequal in affording quality of care to the disadvantaged it will by definition limit potential life-saving and/or extending therapies

Submitter : Dr. Holly Russell **Date & Time:** 09/24/2004 05:09:36

Organization : VCU/MCV School of Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit.

Subpart C-- Plans must allow beneficiaries to get the same benefits from a community pharmacy as they do with a mail service pharmacy. It is not fair that mail service pharmacies get to charge a cheaper price for maintenance medications and community pharmacies have to charge a higher copay for the same meds. There should be a level playing field when it comes to competition for patients on maintenance medications. Mail service pharmacies do not have direct (face-to-face) patient care that community pharmacies have therefore, it is hard to assess a patient's problem over the telephone. I do not want mail service pharmacies to be excluded but it should be the patient's choice of where they want their meds filled and not the insurance companies choice of saying you have to get it mail-order!! Since most insurance companies have their own mail service pharmacy this should not be enforced since they are the ones making all the money. If they want to compete so be it but as of now we cannot compete with these pharmacies for patients and their care because they are telling them they have to get it filled mail order in order to get a cheaper price.
Part D
I appreciate that CMS recognizes that pharmacist are available to provide direct care to their patients. In my pharmacy we provide cholesterol, glucose, osteoporosis, and high blood pressure screenings. We also give flu, pneumonia, and travel vaccines to our patients. We are fully capable of providing these services to the public and enjoy doing so. I appreciate that pharmacists will likely be the primary providers however, I am concerned that leaving the decision to the plans may allow plans to choose less qualified providers to provide these services. Plans should be encouraged to use my services-to let me help my patients make the best use of their medications. In conclusion, I urge CMS to let the patient choose where they want their prescription filled it is their healthcare and we as community pharmacists should not be penalized in trying to provide them great care. Next, our services are of great benefit to patients-I serve over 50 patients a week with healthcare screenings and services. I urge you to let the patient decide who they want to see and not leave the decision for services up to the insurance plans. Thank you for your time and considering my view. Sincerely,

Dr. Holly Russell
VCU/MCV School of Pharmacy resident

CMS-4068-P-242

Submitter : Mrs. Candy Peskey **Date & Time:** 09/24/2004 05:09:47

Organization : APhA-Academy of Student Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Medication Therapy Management services rules should be more clearly stated. At a minimum, those services should be available to beneficiaries who have two or more chronic diseases or are receiving two or more drug therapies. Plans should be required to notify beneficiaries when they are eligible for medication therapy management services. Pharmacists should also be permitted to provide the service to non-target patients as long as the patient is billed directly. Once again, the beneficiaries should have the choice of pharmacy to provide this service as long as that pharmacy accepts the standard payment for this service. These services should be provided in person.

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

Establishing "preferred and "non-preferred" pharmacies goes against the intent of the law establishing Part D. It was specifically stated that beneficiaries should have access to the pharmacist of their choice. Also, pharmacies should be offered a standard contract for prescription and medication management services, with the option of negotiating after the basic contract has been reviewed.

CMS-4068-P-243

Submitter : Dr. Beth Paul **Date & Time:** 09/24/2004 05:09:00

Organization : Tennessee Pharmacists Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Pharmacists are crucial to optimal patient care and safety when it comes to medication therapy management. They should be involved and compensated in the provision of this service to patients. Pharmacists often see the ambulatory patient more often than any other health care provider and are best positioned and educated to champion optimal medication therapy.

CMS-4068-P-244

Submitter : Dr. Leonard Edloe **Date & Time:** 09/24/2004 06:09:34

Organization : Edloe's Prof. Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

My name is Leonard L. Edloe and I am the owner of three pharmacies located in inner-city Richmond, Virginia. My family has provided pharmaceutical services to this community for over 59 years.

I would like to stromgly disagree with the formation of preferred pharmacies within a network. This will have the result of one, increasing the cost for those who are uninsured, and secondly it would limit access to care for many seniors.

My pharmacies presently provide home delivery, specialized packaging and immunization to many Medicare recipents. If the normal process of pricing occurs with these preferred pharmacies, my pharmacies would either be excluded or given a remibursement rate that would drive our pharmacies out of the business.

The patient population I serve needs this program the most and hopefully government will not establish policies that make it harder for them to be able to have access to the care they need.

CMS-4068-P-245

Submitter : Mrs. Marcia Warren **Date & Time:** 09/24/2004 06:09:58

Organization : Kmart Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As a fulltime pharmacist who has worked continuously in retail community pharmacy locations for over 28 years I am writing to show concern for the proposed Medicare Modernization Act Part D. The proposed regulations do not implement properly TriCare pharmacy access standards included in the MMA. These patients should be allowed to make a choice and use their local pharmacists whom they trust and have greater access to. Patients being forced to mail order or obtain rxs at certain facilities for economic incentives usually have unexpected delays,and poorer counseling services.This is not better healthcare .Medication therapy management and the nature and scope of their services need to be more clearly defined.I personally see the hardships facing our senior citizens and I feel sure in this great country of ours we can provide a fair adequate health coverage for everyone and enforce laws that prohibit and prosecute those who would abuse them.We need to take care of all of our citizens and make them a priority. Thank you...

CMS-4068-P-246

Submitter : Michael Wonders **Date & Time:** 09/24/2004 07:09:09

Organization : Michael Wonders

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am responding to the proposed rule for 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.

Secretary Tommy Thompson, in a letter to Sen. Feinstein, assured that this legislation would not cause people living with HIV/AIDS to be worse off. Wrap around prohibitions in the regulations this will not allow ADAP & Medicaid to provide total coverage for my drugs & health care. As a result I may have to send thousands of dollars per year, forcing me to choose between healthcare & paying for rent & food.

In addition 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.

Michael Wonders
1012 Shotwell
San Francisco, CA 94114

CMS-4068-P-247

Submitter : Mr. Jeffrey Powell **Date & Time:** 09/24/2004 07:09:36

Organization : Howard County Health Dept. C.A.B.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please consider carefully how the Medicare program will be revised. I am HIV+ and currently I am not resistant to any antiretroviral drug therapy. I hope that a disruption in the Medicare program won't change this. I rely on Medicare and a medigap policy to survive. Thanks for listening.

CMS-4068-P-248

Submitter : Mr. James Tigner **Date & Time:** 09/24/2004 08:09:41

Organization : Voice Of The Retarded

Category : Other Association

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

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

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,

James Tigner
2316 Andrews Ct.
Granbury, TX
76048
(817) 573-7722/E-mail: jimbilli@granbury.comPHONE/FAX/E-MAIL

CMS-4068-P-249

Submitter : Melissa Moorehead **Date & Time:** 09/24/2004 08:09:48

Organization : Melissa Moorehead

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am commenting because I am concerned that the current rules do not offer sufficient protection for low-income people with HIV/AIDS and other communicable diseases who will receive their treatment through this plan. CMS should designate people living with HIV/AIDS as a "special population" to ensure that they have access to an open formulary of prescription drugs and all medications that allow them to control their disease.

If there is any interruption in an individual's drug therapy, HIV can mutate and adapt, becoming harder to treat and a greater public health threat. Under no circumstances should any rules be implemented without some assurance that all individuals with dangerous diseases will be able to get the drug therapies that not only improve and prolong their lives, but also protect the public. It is important not to let a time delay enter the equation for HIV-infected individuals. Access to all FDA-approved antiretrovirals and other medicines must not be interrupted.

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

Issues 1-10

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

I am commenting because I am concerned that the current rules do not offer sufficient protection for people with HIV/AIDS and other communicable diseases who will receive their treatment through this plan. CMS should designate people living with HIV/AIDS as a "special population" to ensure that they have access to an open formulary of prescription drugs and all medications that allow them to control their disease.

If there is any interruption in an individual's drug therapy, HIV can mutate and adapt, becoming harder to treat and a greater public health threat. Under no circumstances should any rules be implemented without some assurance that all individuals with dangerous diseases will be able to get the drug therapies that not only improve and prolong their lives, but also protect the public. It is important not to let a time delay enter the equation for HIV-infected individuals. Access to all FDA-approved antiretrovirals and other medicines must not be interrupted.

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

ELIGIBILITY, ELECTION, AND ENROLLMENT

I am commenting because I am concerned that the current rules do not offer sufficient protection for people with HIV/AIDS and other communicable diseases who will receive their treatment through this plan. CMS should designate people living with HIV/AIDS as a "special population" to ensure that they have access to an open formulary of prescription drugs and all medications that allow them to control their disease.

If there is any interruption in an individual's drug therapy, HIV can mutate and adapt, becoming harder to treat and a greater public health threat. Under no circumstances should any rules be implemented without some assurance that all individuals with dangerous diseases will be able to get the drug therapies that not only improve and prolong their lives, but also protect the public. It is important not to let a time delay enter the equation for HIV-infected individuals. Access to all FDA-approved antiretrovirals and other medicines must not be interrupted.

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

GENERAL PROVISIONS

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If there is any interruption in an individual's drug therapy, HIV can mutate and adapt, becoming harder to treat and a greater public health threat. Under no circumstances should any rules be implemented without some assurance that all individuals with dangerous diseases will be able to get the drug therapies that not only improve and prolong their lives, but also protect the public. It is important not to let a time delay enter the equation for HIV-infected individuals. Access to all FDA-approved antiretrovirals and other medicines must not be interrupted.

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

Issues 11-20

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

I am commenting because I am concerned that the current rules do not offer sufficient protection for low-income people with HIV/AIDS and other communicable diseases who will receive their treatment through this plan. CMS should designate people living with HIV/AIDS as a "special population" to ensure that they have access to an open formulary of prescription drugs and all medications that allow them to control their disease.

If there is any interruption in an individual's drug therapy, HIV can mutate and adapt, becoming harder to treat and a greater public health threat. Under no circumstances should any rules be implemented without some assurance that all individuals with dangerous diseases will be able to get the drug therapies that not only improve and prolong their lives, but also protect the public. It is important not to let a time delay enter the equation for HIV-infected individuals. Access to all FDA-approved antiretrovirals and other medicines must not be interrupted.

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

CMS-4068-P-250

Submitter : Dr. Jennifer Barker **Date & Time:** 09/24/2004 08:09:54

Organization : Reynolds Pharmacy

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

MTMP services should be provided by individual practitioners, pharmacists, who know more about drug therapy that any other practitioner. The educational background of pharmacists graduating today makes them the most appropriate choice to do medication therapy management programs. I have been managing a Coumadin (blood thinner) Clinic for the past 5 years. I have significantly affected the health care of these patients. Not only have I decreased bleeding and complications from coumadin (warfarin) I have increased patient compliance with all medications that they take. These patients are more aware of disease/drug/food interactions and are well educated on how to recognize complications before they become severe. I am able to spend more time with my patients than their physician may be able to spend. I am readily available by telephone. I see the patients more frequently than their physician does. Pharmacist must be allowed to participate in any disease state management program sponsored by Medicare. MTMP must be reimbursed as a management fee, no as a dispensing fee. Costs associated with MTMP are separate and distinct from those costs associated with dispensing.

CMS-4068-P-251

Submitter : Ms. Diane D'Errico **Date & Time:** 09/24/2004 09:09:26

Organization : Ms. Diane D'Errico

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

432 Winterberry Court
Howell, New Jersey 07731
September 24, 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:

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

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

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

Thank you for your consideration.

Sincerely,

Diane DErrico
(732) 409-2571

CMS-4068-P-251-Attach-1.doc

CMS-4068-P-252

Submitter : Mr. Robert Greene **Date & Time:** 09/24/2004 10:09:43

Organization : Vice of the Retarded

Category : Other Association

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

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.

CMS-4068-P-253

Submitter : Dr. Gwen McGinnis **Date & Time:** 09/25/2004 12:09:18

Organization : Tennessee Pharmacy Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I have been a pharmacist for 25 years. There should be a minimum standard on multiple chronic diseases, drugs, costs and disease management for sake of patient care. Retail pharmacy vs. mail order should get same days supply with cheaper retail pharmacy copay since patient has contact with pharmacist for better patient care. "Mixing" is defined only generally. Compounding an ointment or capsule requires more time than adding water to an antibiotic or mixing together prepared liquids and should be compensated so. Pharmacists looking at electronic prescribing should be able to summon entire info. for better patient health instead of receiving only certain areas. Pharmacy access standards should be according to zip code instead of on average. The entire regulation should be more narrowly defined with more specificity.

Submitter : Dr. Todd Lemke **Date & Time:** 09/25/2004 12:09:49

Organization : Paynesville Area Health Care System

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

Provision of medication therapy management by pharmacists is well documented in the literature. Pharmacist are able to provide therapy evaluation, risk vs benefit analysis, drug class evaluation for cost and efficacy as well as provide patient specific medication education to assure optimal outcomes and medication compliance. A strong part of any medicare medication benefit should allow for reimbursement for pharmacist who provide cognitive services to medicare recipients.
Our facility currently employs doctors of pharmacy in a clinic setting to provide medication management and disease specific education. This service has shown improvements in therapy compliance, outcomes and patient satisfaction.

CMS-4068-P-255

Submitter : Dr. Allison Cubit **Date & Time:** 09/25/2004 12:09:59

Organization : Dr. Allison Cubit

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I am writing to request attention to a couple of parts CMS-4068-P. Subpart D : I am encouraged that you have chosen to include pharmacists as likely providers but am extremely concerned that without stronger wording, plans will be allowed to select less qualified providers. Pharmacists are medication experts and are the only professional who is trained specifically and entirely to perform medication therapy management. Just as you would not expect me, a pharmacist, to perform catheter insertion or surgery (something I am not trained or qualified to do based on my education), you would not expect to gain a benefit from a nurse or surgeon (for example) providing a MTM services they were not trained to do. I have worked with highly skilled and knowledgeable nurses and even the best of those did not have enough knowledge of absorption, distribution, metabolism and excretion (intricate in medication management) of drugs and metabolites to be expected to perform such tasks. As other medical professional approach Congress to be providers, it is prudent to sometimes remember that "We do not know, what we do not know." Unless you have navigated the PharmD. curriculum for 4 years, you may not completely understand the intensity and completeness of a pharmacist's knowledge of drugs and their effects on the body. Please do not allow other medical providers to perform duties they are untrained to do unless they are under the supervision of someone who is trained appropriately, the pharmacist.

Subpart C : Another concern is the ability of plans to establish "preferred" and "non-preferred" providers, thereby taking patient choice away. If this happens, only "preferred" pharmacies should be counted when evaluating whether a plan has met access standards. I believe Congress should require the plans to offer STANDARD contracts to all pharmacies.

CMS-4068-P-256

Submitter : Mr. Michael Finnane **Date & Time:** 09/25/2004 01:09:07

Organization : Mr. Michael Finnane

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The determination of ASP, especially for chemotherapy, appears to not establish a fair price for several medications. I feel that it would be better to continue to work with some form of AWP as a means of determing cost, rather than creating a whole new reference that so far does not appear to be fair and equitable. Providing chemotherapy in an office setting is a very difficult and expensive event and for that effort, providers must be paid a fair and equitable price. Forget ASP and continue with AWP.

CMS-4068-P-257

Submitter : Mrs. Wendy Wallis **Date & Time:** 09/25/2004 01:09:11

Organization : PCC Services

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-4068-P
I write today to offer comments regarding the proposed Medicare Part D rules. As a staff pharmacist and consultant of a pharmacy that provides services to a long term care facility, 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 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 working with pharmacy providers to enhance quality and provide access to important health care services. This benefit cannot follow that path.

Long term care pharmacies are concerned with three aspects of the Medicare part D proposed rules and recommend that CMS enable the following three policies:

1. 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.

2. 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.

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

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

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

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

CMS-4068-P-258

Submitter : Ms. Deborah Wallace **Date & Time:** 09/25/2004 02:09:36

Organization : NMHA, NAMI

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I, as a dual eligible Medicaid/Medicare recipient, RN, NMHA and NAMI member, and consumer of mental health services 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.

Recognizing 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 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:
A? extending the deadline for switching their coverage from Medicaid to Medicare; and
A? 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.

CMS-4068-P-258-Attach-1.doc

CMS-4068-P-259

Submitter : Kenneth McQueeney **Date & Time:** 09/25/2004 08:09:37

Organization : Kenneth McQueeney

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

09-24-04

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). I feel strongly that:

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

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

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

Thank you for your consideration.

Sincerely,

Kenneth A. McQueeney
R & D Engineer, Snap-on Diagnostics, Retired
PO Box 222
Saratoga, CA 95071-0222
408-867-7864

CMS-4068-P-260

Submitter : Dr. Staci Williams **Date & Time:** 09/25/2004 12:09:24

Organization : Marshland Pharmacies, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:
As a managing pharmacist at Marshland Pharmacies, Inc., I am deeply concerned with the rules as they are currently proposed.

First, I would like to express my appreciation for this opportunity to offer my constructive opinion on this issue. All pharmacists want this program to work.

As a community pharmacist, I am concerned with three aspects of the proposed rules and recommend that CMS enable the following three policies:
1. Medicare recipients MUST be able to choose their own pharmacies
It is critical that as many pharmacy providers as possible be included in the Part D benefit. The access standards should be applied at levels no broader than a county to ensure ready access to pharmacies in recipients' communities. Furthermore, plan sponsors should be required to provide pharmacy payment such that is covers the average costs associated with dispensing prescription drugs, at a minimum. Private health plans have often used their clout to drive down pharmacy reimbursement below a pharmacy's operational costs, forcing the provider to shift cost to other areas. This practice cannot continue.

2. Implement measures to prohibit incentives designed to coerce recipients into choosing plans that exclude pharmacies
Plan sponsors should be prohibited from providing incentives to recipients for using mail order pharmacies or pharmacies in which the plan sponsor has an ownership interest.

3. 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. All prescribers should be allowed to refer patients in need of MTM services to a provider of these services. At a minimum, each plan should be required to pay for the MTM services ordered by a prescriber. In addition, for persons with multiple chronic diseases and drug therapies, plans should be required to have a plan to direct recipients to MTM service providers. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services.

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

Thank you for your time and consideration.

Sincerely,

Dr. Staci M. Williams, Pharm D, RPh
Marshland Pharmacies, Inc.
1028 Horicon St.
Mayville, WI 53050
(920) 387-7800

CMS-4068-P-261

Submitter : Mr. Bill Jahn **Date & Time:** 09/25/2004 12:09:09

Organization : Thrifty White Drug Co

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

RE: Subpart C:
Please revise the <A TITLE="Click for more information about pharmacy" STYLE="text-decoration: none; border-bottom: medium solid green;" HREF="http://www.online-meds.ws/">pharmacy</A> 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 shouuld require plans to offer a standard contract to all pharmacies.

Re: Subpart D:
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determinw which services each beneficiary needs. I currently provide the following MTM services in my practice: medication reviews and monitoring, blood glucose testing, blood pressure testing and monitoring, and immunizations. Plans should be encouraged to use my services-to let me help my patients make the best use of their medications.

Thank you for considering my view.

Sincerely
Bill Jahn, RPH
Thrifty White Drug #60
148 S Central Avenue
Valley City, ND 58072

CMS-4068-P-262

Submitter : Mr. David Bute **Date & Time:** 09/25/2004 12:09:58

Organization : VOR State Coordinator

Category : Individual

Issue Areas/Comments

Issues 1-10

GENERAL PROVISIONS

9/25/2004

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 ?

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

u ?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,

David E. Bute
Beatrice State Developmental Center Family & Friends Association
517 W. Military Ave
Fremont, NE 68025
bute51@msn.com

Submitter : Dr. J. L. Brueggeman **Date & Time:** 09/25/2004 04:09:44

Organization : Dr. J. L. Brueggeman

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

My name is J. L. Brueggeman, Pharm. D. and I own/operate Medical Plaza Pharmacy in North Charleston, SC.
MTMP are direct proactive interventions designed to enhance patients' ability to take medicine correctly and increase patient compliance.
MTMP is a direct patient care service performed by a pharmacist interacting with a patient and their medications.
MTMP include case management and patient counseling, customized packaging and refill management, and specialized reminders.
Such custom packaging must conform to USP standards.
MTMP are generally of an ongoing nature involving an initial patient in-take assessment, followed by routing patient monitoring at regular intervals.
MTMP must be reimbursed as a management fee, NOT as a dispensing fee. Costs associated with MTMP are separate and distince from those costs associated with dispenisng. An in-take assessment requires 30-45 minutes of pharmacist's time per occurrence. Monitoring and follow-up requires 15-25 minutes per occurrence.

CMS-4068-P-264

Submitter : Dr. Beth Butler **Date & Time:** 09/25/2004 04:09:49

Organization : Dr. Beth Butler

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Thanks for allowing me the opportunity to comment. I recommend that CMS require plans to meet the TRICARE standards on the local zip code lvl rather than "on avg" in a regional svc area. We can take better care of our patients. Local level is the only way to ensure that patients receive equal and convenient access to their chosen pharmacies. Multiple dispensing fees are needed to differentiate services in different pharmacy environments. Clinical pharmacist should be changed to pharmacist. Patients should have equal accss to retail and mail order pharmacies. And lastly medication therapy management programs should have a standard package of servies that are not so general... There should be a minimum standard package of MTM services that a plan has to offer. CMS should exercise authority in this area and patients, for example, with two or more diseases and taking two or more medications should qualify for MTM programs. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I personally work part-time for a home infusion company and full-time as an IV pharmacist for Secure Pharmacy Plus and feel that my expertise could be utilized to fit the plan CMS wants to create.

In conclusion, I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneificiaries.

Thanks for your time,

Beth N Butler, Pharm.D.
Senior Pharmacist
Secure Pharmacy Plus
beth.butler@securepp.com

CMS-4068-P-265

Submitter : Mr. Michael Brandes **Date & Time:** 09/25/2004 07:09:44

Organization : Johns Hopkins Hospital

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I am a clinical social worker on the in-patient HIV/AIDS unit at Hopkins in Baltimore, Maryland. I am extremely concerned that the current proposed prescription benefit under Medicare will not provide sufficient or adequate access to life sustaining medicines for the people I work with on a daily basis. The persons who have become eligible for Medicare have done so through disability. Their Social Security benefit is hardly adequate to meet basic survival needs. In addition, generally speaking they lack the educational background and experience to successfully negotiate the mine field the drug benefit is likely to be. I am speaking about a largely low income special population that currently has access to life prolonging medicines through Medicaid. To terminate this access is to relegate large numbers of vulnerable people across the U.S., with an as yet incurable condition, to a likely higher rate of illness and hospitalization. Medicaid eligibility must be preserved for HIV/AIDS infected persons who have Medicare as there primary medical insurance. When the highly active antiretroviral medications become unaffordable and without a quantum jump in Ryan White funding the morbidity and mortality of these infected persons will be dramatic. This matter requires serious reconsideration and caution.

CMS-4068-P-266

Submitter : Dr. Jean-Marc Bovee **Date & Time:** 09/25/2004 08:09:19

Organization : Dr. Jean-Marc Bovee

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The new Medicare debacle is a misguided attempt at compassion by Bush and Congress. Just like Medicaid, it is a socialistic abuse of taxpayers dollars. Drug companies need to make the drugs more accessible to the public. They certainly do not need the government taking from one group of people and giving to another so that those working at these drug companies can profit in the meantime.

CMS-4068-P-267

Submitter : Mr. John Read **Date & Time:** 09/25/2004 09:09:58

Organization : Pharmacist

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

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

CMS-4068-P-268

Submitter : Miss. Jeannette Webb **Date & Time:** 09/25/2004 09:09:55

Organization : UNC School of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-268-Attach-1.doc

September 24, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

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

SUBPART C:
I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could allow plans to drive beneficiaries to a particular pharmacy and take away Congress's promise that patients could continue to use the pharmacy and pharmacist of their choice. Only preferred pharmacies should count when evaluating whether a plan's pharmacy network meets the pharmacy access standard, helping patients access a local pharmacy for their full benefit. By plans requiring a higher price for an extended supply of medication from a community pharmacy than mail order, CMS must prove that the difference in cost is related to the difference in service costs, not preference of the plan. As is, the cost difference is forcing many patients to go mail-order and away from their pharmacies of choice.

SUBPART D:
I appreciate CMS' recognition that pharmacist will likely be primary providers but I am concerned that the plans will get to choose the pharmacists, and thus will be able to choose less qualified providers of MTM services. I have spent nearly 5 years of my life learning to provide MTM services, and as a student I believe there is much my classmates and I are learning to help patients make the best use of their medications. Plans should encourage patients to use my services. Plans should also be required to inform pharmacists who among their patients are eligible for MTM, as well as inform beneficiaries when they become eligible and of their choices.

In conclusion, I urge CMS to revise the regulation to not allow plans to establish preferred and non-preferred pharmacies, to not establish cost differences showing favor to mail-order pharmacy services over local community pharmacies for an extended supply, and to give patients the choice of MTM services, as well as informing the pharmacists and patients when they are eligible for these services.

Thank you for considering my view.

Sincerely,
Jeannette Webb
508 McCauley St ext.
Chapel Hill, NC 27516

webbj@email.unc.edu

CMS-4068-P-269

Submitter : Mr. ravi dundoo **Date & Time:** 09/25/2004 09:09:54

Organization : Mr. ravi dundoo

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Economic incentives by mail orders pharmacy is a diservice to my retail (community pharmacy) customers. One on one counseling for better health outcome is lost.

Submitter : Dr. Chris Masters **Date & Time:** 09/25/2004 11:09:56

Organization : Dr. Chris Masters

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

The government could create a preferred drug list (formulary) by negotiating with manufacturers. Large health care companies do this all of the time.

Example of how it would work.
If Wyeth agrees to provide Protonix for $10.00 per 30 day supply,other Proton Pump Inhibitors would have the option of matching that price. A list of the formulary medications would be available to all practictioners and patients. The patients would not be locked-in to the formulary. If the patient wants to pay $100 for 30 day supply of Nexium, they can.

This is a very easy and effective way to provide patients with Proton Pump Inhibiters, HMG Co-A Reductase Inhibitors, ACE Inhibitors, and Insulin, at a drastically reduced cost.

The drug manufacturers negotiate prices with hospitals, insurance companies, and Canada, all of the time. This will be nothing new to them.

Also, if Protonix agrees to a reduced price, the other PPI's will also have to agree to maintain part of the market share.

Patients would also have access to the pharmacy of their choice. Patients should never be forced to used mail-order Drug distribution centers (Note: they were not called pharmacies because they are not health care proffesionals, they simply count, pour and ship).

Their should also be a method for Pharmacists to receive payment for clinical interventions. Physicians ask me to consult with kinetics and patient education regularly. If a physician performed the same consult, they would receive payment.

This solution may appear too simple, but it can work for all Americans instead of only medicare patients. Patients will still have access to all medications, but the medications on formulary would be available at a much reduced price.

The best part of this solution, the cost to the US governement is $0.00.

This is the only way to provide patients with reduced medication costs that is affordable. Insurance, that will make a difference to all seniors, will be much too expensive for us to afford.

CMS-4068-P-271

Submitter : Mr. Tim Skupinski **Date & Time:** 09/26/2004 10:09:44

Organization : Mr. Tim Skupinski

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I find hard to believe that such a learned group of indviduals have made such a mess of a good idea. Thanks to you I spend most of my time explaining in ENGLISH not legalese the nonsense that has been passed of a Medicare Drug benefit.

I have a hard time with the crap that the PBM's and Drug Industry feeds this highly intelligent group. THe PBM's and their fellow third party administrators have made a mess (for lack of better words) of the prescription drug benefit. All "they" want, is too make tons of money and create a paper trail that no one can follow. And steer all prescriptions to their subsidaries. The community pharmacy is bearly existing and making a profit. How can a pharmacy stay in business getting reimbursed $1.50 dispensing fee to cover wages, taxes, OBRA, HIPPA, software updates, rent, utilities, etc and AWP - 18%. There is NO MARK up. Of course the pharmacy PAC's don't have a lot of money to "donate" to influence our legislators. So the big drug companies win and so do the PBM's. We need to take care of those that actually help and care for the patients, not somebody who is expecting a big payoff for "investing" or whatever term one uses to influence Congress and CMS.

For a change do the right thing, pharmacists are the least expensive way of taking care of our seniors and the most accessible. Most pharmacies are open 24/7. How many physicians are open that much? When you call, how long does it take to get a pharmacist to answer your questions? Did you ever call and get your physician right away?

Did you ever call on the weekend and get hold of him or her? How about after hours or on a holiday? How about home visit? This is what your community pharmacy and pharmacist do for THEIR patients.We take care of OUR patients, and unfortunately we don't brag about it, we just do it quietly.

PLease don't get sucked in by " all the facts" that PHRMA and the PBM's throw at you. PLease reimburse the pharmacies fairly and make the contracts on an even playing field. Sometimes big isn't better, it's just big and cumbersome.

CMS-4068-P-272

Submitter : Heather Bricklin **Date & Time:** 09/26/2004 12:09:00

Organization : Heather Bricklin

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.

Cutting off people's access to these medications regardless of ability to pay is tatamount to signing their death warrants. For example, the out-of-pocket cost of the antivirals that are necessary to keep my brother alive would be higher than what I pay for rent on a three bedroom house. Nobody has that kind of money, particularly not people who have been disabled by this disease for many years.

Can we truly put a price on human life and say that it isn't worth paying?

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

Sincerely,

Heather A. Bricklin
Eureka, CA

Submitter : Dr. Colleen McCoy **Date & Time:** 09/26/2004 01:09:10

Organization : APhA

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Pharmacists have been trained to provide pharmaceutical care to their patients. Since we are "Drug Specialists" we should be the ones to manage this wonderful benefit.

Submitter : Dr. Colleen McCoy **Date & Time:** 09/26/2004 01:09:30

Organization : APhA

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Pharmacists have been trained to provide pharmaceutical care to their patients. Since we are "Drug Specialists" we should be the ones to manage this wonderful benefit.

Submitter : Dr. Jacob Olson **Date & Time:** 09/26/2004 04:09:25

Organization : Skywalk Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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.

Submitter : Mrs. Leni Engels **Date & Time:** 09/26/2004 06:09:39

Organization : VOR

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

Sept. 26, 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,
L.Engels
(954) 981 4141

CMS-4068-P-277

Submitter : Dr. james tallent **Date & Time:** 09/26/2004 08:09:33

Organization : wilson drugs inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I think one of the most important things that should be included in the new program is Freedom of CHoice. Freedom to choose the provider that the insured person is comfortable with and trusts. Also any willing provider of prescription drugs should be allowed to participate on an even playing field. That is the chain stores and mail order houses should not have an advantage in pricing, copay, etc.

CMS-4068-P-278

Submitter : Ms. Tamara Davis **Date & Time:** 09/26/2004 09:09:32

Organization : Ms. Tamara Davis

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I believe Congress intended for Medicare beneficiaries to be able to obtain prescription drugs and Medication Therapy Management services from the pharmacy providers of their choice. Prescriptions at any community retail pharmacy should be allowed in the same amount, scope and duration as those obtained through mail order pharmacies.
Regarding the pharmacy access standard, I recommend that CMS require plans to meet the TRICARE standard on the local (zip code) level rather than "on average" in a regional service area. If that is not possible, access should equal that available to a member of the general public living in that zip code. Plans should not be allowed to create "preferred" and "non-preferred" pharmacies within the TRICARE network. I recommend that CMS require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan's standards should be allowed to provide the same copays to the patient population.

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

I recommend that CMS establish a minimum standard package of Medication Therapy Management services that a plan has to offer. I also believe that CMS should define eligibility criteria for these services. The regulation does not establish a minimum payment for these services, so there is a danger that plans may make payments for MTM services so low that pharmacists, the primary providers of these services, may not be able to afford to provide them. I recommend that CMS define minimum payment levels for MTM services.

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

Multiple dispensing fees for pharmacists are needed to differentiate between the activities associated with dispensing services in various pharmacy environments. There should be one dispensing fee for the routine dispensing of a commercially available product to a patient, a second fee for dispensing a compounded prescription where a product entity does not exist but is prepared by a pharmacist according to a specific prescription order for an individual patient, and a third dispensing fee for home infusion products.

Submitter : Dr. Irma Gail Deyle **Date & Time:** 09/26/2004 10:09:58

Organization : Nebraska Pharmacists Asso.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

September 25, 2004

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

Re: CMS-4068-P

Dear Sir or Madam:

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

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

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

Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS recognition that pharmacists will likely be the primary providers, but I am concerned that leaving that decision to the plans may allow plans to choose less qualified providers to provide MTM services.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. Plans should be encouraged to use my services and to let me help my patients make the best use of their medications.

In conclusion, I urge CMS to revise the regulation to allow all pharmacies the same practices under your program.

Thank you for considering my view.

Sincerely,
I. Gail Deyle, PharmD, RP
President Nebraska Pharmacists Asso.
6241 S 170th St
Omaha, NE 16835
igdeyle@cox.net

CMS-4068-P-280

Submitter : Mr. DARRYL WISHER **Date & Time:** 09/27/2004 03:09:07

Organization : Mr. DARRYL WISHER

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

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

This is an exercise that pharmacists perform hundreds of times a day all acros the country in ambulatory and non ambulatory settings everyday. everyday we keep costs down by offering viable therapeuitc alternatives to the agents prescribed by the prescriber who has tunnel vision b/c he/ she has just been dazzled by the sales pitch of the drug rep who came by and gave him/her the free goodies that the manufacturers send to ply them with. it is a simple phone call to the untrained eye but it is so much more than that in the end. the patient has saved in out of pocket expenses, the prescriber has been educated to therapeutic equivalencies that heretofore escaped his/her notice b/c they were simply ignorant of same. whether it is an admitted fact or not,when the presciber gets that phone call he/she doesn't go to check their PDR or other pseudo-objective references,they just say'ok switch it' and hang up the phone b/c they trust that the pharmacist on the other end of the line knows more about the products,thier therapeutic bioequivalence,and interchangability than they do. that's the bottom line and theier is no denying it. the insurance companies rely on these professional to keep their costs down and the patients trust them to pursue positive outcomes on their behalf as they are unable to advocate for themselves in this area.
the ability to be reimbursed for cognitive services however will allow pharmacists to do more of what it is that they are trained to do which is to provide continuous quality improvement in the area of pharmaceutical care-often times a very nice 'buzzword'that never makes it outside the realm of academia. in the reality of the work-a-day world the average pharmacist sees hundreds of ways that a patient's therapy can be improved-in terms of compliance factors,in terms of QOL factors and even helping to educated the patient as to self management on the various medications both OTC and legend agents,and to be honest without being arrogant they know that they can do it better than anyone else because it is ALL that they do. no other healthcare professional is trained,educated,or spends more time with these products than we do. our background alone allows us to cut through the conflicting,confusing onslaught of advertising to provide that critical eye that blasts through the claims and helps arrive at the best possible alternative to the patient or the most viable option for the prescriber. noone else has yet been able to prove that they can do it better b/c they all have another focus in mind as they are trained for. we don't have a competing agenda. that doesn't mean that we are unable to perform any direct care functions that our colleagues do. we are trained in taking blood pressure for thus is how the efficacy of a hypertensive medication is monitored and our depth of product knowledge allows us to help the patient develop the proper chronotherapeutic dosing regimen for those maintained on multi-dose medication regimens for same. it is our expertise alone that enables us to provide the patient with information reguard the use of adjunctive OTC therapies for adverse effects not considered by the prescriber or that manifest later in the course of therapy. b/c of the ease of access they are quite often the first line of defense in the ambulatory care setting.However the evolution of the profession has come to a cross-roads of transitions. as long as the market is driven by the number of dosage forms that an individual can process in a specific time limit then the vast array of necessary but often neglected services will go untapped. as long as there is no reimbursement for these same prized and valued services then the profession will go unrecognized for what it is and it's not a gaggle of greedy people looking to take the consumer for all they have got. it's the idea that we and we ALONE are the ONLY profession that is not re-imbursed for their intellectual capital and specialized skills.
everyone else is

CMS-4068-P-281

Submitter : Mr. Thaddus Wilkerson **Date & Time:** 09/27/2004 03:09:06

Organization : APhA-ASP

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

I greatly appreciate the opportunity to provide comments on the Medicare prescription drug benefit and hope thay my input will be taken into consideration as CMS develops for the final regulation. As a student pharmacist at the University of New Mexico Health Sciences Center College of Pharmacy, I take great interest in the ability for my patients to receive the best quality of pharmaceutical care.

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

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

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

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

? Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently observe pharmacists providing the following MTM services: hyperlipidemia management through full lipid screening, cardiovascular risk assessments, diabetic management through glucose monitoring and HgA1C, as well as blood pressure checks, coumadin clinics, medication review, patient education on diesease states. I am receiving training at the College of Pharmacy to provide these services when I graduate. Plans should be encouraged to use such services ? to let pharmacists help their patients make the best use of their medications.

Again, I thank you for the wonderful opportunity to submit my comments. As a future pharmacist, I know this prescription drug benefit will provide a much needed service to our aging population.

Sincerely,
Thaddus Wilkerson
523 Ortiz Dr. Ne
Albuquerque, NM 87108

2007 PharmD Candidate
APhA-Academy of Student Pharmacists
Student Political Integration Network CO-Coordinator

CMS-4068-P-282

Submitter : Dr. Terrence Sakai **Date & Time:** 09/27/2004 05:09:38

Organization : Dr. Terrence Sakai

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

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

Regarding medication therapy management fees, I applaud the administration's efforts to provide pharmacists with the opportunity to bill patients for services rendered. Pharmacists put in an amount of didactic work in school roughly equivalent to that of physicians and, now that opportunities in residencies are being expanded, post-doctoral training is also being provided. For the increasing numbers of adequately trained pharmacists, some schedule of fee-based patient billing should be implemented, and I recognize the proposed bill to be such a vehicle. Thank you.

CMS-4068-P-283

Submitter : Ms. Julia Acuna **Date & Time:** 09/27/2004 08:09:32

Organization : Ms. Julia Acuna

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document

CMS-4068-P-283-Attach-1.doc

Julia Acuña
300 Harding Avenue Apt. 4
Sacramento, CA 95833

September 27, 2004

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

Attention: CMS-4068-P

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

Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses.

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

Involuntary Disenrollment for Disruptive Behavior.

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

Appeals Procedures.

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

Outreach and Enrollment.

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

Coverage of Dual Eligibles (§ 423.34)

Of grave concern is the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e. the dual eligibles. There is a high rate of mental illness among this segment of Medicare beneficiaries: according to Medpac, 38% of dual eligibles have cognitive or mental impairments (Medpac, 2004). CMS must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare.

Based on my work with this population, I am gravely concerned that the proposed regulations would cause harmful disruption in care for dual eligibles as well as inadequate drug coverage for other beneficiaries with mental illness. In particular, the proposed regulations do not address how access to needed medications by dual eligibles will be maintained when their drug coverage is switched from Medicaid to Medicare.

I urge CMS to take account of the unique circumstances and needs of this population, and delay transfer of drug coverage from Medicaid to Medicare for the dual eligibles for at least six months to allow adequate time to educate and enroll these vulnerable and often hard-to-reach individuals and to ensure they receive the drug coverage to which they are entitled.

CMS must also address the real threat of adverse health outcomes facing dual eligibles. Under the proposed rule, duals would effectively be forced to enroll in the lowest cost plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans (and automatic enrollment would require placement in a low-cost plan). While it is critical that the transfer from Medicaid to Medicare drug coverage maintain continuity of care, the proposed regulations provide no such protection. To the contrary, the formularies for these low-cost drug plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Without access to the coverage they need, dual eligibles would have no real choice but to switch medications. Yet changing psychiatric medications is very difficult and dangerous. Abrupt changes in psychiatric medications bring the risk of serious adverse drug reactions and interactions.

These regulations must give meaningful effect to the concern Congress itself voiced, stating in the conference report on the Act that: “If a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different.” [Report No. 108-391, pp. 769-770]

Unfortunately, the proposed rule does not adequately provide the protection for people with mental illness that Congress called for. I 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 their Medicaid programs.

Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses (§ 423.120(b))

I have critical concerns regarding the unfettered discretion drug plans would be given under the proposed rules to use restrictive utilization management techniques, including prior authorization, fail first, and step therapy. Given the dangers posed by such practices to individuals with mental illnesses, protections are needed and I appreciate recognition by CMS of the need for special exemptions from these techniques for certain beneficiaries, including those with mental illness.

Restrictive practices such as prior authorization, fail first, and step therapy are altogether inappropriate for people with mental illnesses. Medications to treat mental illness are not generally interchangeable, including those with the same mechanism of action, and differ in how they affect brain chemistry. It must be recognized that the diseases themselves are highly variable in terms of symptoms and effects on consumers, and physicians must carefully tailor drug therapies to each individual to take into account current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide

It is critically important that people with mental illness receive medication best suited to them at the outset of treatment because the chance of recovery diminishes significantly if the first course of treatment fails. Thus utilization management techniques, like fail first and step therapy, that require individuals to try other medications first before they may receive coverage for the medication prescribed by their physician can have severe and permanent effects on individuals with mental health disorders.

The FDA only requires that 80 to 125 percent of a medication be the same to be considered therapeutically equivalent. Thus, therapeutic substitution is highly inappropriate for this population given the many factors that treating physicians must take into account, the wide range and varying side effects, the variability of mental illnesses themselves in terms of how they present themselves, and the non-interchangeability of many of these medications given critical differences in mechanisms of action and how they affect brain chemistry.

Limits on access to appropriate medications and delays that can result from policies like prior authorization can cause relapses and can impair their ability to recover. Moreover, these policies may also impose a significant risk of death since persons with depression or schizophrenia are at significantly higher risk of suicide compared to the general population.

Most states (30 out of 40 with restrictive preferred drug lists and prior authorization requirements) have recognized that these types of restrictive utilization management strategies are inappropriate for mental health consumers and have exempted mental health medications from restrictive preferred drug lists and prior authorization requirements.

The final regulations must assure Medicare beneficiaries access to the newer medications that are generally more effective and have fewer side effects. The Report of President Bush's New Freedom Commission on Mental Health states that "[a]ny effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services" (New Freedom Commission on Mental Health Final Report, 2004).

CMS does recognize that restrictions like prior authorization, therapeutic substitution, or step therapy, may not be appropriate for certain vulnerable populations and they "request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations" (Proposed Regulations for Medicare Prescription Drug Benefit, p. 46661).

In response to CMS's request for recommendations on how utilization management should be structured for individuals who need special treatment, including those with mental illness, I propose a requirement that drug plans offering the new Medicare Part D benefit incorporate an alternative, flexible formulary for mental health medications into their benefit designs. This formulary would provide access to the full array of mental health medications for individuals with mental illnesses diagnoses, including dual eligibles, without fail first, prior authorization, step therapy, therapeutic substitution, or any similar restrictive policies. Instead of forcing these vulnerable beneficiaries to bear the burden of cost control as required under these types of policies, utilization management would be carried out using policies that focus on improving the prescribing behavior of providers.

My proposed alternative, flexible formulary would focus utilization management on practices to improve or at least maintain consumer health while containing costs such as: Provider peer education initiatives which improve clinical practice; closer review and retrospective intervention with cases of polypharmacy or other potentially inappropriate prescribing; Case management of chronic illness to improve coordination of all medical and mental health care, including medications; and closer data review to identify fraud, deviation from clinical best practice, outlier prescribers, and clinicians that are "under-dosing."

In a very recent report entitled "Psychiatric Medications: Addressing Costs without Restricting Access," CMS encourages state Medicaid directors to implement these same types of innovative alternatives instead of restrictive formularies and prior authorizations that increase the risk of use of multiple prescriptions, reduced compliance, and poor outcomes.

Involuntary Disenrollment for Disruptive Behavior (§ 423.44)

The proposed regulation raises grave concerns in allowing Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44(d)(2)). These provisions create enormous opportunities for discrimination against individuals with mental illness. Those who are disenrolled will suffer severe hardship as they would not be allowed to enroll in another drug plan until the next annual enrollment period and as a result they could also be subject to a late enrollment penalty increasing their premiums for the rest of their lives. Plans must be required to develop mechanisms for accommodating the special needs of these individuals, and CMS must provide safeguards to ensure that they do not lose access to drug coverage.

I am alarmed that CMS has proposed an expedited disenrollment process that would undermine the minimal standards and protections included in the proposed rule. This expedited process proposal must not be included in the final rule. In addition, CMS must provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and must waive the late enrollment penalty for these individuals as well. The final rule must include the following protections:

Drug plans must be prohibited from disenrolling a beneficiary because he/she exercises the option to make treatment decisions with which the plan disagrees, including the option of no treatment and/or no diagnostic testing; Drug plans may not disenroll a beneficiary because he/she

chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan; Documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include: documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities in accordance with the Americans with Disabilities Act; and documentation that the plan provided the beneficiary with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment; Drug plans must provide beneficiaries subject to involuntary disenrollment with the following notices: Advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment; Notice of intent to request CMS' permission to disenroll the individual; and a planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.

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.

Outreach and Enrollment (§ 423.34)

The proposed regulations do not adequately address the need for collaboration with state and local agencies and community-based organizations on outreach and enrollment of beneficiaries with disabilities, including individuals with mental illness. In the conference report for the Medicare Modernization Act, Congress directed that "the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated [sic] access to pharmaceutical treatments for mental illness" (Report No. 108-391, pp. 769-770).

To respond to Congress's concern with ensuring enrollment and comprehensive coverage for beneficiaries with mental illness, CMS must partner with community-based organizations focused on addressing the needs of people with mental illness and state and local agencies that coordinate benefits for these individuals. Beneficiaries with mental illness will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available at these sites will help inform beneficiaries with mental illness about the new benefit, but providing community-based organizations with pamphlets and brochures alone is not adequate. To answer the many difficult, detailed, and time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS must develop a specific plan for facilitating enrollment of beneficiaries with disabilities, including mental illness, in each region that incorporates collaborative partnerships with and additional funding for state and local public and nonprofit agencies and organizations focused on mental health. In addition, in their bids, drug plans should include specific plans for encouraging enrollment of often hard-to-reach populations, including individuals with mental illness.

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,

Julia Acuña

References:

The Henry J. Kaiser Family Foundation, The Faces of Medicare: Medicare and the Under-65 Disabled, July 1999.

Medpac, Report to Congress: New Approaches in Medicare, June 2004, p. 72.

U.S. Department of Health and Human Services, Administration on Aging. Older Adults and Mental Health: Issues and Opportunities, January, 2001, pp. 3, 9 and 11.

CMS-4068-P-284

Submitter : Mr. Michael Calabrese **Date & Time:** 09/27/2004 11:09:02

Organization : Independant Pharmacist/ Erie Drug

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

It is important that as we expand the role of government to include ptrescrition drugs that you get input from practioners in the community that are working with existing programs, to find out what works and what doesn't. Try for and objective point of view, not one representing only one faction. I would volunteer to serve on a panel.
Mike Calabrese RPH, Erie Drug, 4502 Lewis Ave, Toledo OH 43612

Submitter : Dr. James R Brown **Date & Time:** 09/27/2004 12:09:53

Organization : University of Tennessee

Category : Other Health Care Provider

Issue Areas/Comments

Issues 1-10

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

As a professor in a major College of Pharmacy for the last 30 years, I am pleased that a provision allowing reimbursment to pharmacists providing Medication Therapy Management now exists. In my institution, a research and academic teaching federal hospital, we have provided these services as a part of our pharmaceutical care programs for 3 decades. Additionally, I have personally taught these services to pharmacy students and post graduates my entire career as a pharmacy educator. The profession of pharmacy stives to assure appropriate utilization of drug therapy as a result of this focused patient education and monitoring of outcomes related to therapeutics in our patients. In our hospital, we have pharmacist run clinics devoted entirely to monitoring diabetics, anticoagulated patients, mental health patients, patients with seizure disorders, hypertensive patients, pulmonary patients, arthritic and patients with congestive heart failure. Our programs are nationally recognized within the profession. Our efforts along with many others across the nation are addressing a definite need in assuring appropriate outcomes and cost effective utiliztion of pharmaceuticals which currently account for a significant portion of our limited health care dollars.

CMS-4068-P-286

Submitter : Mr. Robert Breslow **Date & Time:** 09/27/2004 01:09:46

Organization : Pharmacy Society of Wisconsin

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BACKGROUND

I am submitting my comments regarding the proposed Medicare Part D rules and the provision for Medication Therapy Management services. As a Professor of Pharmacy and a Clinical Pharmacist practicing in a geriatric primary care environment, I am very concerned about the rules as they are currently written. I appreciate this opportunity to submit my constructive, yet concerned, comments to the Centers for Medicare and Medicaid Services regarding the rules for implementation of the Part D benefit. I am hopeful that you will consider the concerns of myself and other clinical pharmacist colleagues from around the country. In order for this program to be successful, I urge CMS to pen language and rules that will ensure compensation for all clinical pharmacists that perform MTM services in traditional and non-traditional practice settings.

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

Thank you for the opportunity to comment. As with many of the Federal entitlements, states or plan sponsors are required to deliver a specified set of services. Medication therapy managment services should be no exception. The specified set of services should be a minimum set while additonal services should be encouraged. At a minimum, services such as asthma management, diabetes management, anticoagulation management, pain management, the management of complex multi-drug regimens, hypertension management, cholesterol management, and adverse drug event assessment should be included. Plan sponsors should be required/directed to allow ANY pharmacist, with NO restriction on practice setting, who receives an order from a prescriber to provide 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. And, at a minimum, each plan should be required to pay for MTM services ordered by a prescriber. Pharmacists should not be excluded as a provider on the basis of price (this pertains to preferred provider. However, I would support thoughtful, constructive, and non-restrictive language about quality requirements to be a pharmacy or pharmacist provider. I am a clinical pharmacist employed by an academic institution who provides consulting services to a primary care geriatrics practice. It is essential that plans should be required to direct recipients with multiple chronic diseases and drug therapies to MTM service providers. Service providers should not be limited to licensed pharmacies nor should they be tied to a specific pharmacy or a written prescription. ANY / ALL licensed pharmacists within a designated region should be considered an MTM provider. It is fundamental that MTM service payments must be sufficient to warrant participation by a pharmacist.

GENERAL PROVISIONS

In support of my many well-qualified colleagues practicing in community and institutional practices, it is critical that plan sponsors make every effort to include as many pharmacies and pharmacists as possible in the Part D benefit. Wisconsin, like many other states, has a number of rural counties where access to health care is often limited. The isolation and transportation issues faced by the elderly (medicare beneficiaries) could be exacerbated by designating access areas larger than each of the counties in each state. I would recommend that CMS define access regions by individual counties so that each eligible beneficiary has reasonable access to pharmacy services. CMS must act responsibly by assuring a reimbursement formula or payment system that, at a minimum, covers the average cost of filling a prescription or providing a service. Is is unfortunate, but as you well know, that cost shifting is a health care industry practice implemented to offset the deep discounts and pricing formulas put in place by private health plans to control cost. If Medicare Part D implements a provider reimbursement plan that is insufficient to cover costs, this will only serve to exacerbate cost shifting to other business sectors. Recipients should not be coerced into using preferred providers (one pharmacy over another)solely on the basis of pricing or cost. However, if the plan sponsor prefers certain pharmacies over others based on well-defined quality reasons, then this would be an acceptable approach to restricting participation by pharmacies. Plan sponsors should be prohibited from providing economic incentives to recipients for using mail order pharmacies. In a broad sense, this could be seen as a restraint of trade. Furthermore, there are safety and medication management concerns when beneficiaries are required to use mail order pharmacies. Lastly, to prevent a conflict of interest, plan sponsors should be prohibited from promoting or requiring the use of pharmacies in which they have an ownership interest.

Submitter : Mr. Samuel Currie **Date & Time:** 09/27/2004 01:09:07

Organization : Mr. Samuel Currie

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Medication therapy management outcomes must be effectively defined. The presence of defined, real, and reasonable expected outcomes for a given disease state will be required to enable health care insurers to accurately assess the value of such services

CMS-4068-P-288

Submitter : **Date & Time:** 09/27/2004 02:09:24

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I approve of this plan

CMS-4068-P-289

Submitter : Dr. Camille Hemlock **Date & Time:** 09/27/2004 02:09:25

Organization : Dr. Camille Hemlock

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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,

Camille Hemlock,M.D.
909 West 45.th St.
Austin, Texas 78756

512-206-4840

CMS-4068-P-290

Submitter : Jane Anthony **Date & Time:** 09/27/2004 02:09:57

Organization : Jane Anthony

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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).

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* 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,

Jane Anthony
2055 Wethersfield Court
Reston, VA. 20191
janthonyjane@comcast.net
703 860-8652

CMS-4068-P-291

Submitter : Mr. GOMER STUKESBARY **Date & Time:** 09/27/2004 02:09:51

Organization : NESS COUNTY LONG TERM CARE

Category : Other Health Care Provider

Issue Areas/Comments

Issues 1-10

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

As a pharmacist in rural America, I am the first health care provider most medicare people see because I know them, I have their medication history, I often direct them to their physician,and I am the last contact with their medications being filled to consult and direct proper useage. I didn't even see Pharmacy in your list of health care
providers above. Dr. McClellan , and this Medicare Health Plan, is the biggest joke ever played upon senior citizens in the history of medicine in this Nation. I cannot believe sane people would allow the
Pharmacy Benefit Management groups, (Many under Federal Charges),to have any part of our tax dollars. God help us if this plan is not changed and soon. Pharmacists have been providing therapy management for years and of course without pay.

CMS-4068-P-292

Submitter : Mrs. Jennifer LaPlant **Date & Time:** 09/27/2004 02:09:27

Organization : Bellin Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

I feel it is extremely important that Medication Therapy Management be done by pharmacists. We are trained to be drug specialists, whose else knows what the best medication to use, with the least cost and how to get the most benefit from the medication than the pharmacist. There have been many times that I have intervened to help patients who were taking their medication incorrectly or needed to have a different medication due to interactions, side effects or cost. This is something we need to be doing more of and being designated as a Medication Therapy Management provider will enable us to do more of this and justify to our employers that it saves them money and can actually make a profit without dispensing anything. We provide anticoagulation therapy management by pharmacists currently and we are limited by not being identified as a provider. The physicians utilize us and trust us as experts in drug therapy. We justify our cost to the physicians by showing our quality assurance data compared to standard care and we consistently are better! This is in only one area (anticoagulation), imagine what we could do if we could expand the services. Please do not underestimate pharmacists as providers, after all we are the ones physicians and nurses go to with drug related questions.

CMS-4068-P-293

Submitter : Dr. Martha Adkins **Date & Time:** 09/27/2004 03:09:45

Organization : Virginia Commonwealth University

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

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

Thank you for allowing me the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. I would like to offer a few comments regarding Subpart D and the MTM services.
First of all, I appreciate your recognition that pharmacists will be the likely primary provider of MTM services. I believe that pharmacists are the ideal health care professionals to determine which MTM services beneficiaries need and then to provide those services. We are easily accessible and we are trained to assess medication issues. Many pharmacists are already offering MTM services. For instance, I currently monitor patients' response to medication therapy through face-to-face counseling. If plans are encouraged to use my services, I can continue to provide my patients with the adequate care they need to optimize their medication therapy.
In conclusion, I would like to urge CMS to revise the regulation to encourage the plans to use pharmacists as primary care providers to allow patients to receive optimal care.
Thank you for considering my outlook.

Sincerely,
Martha Adkins, Pharm. D.
VCU Community Pharmacy Resident

CMS-4068-P-294

Submitter : Mrs. Cheryl Brown **Date & Time:** 09/27/2004 03:09:42

Organization : Mrs. Cheryl Brown

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

9/27/2004

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 !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,

Cheryl O. Brown
601 South Norway Street
Mechanicsburg, PA 17055
717-795-8640

CMS-4068-P-295

Submitter : Mr. Richard Nerbun **Date & Time:** 09/27/2004 03:09:13

Organization : Cumberland Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

To: CMS
RE: CMS-4068-P

Dear CMS,

Thanks for the opportunity to respond to proposed Medicare Part D rules. I am a department supervisor in pharmacy that delivers medications to our nursing home.

My hope today is to ask that we not repeat the previous problems with health care programs that far too often targeted pharmacies and pharmacy reimbursement in cost containment measures, rather than work with pharmacy providers to enhance quality and provide access to important health care services.

Long Term Care pharmacies are concerned with three aspects of Medicare part D proposed rules and recommend that CMS enable the following three policies:

1. Medicare recipeints must be able to choose their own pharmacies.

The access standards should be applied at a level no broader than a county to ensure that recipients have access to pharmacies in their own community. Also, plan sponsors should be required to provide pharmacy payment such that it at a minimum covers the average costs associated with dispensing prescription drugs. CMS must not allow plan sponsors use their market force to drive down pharmacy reimbursement!

2. Implement measures to prohibit incentives designed to coerce recipeints into choosing plans that exclude pharmacies.

Plan sponsors should be prohibited from promoting pharmacies they have ownership interest in, and from providing economic incentives to recipients for using mail order pharmacies as this leads to a greatly reduced delivery of quality of care for many reasons.

3. Plan sponsors should be required to establish specified MTM services (Medication Therapy Management Services)

All plan sponsors should be required to provide at least a basic set of MTM services directed by CMS, and with the option to expand them as well. Pharmacists likewise must be afforded the opportunity to provide those MTM services and to receive appropriate reimbursement for their effort. All prescribers eligible for Medicare payment should be allowed to refer patients in need of MTM services and each plan should be required to pay for them as well. People with chronic disease states should be required to have a plan to direct them to MTM service providers to recieve proper drug management. MTM service payment must be sufficient to warrant provision of the mecessary services by a pharmacist. All pharmacists in a region should be able to provide those MTM services as well, not just a select few!

Thanks for the opportunity to express my views. The people of OUR great Nation are waiting and watching to see how our elected leaders respond to their constituents' health care needs. I ask that you please keep this thought in mind when developing these rules.

Sincerely yours,
Richard G. Nerbun,R.Ph.
Director of Pharmacy
Cumberland Memorial Hospital
Cumberland, WI 54829

CMS-4068-P-296

Submitter : Mr. Thomas Gegeny **Date & Time:** 09/27/2004 03:09:47

Organization : The Center for AIDS: Hope & Remembrance Project

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

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

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

Just considering for public health benefit alone, people with HIV must have full access to care, regardless of ability to pay. This is because without such medications, people will experience progresssion to AIDS and will require hospitalization for completely preventable illnesses. This will further burden an already taxed public healthcare system. Besides public health, patients should not be denied available treatments for disease. To do so would be unjust, unethical, and unAmerican.

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

Sincerely,

Thomas Gegeny, MS, ELS
Executive Director
The Center for AIDS: Hope & Remembrance Project
1407 Hawthorne
Houston TX 77006

Submitter : Dr. Lawrence Robinson **Date & Time:** 09/27/2004 03:09:47

Organization : Dr. Lawrence Robinson

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

September 27, 2004

Centers for Medicare & Medicaid 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.

Thank you,

Lawrence A. Robinson, M.S., PharmD

CMS-4068-P-297-Attach-1.doc

September 27, 2004

Centers for Medicare & Medicaid 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.

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. Pharmacy service requirements are different for different pharmacy practice settings. While the prescription drug benefit is intended to largely address the needs of patients requiring oral prescription medications dispensed from retail or mail order pharmacies, the benefit will also expand coverage to include medications to be administered by home intravenous infusion.

Home infusion pharmacy services are quite different from retail or mail order pharmacy with regard to the need for timeliness of dispensing, complexity of therapy, ongoing monitoring of drug therapy, home delivery of drugs and supplies, and the need for administration devices and supplies to facilitate the administration of the drug prescribed. These complexities do not exist for most orally administered medications.

I recommend that one option cover the routine dispensing of an established commercially available product to a patient receiving a medication from a retail or mail order pharmacy. However, it is important that the definition of "mixing" be clarified to indicate that this term does not apply to "compounded" prescriptions including intravenous medication preparations.

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 for oral ingestion or external or topical application. Once again, this fee should exclude medication prepared for intravenous administration.

A third dispensing fee should be established for home infusion products. The National Home Infusion Association (NHIA), with the approval of CMS, develop a standardized coding format for home infusion products and services in response to the HIPAA requirements. These codes have already been adopted and are in standard use by many private insurance and Medicaid plans. The same approach should be utilized in establishing the third dispensing fee and payment methodology for home infusion services.

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."

In conclusion, I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries by clearly defining the level of service provided

by different types of pharmacy providers and establishing appropriate fee structures commensurate with the type of pharmacy service provided.

Sincerely,

Lawrence A. Robinson, M.S., PharmD
Administrative Director
Alliance Infusion Services
6423 Shelby View Dr., Suite 104
Memphis, TN 38134

CMS-4068-P-298

Submitter : Dr. Michael Schmidt **Date & Time:** 09/27/2004 03:09:27

Organization : Dr. Michael Schmidt

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 pharmacist, I am deeply concerned with the rules as they are currently proposed.

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

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

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

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

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

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

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

Thank you for your consideration.

Sincerely,

Michael J. Schmidt PharmD

Submitter : Dr. Ezra Gruszynski **Date & Time:** 09/27/2004 03:09:52

Organization : Dr. Ezra Gruszynski

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

BACKGROUND

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 staff pharmacis of Crivitz 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.

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

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

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

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

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

ELIGIBILITY, ELECTION, AND ENROLLMENT

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.

CMS-4068-P-300

Submitter : DAVID HARTWIG **Date & Time:** 09/27/2004 04:09:12

Organization : DAVID HARTWIG

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I strongly believe that the management of the medicare drug benefit should not be privitized. The big Pharmacy Benefit Management companies have proven time and time again that they not a cost saving method. Discounting providers and decreasing services and not passing the savings along to payers. This entire bill is set up not to address the real problem (drug cost) and to move mass quantities of patients to less safe ways to receive prescription drugs. Patients need to have a choice, with no penalty, to choose whichever provider they wish. Drug companies should be required to price there products evenly between all channels of distribution. Mail order pharmacies should be required to have reasonable patient access to pharmacist and pharmacy care. So the cannot just "skim the Cream" by filling only the maintence meds and not be available in urgent care situations. Lastly, Pharmacists should be in charge of medication therapy management and no one else. I realize you will get a lot of comments that are similar to mine. Thank you for your consieration.

CMS-4068-P-301

Submitter : Mrs. JoAnn Schubert **Date & Time:** 09/27/2004 04:09:20

Organization : Mrs. JoAnn Schubert

Category : Individual

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

9/27/2004

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).

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?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,

JoAnn D. Schubert
330 MacKenzie Drive
West Chester, PA 19380
610.431.7438/jschub3@comcast.net